A review of the Biomedical Regulatory Affairs Masters of Science (BRAMS) program and a comparison to national certification examinations and similar programs nationwide

David Hammond

Clinical Faculty

University of Washington, School of Pharmacy

BRAMS Program Review

1. Open Description of the BRAMS program and this Review

1.1. Description of the BRAMS Program

On the program's website, the BRAMS program has this description:

The University of Washington's Biomedical Regulatory Affairs Master of Science program, offered by the UW School of Pharmacy in partnership with UW Professional & Continuing Education, addresses a growing need for well-trained professionals in the regulatory field. The degree will serve those who wish to advance their careers in the medical products industry or those entering the field from related areas.

The program comprises 45 credits through 11 courses that are offered over two years or six consecutive academic quarters. A class is admitted each year and this cohort proceeds through the program's courses together. Courses are offered in the evening hours on the University of Washington campus in Seattle and in other Seattle locations accessible to working adults. Included in the 45 credits, is a 9-credit practicum which augments the classroom based courses and provides focused, in-depth learning opportunities and the on-the-job experience that is especially important for those entering the field.

The curriculum bridges theory with practice, drawing on the expertise of faculty and resources from the UW as well as professionals from the medical products industry in the Northwest. The program's schedule allows you to earn a master's degree within two years.

1.2. Rationale for this review

The Biomedical Regulatory Affairs Masters of Science (BRAMS) program needs a comprehensive review of its offerings, faculty and teaching styles to assess its effectiveness. This program has been providing post-graduate education in regulatory affairs, quality systems and clinical research for over four years. The certificates in clinical trials and regulatory affairs have been in existence for more than a decade. The BRAMS program has graduated dozens of students, many of whom have begun or continued careers in the field of FDA regulated products such as pharmaceuticals, medical devices and biologics.

The BRAMS program, as with any professional post-graduate program, faces numerous issues, both internal and external regarding the quality of the education provided, the relevance to professionals in the field, competition from similar programs provision of material in a format that is digestible by the student body, and the ability to reach the students who wish to participate.

1.3. The BRAMS Review Overview

This review is broken into four distinct sections.

The first section is a review of the BRAMS program against the four most popular national certification examinations in clinical research and regulatory affairs. There currently exist a set of nationally-recognized certification examinations in clinical research and regulatory affairs. These certifications are offered by groups such as the Association of Clinical Research Professionals (ACRP) who offers the CCRA and CCRC (Certified Clinical Research Associate and Certified Clinical Research Coordinator), the Regulatory Affairs Professional Society (RAPS) who offers the RAC (Regulatory Affairs Certification) and the Society of Clinical Research Associates (SoCRA) who offers the CCRP (Certified Clinical Research Professional).

Each of these certifications, while generally recognized by industry, are narrow in scope, focusing on regulatory affairs or clinical research and, in the case of the CCRA and CCRC from ACRP, are directed at a specific role within the clinical research industry. This means that the broad view of the BRAMS program will exceed that of a certification examination, thus limiting the precision of this comparison.

However, despite this limitation I propose to review of our current syllabus and to compare to the study guides or recommended topics for study for each examination provided by their governing organizations. The comparison will allow me to determine if an area of focus valued by these organizations is being ignored in our syllabus.

The second major activity will be a review of the BRAMS program to other graduate programs in regulatory affairs. In addition to the BRAMS program at the University of Washington, there are numerous universities offering post-graduate degrees in clinical research and regulatory affairs. Several of these programs such as the MS in Regulatory Affairs at San Diego State University predate the BRAMS program. Newer programs, such as the Regulatory Affairs Master's Program at the University of Georgia, started after BRAMS.

None of these programs follow a single unified standard for the content of a post-graduate degree in regulatory affairs or clinical research, the material covered by each of these programs (both core and electives) varies. So my review of the material available from these programs and a comparison of the course material offered to the courses provided in the BRAMS program.

In this review, I focused on:

- Number of credits
- The cost of attendance
- The coursework provided by each program

- Degree granted
- Online or in-person
- Extra-classroom activities (e.g. the BRAMS practicum program)
- Areas of focus (drugs, devices, clinical research, etc.)

The third section of this review is a review of the student evaluations. Any assessment of business activity requires discussion with the customer to determine if the service provided met the customers' needs and if the customer had reasonable expectations of the service to be provided. The BRAMS program was assessed in the same way.

I reviewed the study surveys current and former students completed at the end of each course in which they evaluate the course as a whole and the instructor. These surveys were graphed and the results for each instructor and the program as a whole were evaluated

The fourth section of this document is a course-by-course review of the classes in the BRAMS program. Since 2011, I have attended each class as a student (with the exception of those I taught. They are indicated in the review) and I have documented, not only my own opinions and observations about the course and instructor, but the comments provided to me by students in my cohort and those before and after me.

This four-point evaluation allows me to see gaps in our coursework, areas of improvement for our instruction and places where the BRAMS program is meeting or exceeding the national certification examinations and other master's programs in regulatory affairs. At multiple points throughout this document and in the final section, I propose areas for improvement or gap closure to rectify the issues I have identified.

2. Comparison to Current Clinical Research/Regulatory Certifications

Beyond the professional license that someone working in clinical research or regulatory affairs may have (i.e. a registered nurse who works as a research coordinator), there is no licensing process for professionals in our field. The closest that exists today, is a series of certifications provided by national organizations for regulatory affairs or clinical research. These certifications are well recognized in the industry.

The certifications go beyond only demonstrating knowledge in a proctored exam and usually require a number of years working as a professional field of regulatory affairs or clinical research. The certifications are not required to work in the field, but in over 90% of job listings found online having certification is listed as, at a minimum,

preferred for employment.

Without a single national license exam, as exists for registered nurses, physicians, or CPAs, and the associated educational standards, the best comparison that we can make of the material covered in our program to determine its national applicability is to look to the certification exams and determine if we teach material the covers most of the topics in these examinations. The examinations, however, often cover very detailed hands-on activities that are beyond the scope of what is taught in either the clinical trial series or the BRAMS program at large. It is also important to note that these courses are not designed to teach to the particular exam for certification.

Due to the nature of the certification examinations versus the educational goals of the BRAMS program, I anticipate finding gaps. In addition, these exams are relatively static and only moderately refined each year because the material covered by the tests is relatively unchanged from year-to-year. The program, however, is designed to be more nimble and more quickly address current trends and changes in clinical research and regulatory affairs.

In this section, I evaluate material covered in the Master's of Science in Biomedical Regulatory Affairs against four standard examinations provided by national organizations, the CCRA, the CCRC (these are combined into a single evaluation), the CCRP, and the RAC.

2.1. Description of current certifications/organizations that certify used for this evaluation

The Association of Clinical Research Professionals (ACRP) offers a series of different national certification depending on your defined role in clinical research: the CCRA for monitors, the CCRC for coordinators, the CPI for principal investigators and the CCRT for clinical research trainers. This is the most widely help certification covered in this review. However, the scope of these examinations and the typical roles for described for individuals with the certifications are very narrow. The target audiences are a CRA working for contract research organization as a monitor or a CRC working in a for-profit research site as these are the largest constituencies in ACRP's membership. Given the wide variety of roles in which a CRA may work and the number of types of clinical research sites that employ CRCs, this scope may be unnecessarily restrictive. In addition, the major focus of this organization and these examinations is pharmaceutical clinical research with only small consideration given to medical devices or biologics.

The Regulatory Affairs Professional Society (RAPS) grants a Regulatory Affairs – Certified (RAC) certification to those who pass its exam. The RAC is broken into several categories depending on the global reach for which the regulations

are being tested (US, EU, Canada and Global). As opposed to ACRP, RAPS does a good job of distributing their regulatory testing across pharmaceuticals, medical devices, and biologics and considering a broad swath of potential roles for individuals who hold this certification.

The final certification used is a general clinical research certification offered by the Society of Clinical Research Associates or SoCRA. Designated the Certified Clinical Research Professional or CCRP, it is a general examination favored among clinical research professionals at academic research centers, but popular in industry also.

ACRP indicates that there are 17,000 Certified Clinical Research Coordinators and 9,000 people hold the CCRA. The Regulatory Affairs Professional Society states that as of July 2012 there are 6,000 of people holding their national certification. The Society of Clinical Research Associates that there are approximately 3500 people who have achieved the CCRP.

2.2. Description of certifications not used for the comparison and the reason for their exclusion

There are several certifications that were not used in this comparison due to either their relative rarity in the clinical and regulatory community or the specificity of the examination to a smaller aspect of the clinical research or regulatory affairs spectrum.

- The Certified IRB Professional (CIP) from CCIP
- The Certified IRB Manager (CIM) from NAIM
- The Certified Clinical Data Manager (CCDM) from the Society of Clinical Data Management
- The Clinical Research Contract Profession (CRCP) from the Model Agreements & Guidance International
- The Certified Research Administrator (CRA) from RACC
- The Registered Quality Assurance Professional (RQAP) from the Society of Quality Assurance

2.3. Comparison of BRAMS to RAC

In 2012, the instructors in the BRAMS program evaluated the areas of knowledge that RAPS states are indicators of a person's ability to pass the RAC examination against the classes that they teach. These tables are the result of that program-wide analysis by the BRAMS faculty. In these tables, each area of knowledge is mapped against the series of classes taught throughout the BRAMS program. These original tables were reviewed and updated for this document. This differs from the evaluations of the CCRP and CCRC/CCRA examinations, as the CCRP

and CCRC/CCRA exams are mapped against the clinical trials courses. The reason for this is that the areas covered by the CCRP and CCRC/CCRA examination are specific to clinical trials, and when a comparison was done against the larger BRAMS program, there was no added coverage, so the evaluation was limited to the clinical trials courses.

RAC Examination Content Outline	Sections not covered (missing)	Biomedical Regulatory Affairs Certificate	Clinical Trials Certificate	Technical Writing for Medical Products Industries	Statistical Basis of Quality Assurance for Regulated Industries	International Regulatory Affairs	Medical Products Risk Analysis and Management	Advanced Topics in Medical Products Regulation	Biomedical Regulatory Affairs Practicum
1 STRAGEIC PLANNING		Material not covered							
a) Product Classification i) Evaluate proposed products for jurisdiction/regulatory classification status ii) Determine substantial equivalence to marketed devices iii) Evaluate regulatory advantages/disadvantages of non-US market introduction and non-US development iv) Identify lead agency for combination products	**None**		iv	a	i ii iii iv	iv	a	a	a
b) Regulatory Pathways / Regulatory Options i) Advise management on requirements and options for regulatory submissions/approvals ii) Analyze laws, regulations and guidelines for compliance requirements. iii) Develop effective regulatory submission strategies for timely FDA product review. iv) Perform benefit/risk analysis of options for regulatory compliance. v) Prepare justification for accelerated mechanisms for review. vi) Develop and implement global regulatory strategy. vii) Interface with marketing and manufacturing to assure development plans are in alignment with objective / capabilities.	**None**	v vi vii	ii	b	b, content implicit, but not explicit to regulatory pathways	ii	Iii v vi vii	i iii iv v vi vii	vi vii

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2. DESIGN and DEVELOPMENT	Material not covered								
a) Documentation i) Advise master file sponsor of regulatory requirements. ii) Ensure specifications / methods for testing of active pharmaceutical ingredients (API) comply with regulatory requirements. iii) Evaluate manufacturing changes for regulatory filing strategies. iv) Ensure procedures for appropriate change control systems are in compliance. v) Ensure clinical trial design, conduct and documentation are in compliance with GCPs. vi) Obtain required clinical research and associated documentation vii) Write/review SOPs for compliance with GCPs and regulatory affairs practice. viii) Ensure appropriate record retention.	**None**			a	i v vi vii viii		a	i iv vii	v vi
b) Testing Requirements / Compliance i) Determine testing requirements with regard to: 1.clinical safety and efficacy 2.nonclinical safety ii) Ensure compliance and adequacy of documentation regarding: 1. clinical safety and effectiveness (e.g., GCPs, IRBs); 2. Internal / external laboratories; 3.nonclinical safety and effectiveness and 4. Product iii) Ensure nonclinical data supports initiation of the proposed clinical program. iv) Recommend relevant biocompatibility assessments for medical devices. v) Monitor clinical trial batch in compliance with GMPs/QSRs.	**None**	b	ii-1	b	i ii-1, 2, 3 iii iv			i1 ii1, 2, 4 iv	i1 ii2,3,4 iii iv v

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3. PREMARKET/REGULATORY REVIEW	Material not covered								
a) Regulatory Authorities, Vendors and Subcontractors i) Monitor applications under regulatory review. ii) Negotiate/interact as appropriate with regulatory authorities during the review process. iii) Negotiate labeling claims between government agencies and company. iv) Ensure raw materials, services, and subcontracted activities comply with applicable regulations and specifications.	**None**	a		a	a		a	I ii iv	a
b) Submission / Listing / Registration / Obtaining Approval i) Acceptability of biologic, medical device or pharmaceutical premarket data. ii) Prepare premarket submissions and master files for drugs, biologics and medical devices iii) Review applications for completeness according to "refuse-to-file" guidelines. iv) Ensure readiness for preapproval inspections. v) Oversee and advise on processes to allow electronic submissions. vi) Ensure procedures in place for appropriate responses to Regulatory Agency Queries. vii. Prepare and submit forms for drug and device listing and establishment registration. viii. Ensure clinical trial monitoring and clinical trial audits are performed.	**None**	b		b	b		b	I ii iii iv v vi vii	I iii iv vi viii

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4. MANUFACTURING/QUALITY SYSTEMS	Material not covered								
a) Documentation i) Establish and ensure development of SOPs necessary for regulatory compliance ii) Ensure/develop internal audit procedures to ensure regulatory compliance (e.g., GMPs/QSRs). iii) Develop procedures for audit of vendors, suppliers or contractors iv) Develop records retention policies and procedures that minimize risks and ensure regulatory compliance.	**None**	a	i	a	a		a	I ii iii	a
b) **Training** i) Develop / deliver / ensure in-house training programs for company personnel in order to ensure regulatory compliance ii) Ensure implementation and documentation of training programs including identification of training needs iii) Provide trainers with updated information on regulatory requirements to incorporate in ongoing training programs.	**None**	b		b	b		b	b	iii

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4. MANUFACTURING/QUALITY SYSTEMS	Material not covered								
c) Compliance i) Analyze guidelines/points to consider as related to products/ processes. ii) Assess quality systems iii) Perform audits to determine compliance to Quality System Regulations (QSR) and drug GM iv) Ensure compliance to established SOPs for QSR and drug GMPs. v) Make recommendations for improvement of quality systems, based on audit findings and QSR or GMP requirements vi) Implement and/or administer SOPs for compliance with QSR and drug GMP. vii) Direct internal functional areas regarding regulatory compliance. viii) Monitor product failure trends as required. ix) Review documentation supporting proposed changes to products/ processes. x) Review/monitor contractual obligations/agreements to ensure regulatory compliance. xi) Participate in the identification of necessary corrective actions needed as a result of internal audit reports and communicate to management. xii) Ensure implementation of validation for product software and quality systems software. xiii) Ensure implementation of validation for equipment and manufacturing processes/procedures. xiv) Ensure the use of valid statistical tools including risk management and total quality management (TQM) tools throughout the life cycle of the product.	**None**	Iii vii viii		c	iii vii x		i ii iii iv v vi vii viii ix x xi xii xiii	Iii iv v vi vii viii ix x xi xii xiii xiv	i iv v vi vii viii ix x xi xii xiii xiv

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5. MARKETING/POST-APPROVAL	Material not covered								
a) Advertising/Promoting/Labeling i) Approve advertising / labeling / promotional items for compliance before release ii) Develop Freedom of Information Act strategy regarding: 1. confidentiality and protection of proprietary information, and 2. document requests. iii) Evaluate data to support comparative claims in advertising.	**None**	a		a	a		a	a	a
b) Post-marketing Surveillance/Vigilance i) Evaluate reports of product complaints. ii) Ensure that appropriate systems are in place to document and track product complaints and ADR reports iii) Ensure implementation of necessary corrective actions based on results of inspections, audits and failure analysis. iv) Report product safety issues/failures to regulatory agencies as required v) Review adverse drug reaction reports and medical device reports.	**None**	b		b				b	b
c) Distribution i) Comply with import/export requirements. ii) Ensure compliance with applicable requirements/regulations for distribution of controlled substances. iii) Review regulatory aspects of contracts for product distribution iv) Advise on the issues related to drug/product/lot releases. v) Ensure adequacy of product traceability systems.	**None**	c		c	c		c	c	c
d) Post-marketing/Maintenance: i) Submit required periodic reports and updates ii) Comply with product post-marketing approval requirements iii) Ensure regulatory compliance of post-approval marketing studies iv) Prepare strategy and policy for alerts/notifications/recalls/market withdrawals. v) Implement and monitor effectiveness of alerts/notifications/ recalls vi) Advise management on alerts/notifications/recalls.	**None**	d		d	Iv, v, vi		d	d	i iii iv, v, vi

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5. MARKETING/POST-APPROVAL	**Material not covered**								
e) Crisis Management i) Advise management regarding the regulatory impact of a crisis event. ii) Advise management on regulatory implications of proposed crisis resolution strategies. iii. Participate in the development and functioning of the crisis management program.	**None**	e		e	i ii iii			e	e

RAC Examination Content Outline	**Sections not covered (missing)**	Biomedical Regulatory Affairs Certificate	Clinical Trials Certificate	Technical Writing for Medical Products Industries	Statistical Basis of Quality Assurance for Regulated Industries	International Regulatory Affairs	Medical Products Risk Analysis and Management	Advanced Topics in Medical Products Regulation	Biomedical Regulatory Affairs Practicum
6. INTERFACING	Material not covered								
a) Regulatory Agencies i) Communicate directly with various domestic and international regulatory authorities on product regulatory matters ii) Coordinate technical presentations to health regulatory advisory committees/agencies. iii) Participate in the development of new regulations/guidelines/ standards to be followed by industry and FDA (e.g., comment on proposed regulations published in the Federal Register).	**None**			a	a	i	a	a	a
b) Regulatory Authority Inspections i) Interact with and coordinate use of outside consultants with company personnel ii) Negotiate wording of inspection findings. iii) Manage / accompany / chaperone inspection teams or auditors iv) Communicate corrective follow-up actions to management.	**None**		i	b	b	b	b	b	b
c) Government and Public Relations i) Contribute to / oversee preparation of strategy / briefing documents for company use before panel hearings and informational meetings. ii) Develop presentation strategy iii) Communicate/refer external requests for information.	**None**	iii		c	c		c	I iii	i ii

RAC Examination Content Outline	**Sections not covered (missing)**	Biomedical Regulatory Affairs Certificate	Clinical Trials Certificate	Technical Writing for Medical Products Industries	Statistical Basis of Quality Assurance for Regulated Industries	International Regulatory Affairs	Medical Products Risk Analysis and Management	Advanced Topics in Medical Products Regulation	Biomedical Regulatory Affairs Practicum
6. INTERFACING	Material not covered								
d) Interdepartmental Guidance i) Advise marketing regarding claims that can/cannot be made. ii) Advise management on proposed and newly finalized regulations and legislation iii) Advise appropriate company personnel when a regulatory body exceeds its authority iv) Communicate agency/industry positions within the organization. v) Develop "early warning system" to identify potential regulatory problems affecting the company/agency. vi) Notify/consult/brief legal counsel when necessary or appropriate. vii) Advise internal functional groups regarding regulatory compliance viii) Assure and document proper training of R&D scientists/engineers and other non-regulatory personnel in regulatory obligations/ requirements. ix) Advise manufacturing and QA on changes requiring preapproval or notification.	**None**	d	i	d	d		d	Iii iv v vi vii viii ix	I iii v vi vii viii ix
e) Standards Organizations i) Identify the standards developing organizations appropriate for the products ii) Review draft documents when routed for comment.	**None**	e		e	e		e	e	e

As you can see from the tables in this section, the RAC exam is well covered by the classes taught in the BRAMS program. While it is never the intention of this program to teach to a certain examination and a student completing this program would still need employment experience in the field of regulatory affairs to qualify for the examination, this test represents the areas that RAPS feels are important for a professional in the field of regulatory affairs to have mastered. This table also demonstrates that the program goes well beyond what is to be studied for this test.

2.4. Comparison of BRAMS to CCRA/CCRC

In Table 1 below, I recorded the 110 areas of knowledge that the ACRP indicates are key to successfully completing the CCRA or CCRC examination. In this table, I indicate the level of coverage that each element receives in the BRAMS program. These ratings are based on the number of class sessions in which the topic is covered and my subjective evaluation of the depth of coverage for each.

Table 1 – Evaluation of ACRP topics and their coverage in the program

ACRP Item Number	ACRP Item Name	Well Covered	Covered, but could be improved	Not Covered in clinical trials program
1	Develop and update the instructions for use of investigational product	X		
2	Initiate shipment of investigational product to site		X	
3	Ensure adequacy of investigational product and other supplies at site	X		
4	Ensure randomization and emergency codes of investigational product have been maintained		X	
5	Ensure proper storage, dispensing, handling, and disposition of investigational product and other supplies		X	
6	Reconcile investigational product and other supplies	X		
7	Maintain accountability of investigational product	X		
8	Prepare investigational product according to the protocol			X
9	Dispense investigational product according to the protocol			X
10	Retrieve investigational product and calculate subject compliance			X
11	Maintain randomization and emergency codes of investigational product dispensing		X	
12	Prepare emergency use report			X
13	Review product development plan	X		
14	Identify study objective/design	X		
15	Develop the protocol (e.g., inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)	X		
16	Evaluate protocol for scientific soundness	X		

17	Evaluate protocol for feasibility	X		
18	Evaluate congruence of data collection tools (e.g., case report form (CRF), electronic data capture (EDC) with the study protocol	X		
19	Verify the eligibility of potential trial subjects		X	
20	Review protocol for feasibility	X		
21	Review protocol during Investigator's meeting	X		
22	Execute study per protocol	X		
23	Assess safety during trial participation		X	
24	Minimize potential risks to subject safety		X	
25	Oversee safety risks (e.g., clinical holds, product recalls)		X	
26	Report required adverse events to regulatory authorities and/or IRB/IEC	X		
27	Ensure adverse events reporting is documented (e.g., serious, severe, moderate, mild, expected, unexpected)	X		
28	Ensure reasons for subject discontinuation are documented (i.e., causes, contact efforts)		X	
29	Handle medical monitor oversight	X		
30	Conduct study-related procedures and monitor the safety of the trial subjects and investigational staff	X		
31	Manage and motivate the investigational staff and other disciplines involved, and take measures to minimize any potential risks	X		
32	Inform the sponsor and IRB/IEC of any changes to the protocol or safety concerns and submit progress reports to the IRB/IEC per requirements	X		
33	Review common laboratory values and alerts		X	
34	Determine and document the causality of adverse events	X		
35	Identify expected or unexpected results associated with investigational products	X		
36	Implement Investigator's plan of action for management of adverse event (e.g., stop investigational product; call, retest, treat subject)		X	
37	Maintain follow-up to determine resolution of adverse event		X	
38	Report serious adverse event to Sponsor/CRO and IRB/IEC		X	
39	Classify adverse events (i.e., serious, severe, moderate, mild, expected, unexpected)		X	
40	Record adverse event and relevant information on source document	X		
41	Initiate unblinding procedures		X	
42	Verify investigator/site feasibility	X		
43	Develop timelines for conducting and completing the clinical trial	X		
44	Prepare and conduct initiation activities	X		
45	Ensure appropriate training of the investigational staff		X	
46	Develop a recruitment strategy and study management plan	X		
47	Review, clarify, and obtain data changes from sites	X		
48	Schedule and coordinate pre-study site visit	X		

49	Identify minimum regulatory document requirements for site trial master file (e.g., country specific regulatory documents)	X		
50	Ensure IRB/IEC review/approval of study and study documents	X		
51	Facilitate site budget/contract approval process	X		
52	Develop Case Report Forms (e.g., CRFs, eCRFs)	X		
53	Develop CRF completion guidelines	X		
54	Develop monitoring guidelines/plans	X		
55	Develop project tools		X	
56	Submit documents to regulatory authorities	X		
57	Document and communicate site visit findings	X		
58	Ensure clinical trial registry requirements are met	X		
59	Ensure timely review of study data (e.g., laboratory results, x-rays)	X		
60	Maintain current vendor credentials (e.g., lab certification/licensure and normal ranges)			X
61	Prepare and conduct interim monitoring visit(s)	X		
62	Prepare and conduct close-out monitoring visit(s)	X		
63	Prepare study summary and/or close-out letter for IRB/IEC	X		
64	Reconcile payments to sites per contract		X	
65	Document protocol deviations/violations	X		
66	Schedule subjects		X	
67	Obtain informed consent and screen trial subjects		X	
68	Prepare study documents for IRB/IEC and/or sponsor review/approval	X		
69	Prepare study documentation (e.g., schedule of events, description of procedures)	X		
70	Reconcile safety and clinical databases		X	
71	Conduct co-monitoring/training visits	X		
72	Perform remote monitoring activities	X		
73	Train site personnel on Sponsor/CRO and regulatory requirements for study conduct (e.g., protocol procedures, EDC)	X		
74	Select the investigational staff and assign roles and responsibilities recruitment strategy and site study management plan	X		
75	Transmit CRFs to Data Management	X		
76	Review CRF queries from Data Management	X		
77	Obtain, negotiate, and seek approval of study budgets and clinical trial agreement	X		
78	Conduct subject visits according to requirements		X	
79	Implement corrective actions plans		X	
80	Maintain trial master file (e.g., regulatory binder)			X
81	Maintain standards for handling hazardous goods (e.g., IATA)			X
82	Manage study supplies (e.g., lab kits, case report forms)		X	

83	Maintain equipment (e.g., calibration and preventive maintenance)		X	
84	Manage study record retention and availability		X	
85	Manage financial agreements		X	
86	Comply with subject privacy regulations		X	
87	Prescreen telephone calls for eligibility requirements			X
88	Maintain subject screening/enrollment log			X
89	Collect, record, and report accurate and verifiable data		X	
90	Manage study issues		X	
91	Ensure consistency between the sites' standard operation procedures (SOPs) and the study requirements	X		
92	Ensure investigator/site protocol compliance	X		
93	Facilitate investigator/site corrective actions	X		
94	Oversee vendors (e.g. Contract Research Organizations (CROs)	X		
95	Ensure compliance with electronic data requirements (e.g., electronic health records, eCRF)	X		
96	Ensure adequate site management	X		
97	Prepare the study site for audits and inspections	X		
98	Respond to or facilitate response to audit/inspection findings		X	
99	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)			X
100	Ensure proper adverse event reporting by the investigator	X		
101	Escalate problems to appropriate in-house management		X	
102	Investigate potential fraud and misconduct		X	
103	Report potential fraud and misconduct		X	
104	Ensure follow-up medical care for study subjects is documented, as applicable			X
105	Ensure adequate consent and documentation	X		
106	Ensure staff, facility, and equipment availability throughout the study		X	
107	Ensure compliance with study requirements and regulations	X		
108	Prepare for audits, inspections, and follow up	X		
109	Ensure access to source data by authorized parties, in accordance with ICH-GCP, and protect confidentiality by limiting unauthorized access	X		
110	Ensure that IRB/IEC documentation is adequate and that details of the IRB/IEC composition are on file	X		

In Table 2 below, I evaluate each class section and indicate which item numbers in Table 1 are reviewed in each class.

Table 2 – Comparison of syllabus to areas of the ACRP examination

Class Session	Current Agenda	ACRP Item Numbers that are covered in this session

1	Class Basics, FDA History, FDA's Phased Approach to Drug Testing	13
2	Human Subjects Protection Regulations, Case Study Discussion, Clinical Protocol Design	14, 15, 16, 17, 20, 49, 50, 68
3	GCPs, Medical Device Regulations	49
4	Human Subjects Protection, FDA Inspections	26, 32, 63
5	Statistical Concepts and Study Design	59
6	Informed Consent and Consent Forms	19
7	IRB perspectives on advertising and recruitment, Mock IRB Meetings	50, 63
8	Study Set-Up, Site Operations, Budget Concepts	22, 23, 27, 33, 40, 45, 44, 46, 48, 51, 66, 67, 77, 78, 82, 83, 84, 85, 86, 96, 98, 105, 107, 108, 109, 110
9	Conflict of Interest, "The Legacy of Jesse Gelsinger"	
10	Voices from the Trenches	
11	Bringing a product to market, Sponsor Types, Academic v. Industry Research	13
12	Regulatory Pathways, IND/IDE/NDA/PMA/510k	49, 56, 86
13	Types of clinical trials, Elements of the protocol, beyond the protocol	1, 14, 15, 16, 17, 20, 69
14	SOPs, Site Selection, DSMC/CEC/AEAC, Study Manual	27, 12, 23, 31, 42, 49, 91, 100
15	Case Report Forms, Data Mgmt, EDC	18, 27, 28, 34, 35, 39, 40, 47, 52, 53, 59, 70, 75, 76, 89, 95
16	Investigator Meetings, Start-up Visits, Interim monitoring, close-out	2, 3, 4, 5, 6, 7, 11, 21, 26, 30, 33, 34, 35, 44, 45, 48, 54, 57, 58, 61, 62, 71, 72, 73,74, 79, 82, 83, 84, 85, 90, 92, 93, 96, 101, 102, 103, 105, 107, 108, 109, 110
17	Group Presentations/Interpreting clinical research	
18	Clinicaltrials.gov	
19	Clinical Reports, Safety Reports, NDA	12, 23, 32, 37, 38, 39, 100
20	Marketing, PR, OPDP	
21	Principles of Project Management	31
22	Business Presentations & Financial Management Tools	51, 65, 77
23	Preparing the Project	43, 36, 46, 47, 54, 55, 65
24	The Art of Negotiation	51,77
25	Contracts & Financial Forecasting	43
26	Outsourcing & Ancillary Documents	38, 94
27	Managing Yourself & Others	
28	Project Maintenance & Disaster Planning	7,11, 22, 23, 24, 25, 26, 27, 29, 33, 39, 41, 47, 90, 96, 101, 102, 103
29	Project Close-out	22, 59, 63, 64, 65, 97

30	What it's really like out there	

As we can see from Table 1 and Table 2 above, the clinical trials series matches fairly well with the CCRA and CCRC examination from the ACRP. There are lectures that do not match with topics from the ACRP examinations, but this is to be expected in a program designed to go beyond teaching to a certification exams. There are a few gaps in coverage of the program to the ACRP examinations (including the handling of lab samples and product accountability); these are addressed in global redesign of the clinical trials program in Section 5.5.

2.5. Comparison of BRAMS to CCRP

In Table 3 below, I recorded the 34 areas of knowledge that SoCRA indicates are key to successfully completing the CCRP examination. In this table, I indicate the level of coverage that each element receives in the BRAMS program. These ratings are based on the number of class sessions in which the topic is covered and my subjective evaluation of the depth of coverage for each.

Table 3 - Evaluation of the coverage of the areas of the CCRP examination

CCRP Item Number	CCRP Item Name	Well Covered	Covered, but could be improved	Not Covered in clinical trials program
1	Identify and differentiate the foundations and principles of clinical research ethics	X		
2	Demonstrate knowledge of laws, regulations, guidance and standard operating procedures and their application to regulated clinical research	X		
3	Distinguish and define the responsibilities of sponsors, monitors and investigators according to the principles of the ICH/GCP and the CFR	X		
4	Identify and apply the regulations and guidance as they relate to informed consent, IRB/EICs, and financial disclosure	X		
5	Identify the principles of study design, study closure, and record retention	X		
6	Demonstrate knowledge and application of safety reporting requirements	X		
7	Demonstrate the ability to utilize critical thinking skills in practical applications	X		
	Conduct of Clinical Trials			
8	Roles and responsibilities of sponsors and investigators	X		
9	Study development, design, trial phases, blinding	X		
10	Study initiation	X		

11	Protocol development		X	
12	Protocol amendments		X	
13	Study recruitment/enrolling		X	
14	Study visits, assessments, procedures		X	
15	Source documentation	X		
16	Develop/complete/verify case report forms (paper/electronic)	X		
17	Essential documents		X	
18	Investigational product accountability			X
19	Safety assessment, documentation and reporting		X	
20	Reporting requirements			X
21	Monitoring and quality assurance	X		
22	Audits		X	
23	Record Retention		X	
24	Study closeout	X		
	Institutional Review Boards			
25	Roles and responsibilities of IRB	X		
26	IRB/IEC membership	X		
27	Standard Operating Procedures		X	
28	IRB/IEC review and approval	X		
29	Vulnerable patients and children	X		
30	Record retention		X	
	Ethical issues			
31	Ethical principles with their foundation in Nuremburg Code, Belmont Report, DoH	X		
32	Informed Consent/Assent	X		
33	Research misconduct	X		
34	Disclosure of Financial Information	X		

In Table 4 below, I evaluate each class section and indicate which item numbers in Table 3 are reviewed in each class.

Class Session	Current Agenda	CCRP Section
1	Class Basics, FDA History, FDA's Phased Approach to Drug Testing	9, 1, 2, 31
2	Human Subjects Protection Regulations, Case Study Discussion, Clinical Protocol Design	9, 1, 11, 12, 25, 26, 31, 33
3	GCPs, Medical Device Regulations	2, 3, 8, 26
4	Human Subjects Protection, FDA Inspections	1, 2, 4, 25, 26, 29, 31, 32
5	Statistical Concepts and Study Design	9, 1, 2, 11, 12
6	Informed Consent and Consent Forms	2, 4
7	IRB perspectives on advertising and recruitment, Mock IRB Meetings	4, 13, 25, 26, 29, 30
8	Study Set-Up, Site Operations, Budget Concepts	3, 5, 8, 11, 12, 13, 14, 32
9	Conflict of Interest, "The Legacy of Jesse Gelsinger"	4, 13, 29, 34, 33
10	Voices from the Trenches	
11	Bringing a product to market, Sponsor Types, Academic v. Industry Research	2, 3, 5, 8, 11, 12
12	Regulatory Pathways, IND/IDE/NDA/PMA/510k	2, 5, 9, 11, 12
13	Types of clinical trials, Elements of the protocol, beyond the protocol	5, 9, 11, 12, 14, 15
14	SOPs, Site Selection, DSMC/CEC/AEAC, Study Manual	2, 5, 6, 14, 15, 16, 17, 18, 27, 32
15	Case Report Forms, Data Mgmt, EDC	14, 15, 16
16	Investigator Meetings, Start-up Visits, Interim monitoring, close-out	3, 5, 8, 10, 13, 14, 18, 21, 22, 23, 24, 27
17	Group Presentations/Interpreting clinical research	7
18	Clinicaltrials.gov	2
19	Clinical Reports, Safety Reports, NDA	6, 19, 20
20	Marketing, PR, OPDP	
21	Principles of Project Management	5
22	Business Presentations & Financial Management Tools	
23	Preparing the Project	5, 10, 13, 14, 15, 28
24	The Art of Negotiation	7
25	Contracts & Financial Forecasting	7
26	Outsourcing & Ancillary Documents	17, 16, 15, 21, 22
27	Managing Yourself & Others	
28	Project Maintenance & Disaster Planning	13, 7
29	Project Close-out	14, 23, 24, 22
30	What it's really like out there	

As we can see from Table 3 and Table 4 above, the clinical trials series matches fairly well with the CCRP examination from the SoCRA. There are lectures that do not match with topics from the CCRP examination, but this is to be expected in a program designed to go beyond teaching to a certification exams. There are a few gaps in coverage of the program to the CCRP examinations (including the handling of lab samples and product accountability); these are addressed in global redesign of the clinical trials program in Section 5.5.

2.6. Overall gap analysis of BRAMS to certification tests

This analysis shows that the three exams (RAC, CCRP and CCRA/CCRC) are well covered by the material taught in the BRAMS program. As stated above, there are no national standards for these types of programs so a comparison of the material taught to these national certification examinations helps us demonstrate the relevance of the material taught and the appropriate coverage that this topic should be given.

There were a few minor areas in the CCRP and CCRC/CCRA examinations that do not have adequate coverage in the clinical trials coursework and those areas, identified in sections 2.4 and 2.5 above, are addressed in the proposed reconfiguration of the clinical trials program discussed in section 5.5. The RAC exam shows no gaps that require changes in the BRAMS program for coverage.

3. Comparison of BRAMS to other existing degree programs in regulatory affairs

There are currently more than 20 programs in the United States that offer graduate degrees in Regulatory Affairs or in Clinical Trials. There are currently no standards for the materials to be covered or minimum requirements for these programs. In order to stay competitive and ensure that the BRAMS program is offering comparable material at a comparable cost, I researched twenty of these graduate programs and performed a gap analysis against the BRAMS program.

In this section of the document, I summarize the 20 separate degree programs and the information gathered about each one. This information includes the basic topics covered, the time and credits to completion, the estimated cost and the presence of a capstone or practicum project.

3.1. Description of the general landscape of regulatory affairs programs

The BRAMS program began admitting students in 2008. In the five years since the BRAMS program began, several other programs have emerged around the United States. At this point the programs only number in the dozens and are offered as both in-person programs and via distance learning.

The courses are all of a similar length, approximately 2 years, and cover a similar set of material. In this section, I review several degrees other graduate degrees in regulatory affairs and evaluate how the BRAMS program at the University of Washington compares.

3.2. Listing of programs to which BRAMS was compared and how information was gathered

The following programs were included in the review. The information on these programs was gathered from three sources: online information provided by the school, written information available upon request from the school, personal conversations with representatives at the school.

1. Northeastern University – Master's of Science in Regulatory Affair for Drugs, Biologics and Medical Devices
2. San Diego State University – Master's of Science in Regulatory Affairs
3. Arizona State University – Master's of Science in Clinical Research Management
4. Cal State Fullerton – Master's of Science in Applied Biotechnology Studies with a focus on Regulatory Affairs
5. Campbell University – Master's of Science in Clinical Research
6. Johns Hopkins University – Master's of Science in Biomedical Regulatory Affairs
7. Keck Graduate Institute – Master's of Bioscience with a focus in Clinical & Regulatory
8. Long Island University – Master's of Science Degree with specialization in Drug Regulatory Affairs
9. Massachusetts College of Pharmacy – Master's of Science in Regulatory Affairs and Health Policy
10. Northwestern University – Master's of Science in Regulatory Compliance
11. Purdue University – Master's of Science with a concentration in Regulatory and Quality Compliance
12. Regis College – Master's of Science in Regulatory and Clinical Research Management
13. St. Cloud State University – Master's of Science in Regulatory Affairs and Services
14. St. Cloud State University – Master's of Science in Applied Clinical Research
15. University of Georgia – Master's of Science for Regulatory Affairs
16. University of Southern California – Master's in Regulatory Science
17. University of St. Thomas – Master's of Science in Regulatory Science
18. University of Washington – Master's of Science in Biomedical Regulatory Affairs

3.3. A description of the types of program to with BRAMS was not compared

The BRAMS program was not compared to post-graduate certificates offered by several of the schools included in this review and by dozens of other educational institutions, as well. The University of Washington offers these certificates. The certificates are not reviewed as they have different standards for admission, are generally much shorter than a graduate degree, do not have similar academic standards for admission or completion and are not viewed in a similar manner by the industry in terms of educational value.

In addition, the MS in Pharmacy Administration with a focus on Regulatory Affairs and Quality Assurance and the Master's Degree offered by Temple University were not included as the online information was not available and, despite requests no further information was forthcoming from either program.

3.4. Program Comparisons

3.4.1. Credit Hours, Cost and Time

These Master's degrees vary in the number of required credit hours, time to completion and quoted cost.

The mean cost of completing a Master's Degree in regulatory affairs is $34,451.83 with a range of $21,450 to $68,862 (no estimated costs were available from Cal State Fullerton and Purdue University) and a median cost of $29,492.50. The University of Washington estimates the cost of their degree as $31,000 and that aligns fairly closely with the mean and median costs. In a few cases, the cost of the program was calculated using the number of credit hours, the cost per credit hours and the fees for a student on a quarterly or semester basis.

The programs require a range of 30 to 45 credit hours with a mean of 36.2 and a median value of 36 credit hours. The University of Washington requires 45 credit hours for completion of the program.

The mean time for completion of the degree is 25.8 months, with a range of 24-42 months and a median completion time of 24 months. The University of Washington's course schedule is designed to be completed in 24 months.

In each of these cases, the BRAMS program at the University of Washington is fairly closely aligned with the vast majority of the graduate programs available in the United States.

3.4.2. In-Person or Distance Learning

One of the newest trends in education is a move to distance learning. In section 6.2, I discuss the potential for moving the BRAMS program to

distance learning and the steps that would need to be taken and the risks and benefits of this change.

Current, some of these programs offer distance learning while some offer the option of distance learning or in-person education.

Currently, 11 of 19 programs reviewed (58%) offer their Master's in Regulatory Affairs only as an in-person program. Four programs (21%) are offered only as distance learning and the other four programs (21%) can be taken as distance learning or in person.

While the BRAMS program is looking to a move to a combination of distance learning and in-person classes, the current norm in this field is in-person education.

3.4.3. Requirement for a Capstone Project

The BRAMS program currently requires a student to complete a practicum project as a part of the completion of the MS in Biomedical Regulatory Affairs. This practicum project accounts for 9 of the 45 credits required to complete the degree.

A capstone project, thesis or internship is required for all but three programs included in this review. No information was available for Temple or St. John's University.

3.4.4. Areas of Focus

In a comparison of the areas of focus each program, I examined the major topics covered in the BRAMS program with the level of coverage provided in each of the other programs. The BRAMS program has coverage of regulatory affairs, clinical trials, medical devices, pharmaceuticals, biologics, international regulatory affairs and coursework on writing. Eighteen programs were included in this portion of the review.

- Regulatory affairs – all programs provide coverage of the regulations, the Act and the FDA's guidance documents
- Clinical Trials – Sixteen programs provide coursework specifically dedicated to clinical trials. In five of the sixteen programs, clinical trials is an optional course and not required for graduation.
- Medical Devices – Two programs provide no coursework on medical devices. In two additional programs, medical devices are an option. In two further programs, medical devices are only included as a portion of the coursework on clinical trials.
- Pharmaceuticals – Sixteen programs include pharmaceuticals as a component of the regulatory affairs coursework. The two programs that do not include pharmaceuticals are different than the two programs that do not cover medical devices.

- Biologics – Thirteen programs include biologics as a key product class in their program. Five programs have no reference to the specifics of biologics or biologic licensing. Two of the programs that do not include biologics are programs that also do not cover pharmaceuticals.
- International Regulatory Affairs – Twelve of the eighteen programs in regulatory affairs have specific coursework dedicated to international regulatory affairs. Of these twelve programs, international regulations are an optional course in two and in an additional two programs, the coverage of international regulatory affairs is limited to a single country instead of a broad review of the global regulatory environment.
- Writing Coursework – Ten of the eighteen programs have coursework in writing as a part of their regulatory affairs program. In two of these programs, the coursework is optional.

In addition, I reviewed the other programs to find areas of study or instruction that were covered by these programs, but not included in the BRAMS program. The University of Southern California has a course on Food & Dietary Supplements and Northeastern University includes courses on Clinical Laboratory activities and a separate class on Intellectual Property.

3.5. Overall gap analysis of BRAMS to other regulatory affairs degrees

At this time, the BRAMS program aligns well with other Master's Degree programs in Biomedical Regulatory Affairs. The costs, time to completion and academic requirements are similar to the majority of the programs reviewed. The BRAMS program is ahead of the curve in its coverage of pharmaceuticals, medical devices and biologics and its inclusion of international regulatory affairs and required coursework in writing.

There appear to be no significant gaps to close.

3.6. Areas of improvement

Based on my review of the available master's degree programs in Regulatory Affairs, I suggest two areas for improvement.

The first is a consideration of coursework in Food & Dietary Supplements and Laboratory Services. This coursework is offered by only a few other programs and would help distinguish BRAMS from the majority of regulatory affairs programs.

The second is a move toward distance learning as an option for students. This will be discussed in more detail in Section 6.2.

4. Student Surveys

4.1. Description of the current surveys

At the end of each class in the BRAMS program, the students are asked to complete a class survey that asks questions about the course overall, the primary instructor and each of the guest lecturers. The survey provides the following statements and allows the student to rate each statement from 0-5: 5 = Excellent, a 4=Very Good, a 3=Good, a 2=Fair, 1=Poor, 0=Very Poor. The statements are:

- The course as a whole was
- The course content was
- The course organization was
- Availability of extra help when needed was
- Use of class time was
- Amount you learned in the course was
- Evaluative and grading techniques were
- Reasonableness of assigned work was
- Clarity of student assignments and responsibilities was

In addition, the student is asked to respond to the following three statements about the instructor. Again, the student is to rate each statement from 0-5.

- Instructor's contribution to the course was
- Instructor's effectiveness in teaching the subject matter was
- Instructor's clarity in organizing the subject matter was

The surveys are provided via Catalyst and the students have a greater than 75% completion rate. After the completion of the quarter, the instructors are given their scores and any accompanying comments.

For this review, I calculated what I have termed as the Instructor Score (IS). This score is the average of the three instructor specific questions and the nine questions regarding the course as a whole. These scores are used in the graphs included in this document. These instructor scores follow the same scale of 0-5: 5 = Excellent, a 4=Very Good, a 3=Good, a 2=Fair, 1=Poor, 0=Very Poor.

Due to a change in the survey in 2010, the previous scores were not able to be included in the analysis as the questions were not the same and the scoring ranges were different. For this evaluation, the following classes were included:

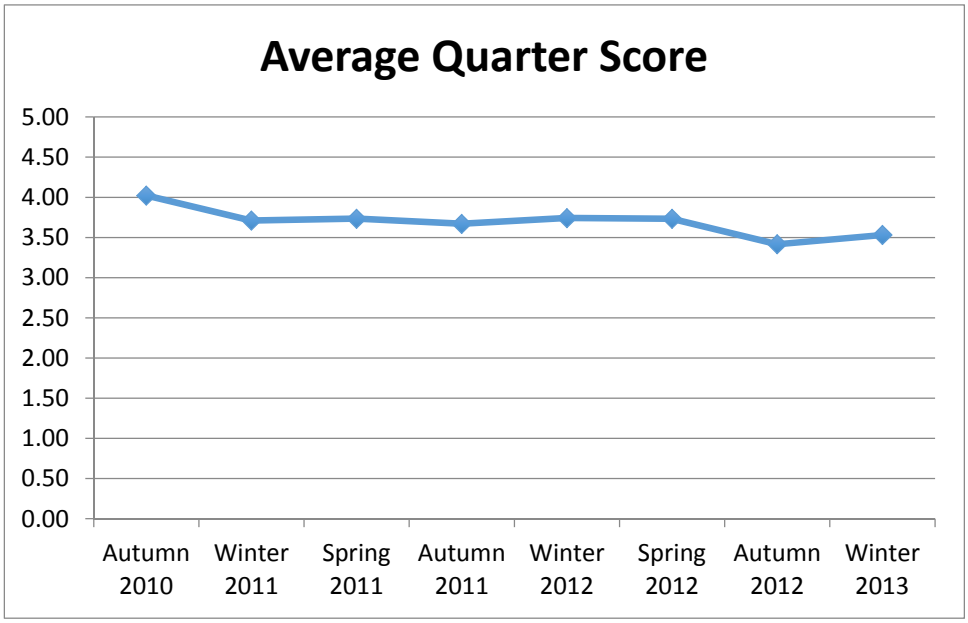
Course Number	Course Name	Instructor	Quarter	Year
PHARM 516	Regulatory Affairs 1	Hazlet	Autumn	2010
PHRMRA 524	Clinical Trials 1	Jonlin	Autumn	2010
PHRMRA 527	International Regulatory Affairs	Hammond	Autumn	2010
PHRMRA 536	Skills for the Regulatory Professional	Feagin	Autumn	2010
PHARM 517	Regulatory Affairs 2	Hazlet	Winter	2011
PHRMRA	Clinical Trials 2	Hammond	Winter	2011
PHRMRA 528	Risk Management for Medical Products	Loboda	Winter	2011
PHRMRA 546	Intro Tech Writing	Teal	Winter	2011
PHRMRA 547	Advanced Medical Products Regulations 2	Feagin	Winter	2011
PHARM 518	Regulatory Affairs 3	Hazlet	Spring	2011
PHRMRA 526	Clinical Trials 3	Hayashi	Spring	2011
PHRMRA 550	Advanced Technical Writing	Teal	Spring	2011
PHRAMRA 545	Statistical Basis for Quality Systems	Magee	Spring	2011
PHRMRA 536	Skills for the Regulatory Professional	Feagin	Autumn	2011
PHRMRA 554	Advanced Medical Products Regulations 1	Feagin	Autumn	2011
PHRMRA 527	International Regulatory Affairs	Hammond	Autumn	2011
PHARM 516	Regulatory Affairs 1	Hazlet	Autumn	2011
PHARM 524	Clinical Trials 1	Jonlin	Autumn	2011
PHARM 517	Regulatory Affairs 2	Hazlet	Winter	2012
PHARM 525	Clinical Trials 2	Hammond	Winter	2012
PHRMRA 528	Risk Management for Medical Products	Loboda	Winter	2012
PHRMRA 555	Advanced Medical Products Regulations 2	Feagin	Winter	2012
PHRMRA 546	Introduction to Technical Writing	Teal	Winter	2012
PHARM 518	Regulatory Affairs 3	Hazlet	Spring	2012
PHARM 526	Clinical Trials 3	Hayashi/Hammond	Spring	2012
PHRMRA 545	Statistical Basis for Quality Systems	Magee	Spring	2012
PHRMRA 550	Advanced Technical Writing	Teal	Spring	2012
PHARM 516	Regulatory Affairs 1	Hazlet	Autumn	2012
PHRMRA 524	Clinical Trials 1	Jonlin	Autumn	2012
PHRMRA 527	International Regulatory Affairs	Hammond	Autumn	2012
PHRMRA 536	Skills for the Regulatory Professional	Feagin	Autumn	2012
PHRMRA 554	Advanced Medical Products Regulation 1	Feagin	Autumn	2012
PHRMRA 525	Clinical Trials 2	Hammond	Winter	2013

PHRMRA 528	Risk Management	Loboda	Winter	2013
PHRMRA 546	Intro Tech Writing	Teal	Winter	2013
PHRMRA 555	Adv Med Prod Reg 2	Feagin	Winter	2013
PHARM 517	Regulatory Affairs 2	Hazlet/Graham	Winter	2013

4.2. Review of program wide graphs and trends

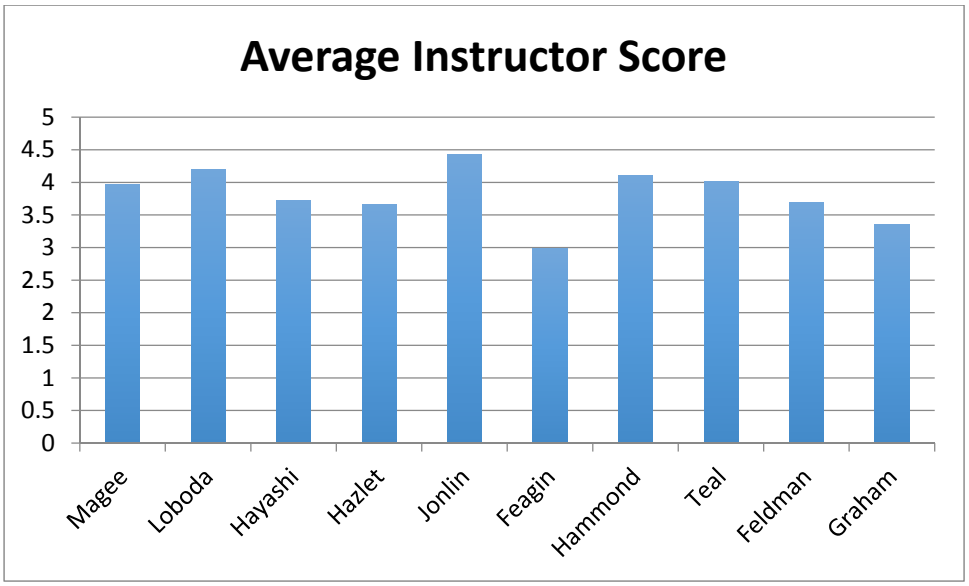
4.2.1. Average Quarterly Score

In this graph, I averaged the IS for all instructors teaching a class in a particular quarter. This graph shows a fairly consistent score across all quarters of the program indicating that the quality of the program has remained steady. The score has remained fairly consistent at Good to Very Good.



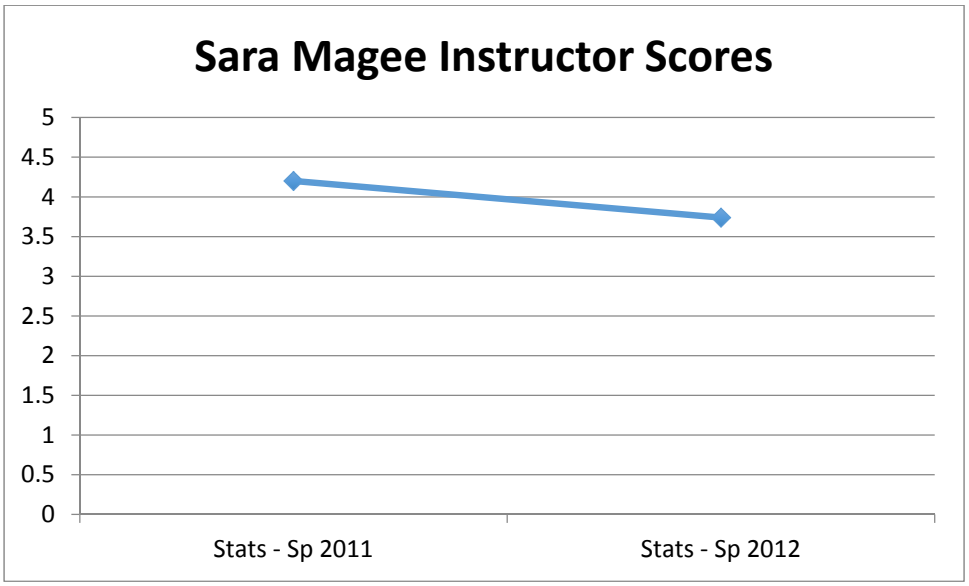
4.2.2. Overall Instructor Score

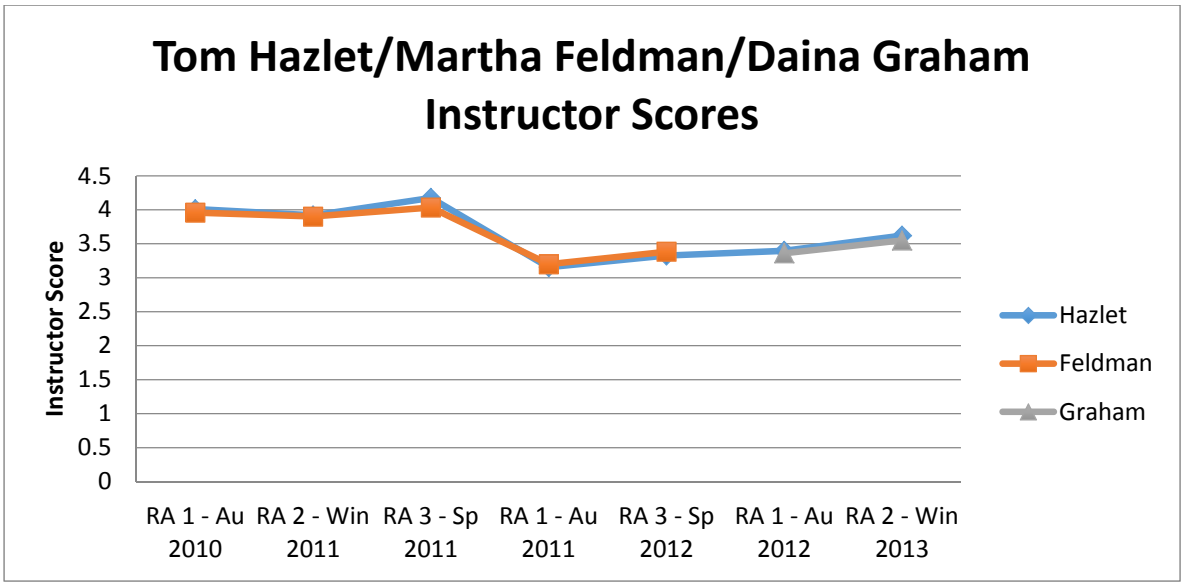
In this chart, I averaged each instructor's individual instructor scores to find an overall score for the instructor. Four instructors ranked Very Good to Excellent (Loboda, Jonlin, Hammond, Teal). Five instructors were scored as Good to Very Good (Magee, Hayashi, Hazlet, Graham, Feldman). One instructor was rated as Fair to Good (Feagin).

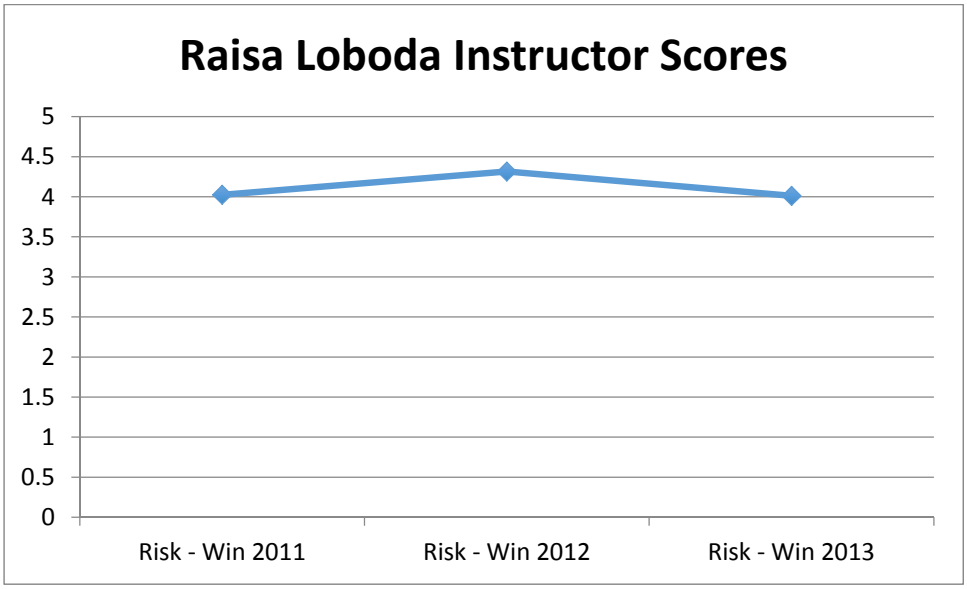


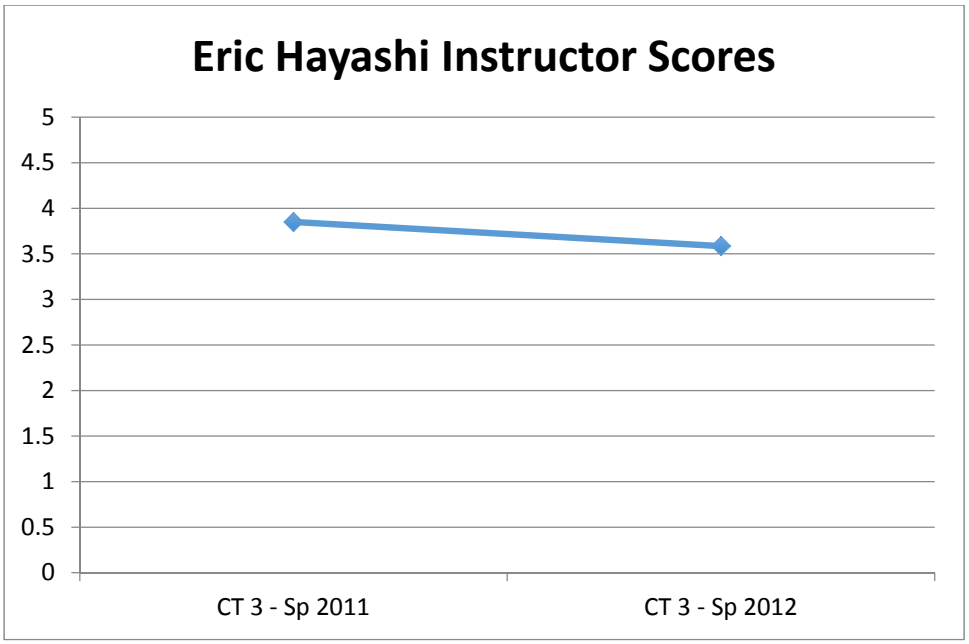
4.2.3. Individual Instructor Scores

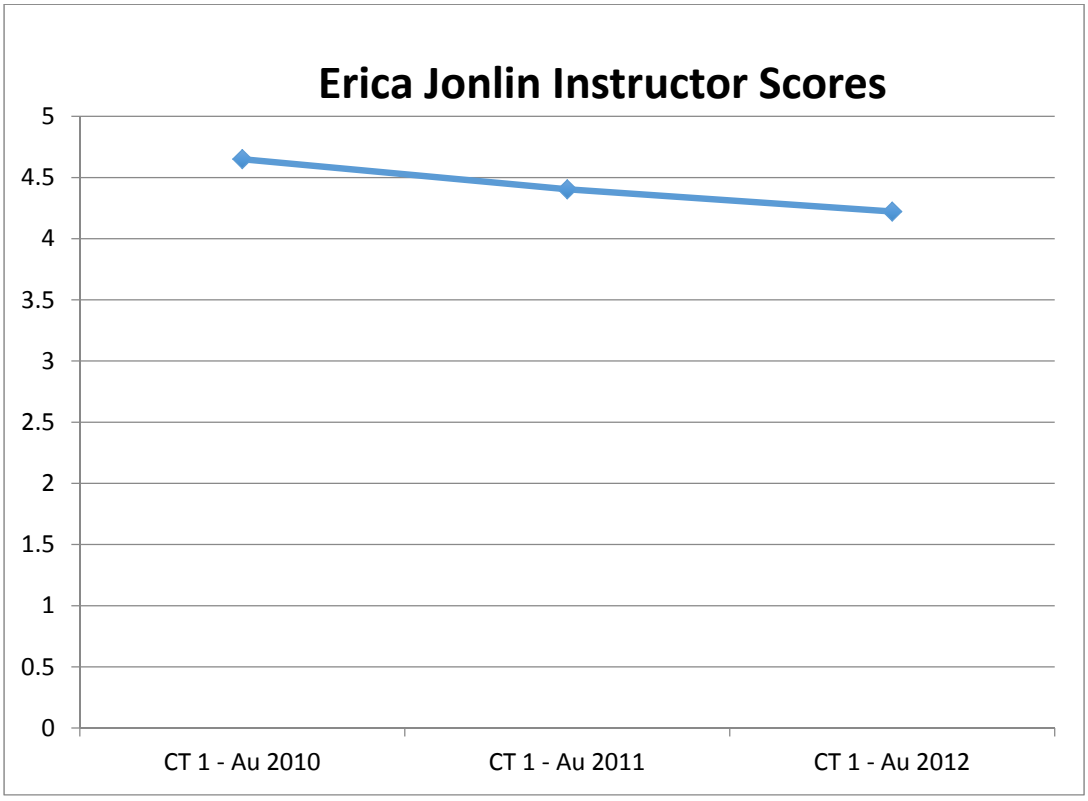
In this section, I graphed each individual instructor's scores over the quarters taught to identify any potential trends in his or her instruction.

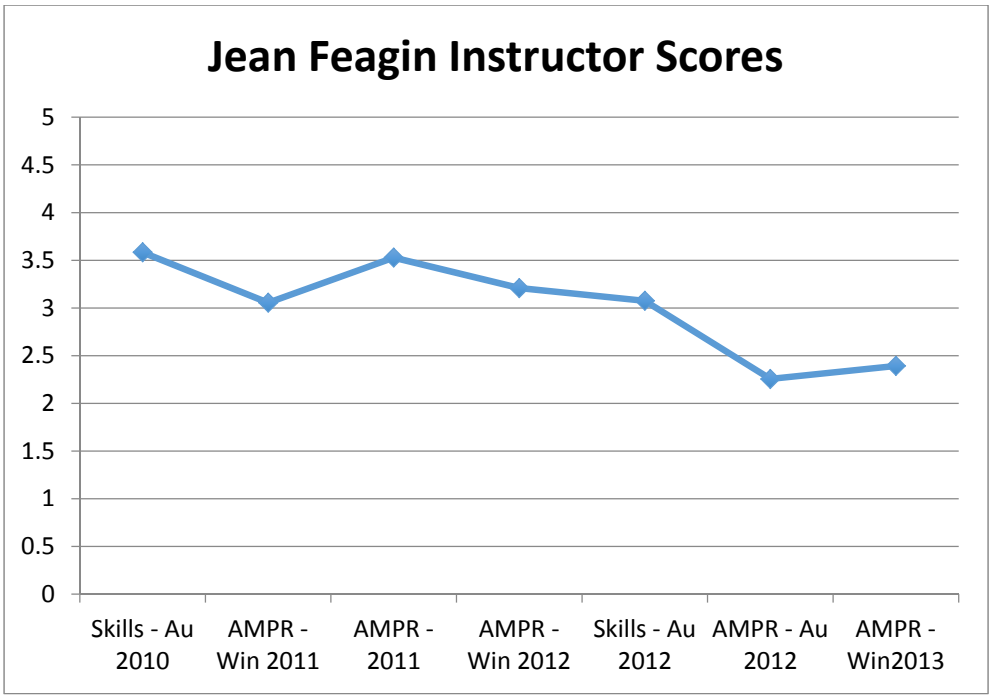


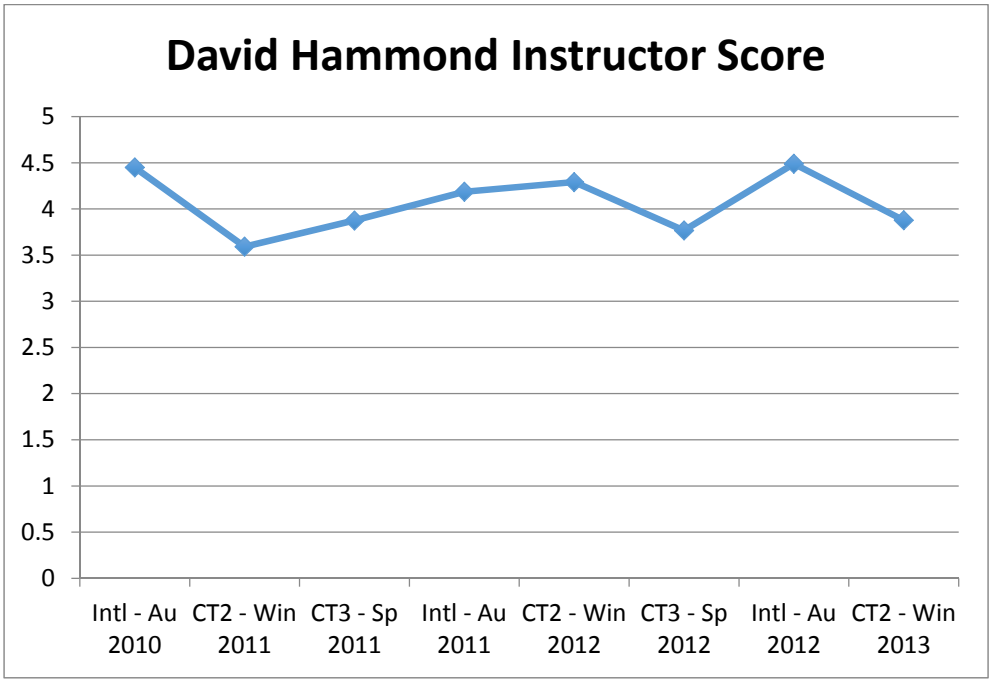

Tom Hazlet/Martha Feldman/Daina Graham
Instructor Scores
Instructor Score
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
RA 1 - Au 2010
RA 2 - Win 2011
RA 3 - Sp 2011
RA 1 - Au 2011
RA 3 - Sp 2012
RA 1 - Au 2012
RA 2 - Win 2013
Hazlet
Feldman
Graham

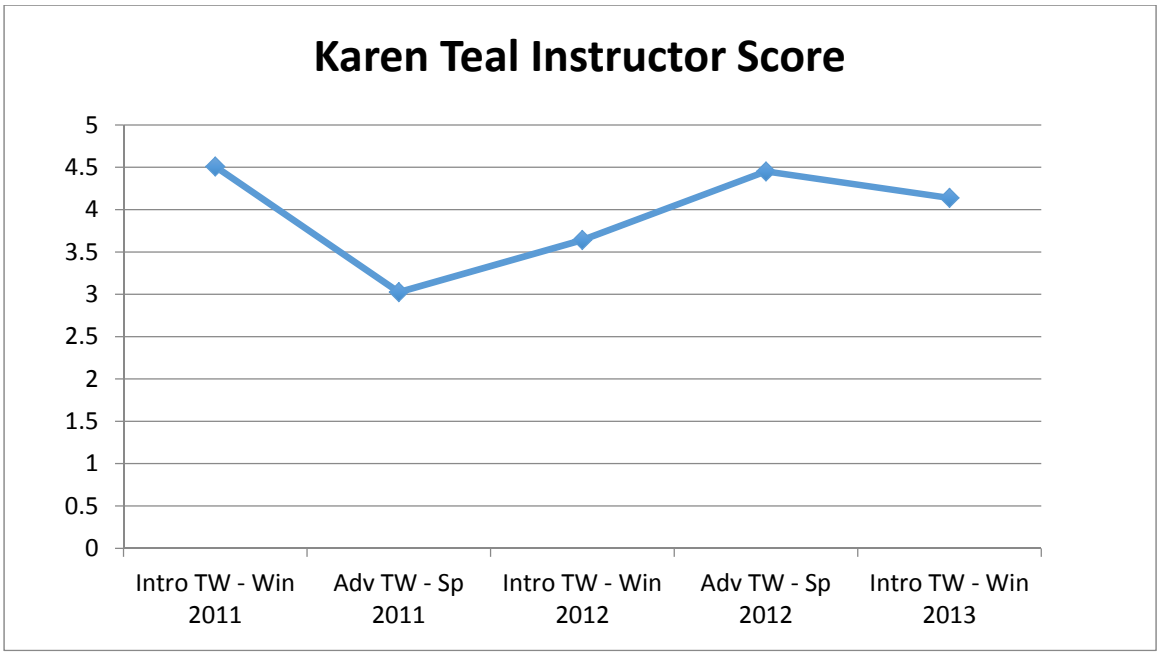

Raisa Loboda Instructor Scores
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Risk - Win 2011
Risk - Win 2012
Risk - Win 2013


Eric Hayashi Instructor Scores
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
CT 3 - Sp 2011
CT 3 - Sp 2012


Erica Jonlin Instructor Scores
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
CT 1 - Au 2010
CT 1 - Au 2011
CT 1 - Au 2012


Jean Feagin Instructor Scores
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Skills - Au 2010
AMPR - Win 2011
AMPR - 2011
AMPR - Win 2012
Skills - Au 2012
AMPR - Au 2012
AMPR - Win2013


David Hammond Instructor Score
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Intl - Au 2010
CT2 - Win 2011
CT3 - Sp 2011
Intl - Au 2011
CT2 - Win 2012
CT3 - Sp 2012
Intl - Au 2012
CT2 - Win 2013



These charts, in general, show good scores for the instructors in this program. They are consistently above 3.0 (Very Good) and while they may trend up or down slightly, most tend to vary in the Good to Very Good range indicating consistent performance with minor variations from quarter to quarter.

There is one exception to this trend. The chart for Jean Feagin shows a consistent downward trend, with a move over the last two quarters well below 3.0. These scores meet all three of the criteria defined in Section 4.3 needing further involvement.

4.2.4. Evaluation of individual student survey criteria

In the chart below, I averaged the scores for the individual criteria for course evaluation. This review was to determine if there was a single one of these criteria that stood out as exceptionally high or low and could indicate a trend among instructors as a global fault within the program. The scores in the chart below do indicate a single systemic failure among the instructors.

Criteria for Evaluation	Average Score
The course as a whole was	3.83
The course content was	3.79
The course organization was	3.64
Availability of extra help when needed was	3.89
Use of class time was	3.70
Amount you learned in the course was	3.74

Evaluative and grading techniques were	3.54
Reasonableness of assigned work was	3.61
Clarity of student assignments and responsibilities was	3.46

It appears that there were concerns among the students about the clarity of the student assignments and responsibilities. This can be addressed with improved used of Catalyst or Canvas LMS and with a more consistent syllabus structure and better compliance with the syllabus by the instructors.

4.3. Recommended use of metrics and triggers

The gathering of the metrics discussed in this section can be used set triggers that indicate that changes are needed in the course or with an instructor. While there maybe situations in which a trigger may be met and the instructor or course may not require corrective and preventative actions, these triggers should at least be used to identify situations requiring further attention.

I proposed that any of the following should trigger a review and possible corrective or preventative action:

- Any drop in an average Instructor Score (course criteria and primary instructor criteria) below 3.0 during any quarter
- A downward trend that extends for four or more quarters
- A drop of more than .75 points over two quarters

4.4. Corrective Actions and Preventative Actions

When a trigger is met and there is a need for corrective actions or preventative actions (CAPA), the program director should work with the faculty to determine the best course of amend the course material or to provide the instructor with the necessary tools to improve his or her performance.

4.5. Plan for increased metrics and tracking

The review of these student surveys has identified areas that can be improved. These numbers indicate there are instructors that may benefit from greater feedback and assistance viewing the trends of scores over time. These students will see several of these instructors for multiple classes and an opportunity to correct poor instructor scores quickly will help the instructors perform better in later quarters. A quarterly review of the metrics used in this report will help the BRAMS program better determine which instructors may need feedback or assistance and detect poor performing classes for correction.

5. Class and instructor discussion

In this section, I evaluate each individual course providing a basic description, a discussion of the strengths and weaknesses and a series of suggestions for improvement. These evaluations are based on observations made during my attendance in these classes, as well as, based on comments made to me by current and former students. In the courses for which I am an instructor or co-instructor, my review is based on comments made during class wrap-ups and on the end of quarter surveys, as well as, my thoughts on my teaching style.

5.1. Skills for the Regulatory Professional – Feagin

5.1.1. General description:

Skills for the Regulatory Professional, is taught in the autumn of the first year. I took this class in the autumn of 2011. The stated description for this class is: This course covers essential skills in regulatory affairs and includes an overview of local medical products companies. Lecture presentations, student presentations, homework assignments, and discussions are employed to extend students' skill sets and facilitate their growth as regulatory affairs professionals.

Jean Feagin taught this class for 7 weeks for three hours a week. The course is unique in that it is the first class in the normal sequence of BRAMS that is only for graduate students. Over the 7 weeks of the class, there were five lecture sessions and two sessions of student presentations. The course covers good writing practices, presentation skills, teamwork, structures of FDA regulated companies, interpersonal skills, business ethics and helpful hints for using Microsoft Word.

Two sessions of this class were taught by Dr. Feagin and three sessions were presented by guest lecturers. The students were graded on multiple HW assignments and their final presentations. The final presentations were done in groups on topics assigned by the instructor. These presentations were graded, not so much for the content, as for the utilization of the good presentation practices the students were taught early in the quarter.

This class was designed to serve the basic purpose of providing some general skills to the students that will be helpful in the upcoming coursework. Another intention was provide students without experience in an FDA regulated environment a basic familiarity with the environment.

5.1.2. Strengths:

The class allowed the graduate students an opportunity to gather separately from the joint classes with the certificate students. This gathering allowed for relationship building between the graduate students through class and group work. These students will have multiple opportunities over the next two years in which group work will be required and starting these relationships in the first quarter of the program accelerates that necessary familiarization.

5.1.3. Weaknesses:

The class suffers from several weaknesses; it duplicates material covered in later classes, it has multiple disjointed sessions that do not follow a logical progression, it relies heavily on guest lecturers that vary greatly in their quality, has a high percentage of sessions dedicated to student presentation, the relevance of these topics to the field of regulatory affairs is poorly explained or is simply poor, the instructor has limited experience in the field of regulatory affairs and so is unable to provide personal experiences to reinforce the material taught, and the time is this class could be used on more relevant topics.

Many of the topics covered in this class are duplicated in subsequent courses, often with conflicting information. The first two sessions of this class focused on technical writing and presentation techniques. The technical writing material strongly conflicted with the material taught in the first quarter of technical writing. For example, in Skills for the Regulatory Professional, a student is taught that it is never appropriate to end a sentence with a preposition. In the first session of Technical Writing, the student is taught that there are instances in which ending a sentence with a preposition is acceptable. The second session of the course on presentation techniques is duplicated in Clinical Trials III. In Skills, the student is provided with suggestions for PowerPoint design that conflict with the material presented in Clinical Trials III.

In this class, in moving from session to session, the topics have little relationship to previous topics and start and stop abruptly within the session.

Of the seven total sessions in this class, two (or 28%) are dedicated to student presentation.

Of the five sessions that are not student led, guest lecturers do three or sixty percent.

One of the dangers of teaching materials not directly related to the field of regulatory affairs is that students have traditionally expressed confusion as to the relevance of the material to performance in the field. With careful explanation of the rationale for including each individual topic,

these student complaints lessen. The explanation of relevance was missing or vague for these sessions.

5.1.4. Suggestions for improvement:

Reduce the use of guest lectures. If guest lecturers must be used, ensure that they are drawn primarily from existing faculty to ensure that the lecturer is available for follow-up and can assist with assessing understanding.

Spend additional time on explaining the relevance of the material presented so that the students are able to appropriately categorize the knowledge for later use.

Reconsider the topics in this course. This class consists of 21 classroom hours. More relevant topics such as high-level overviews of the regulatory processes in the US, regulatory terminology, explanation of proper research techniques and navigation of the FDA website and a review of the history and current state of biotechnology in the Pacific Northwest. A review of interview techniques, resume design and project management would also be helpful to students who are beginning to look for practicum opportunities and meet with the students.

5.2. Clinical Trials 1 – Jonlin

5.2.1. General Descriptions of the Class

This class is the first of three consecutive courses on clinical trials. It is taught in the autumn of the first year and is taught in combination with the certificate program. I took this class in the autumn of 2011. The stated description is: This course introduces the major concepts under which clinical trials are designed and run. It focuses on the phases of clinical trials, the role of the U.S. Food and Drug Administration, Institutional Review Boards, the Code of Federal Regulations and ethical principles. The study design and statistical concepts are also addressed.

Over the ten weeks of this class, the students are introduced to the basic principles of clinical trials, the history of clinical research (including the disasters that led to the introduction of key regulations), the role of the Institutional Review Board, the elements of the consent form, biostatistics and some of the key activities at a clinical site.

Dr. Jonlin presents most of the material in this class. There are two sessions taught completely by guest lecturers and several other guest lecturers who conduct part of the lecture with Erica covering the remaining material.

The course is designed to set the groundwork in clinical trials for the remaining quarters of the clinical trials program and provide a historical and ethical perspective on clinical research.

There were two homework assignments, a final assignment of a submission to the University of Washington Institutional Review Board and participation / attendance credit toward the final grade.

5.2.2. Strengths

The major focus of this section of the clinical trials series is human subject protections, institutional review boards, consent forms and clinical research history. Erica Jonlin is an engaging lecturer who is passionate about the material taught. She uses in class examples and goes beyond simple lecture style presentation to help the class understand what is being taught. Her experience in the basic areas (history, ethics, consent, IRBs) is quite good and is apparent in her presentation as her lectures are often dotted with real-life examples to reinforce the material presented.

Erica consistently scores well with the students (see Student Surveys) and has maintained a consistent instructor score in her class. In speaking with students in the following quarters, they emerge well-versed in the material covered and with a positive response to her instruction.

5.2.3. Weaknesses

The material covered in this course feels stretched to fill 10 weeks. Multiple class sessions are spent on the history and ethics of clinical research, as well as, the consent form. While it is important, the time dedicated to this information could be reduced by 30-40%, and, in my opinion, it would not significantly detract from the ability of the students to retain this knowledge. The material in this quarter covers quite a bit of the clinical trial life-cycle, leaving large gaps that need to be filled in later quarters. In section 5.5, I propose a global restructuring of the three clinical trial classes to better arrange the material in a logical order and fill some possible gaps in our instruction. To make time to fill these particular gaps, it is proposed that the 10 weeks of material in this class be reduced to approximately six weeks and spread across multiple quarters of instruction.

Erica Jonlin has a tendency in her teaching to present information with a particular bias against the pharmaceutical or biotechnology industry often using sweeping generalizations about the practices of corporations that are either untrue or slanted in their presentation.

The guest speakers utilized in this class session were mixed in their effectiveness and the breadth of their knowledge on their particular topic.

Many presented from the position of an academic medical center and therefore brought that limited perspective.

The final assignment involved the creation of an IRB submission for the UW IRB using a protocol provided by Dr. Jonlin. This assignment had two significant issues. The protocol provided is over 20 years old, arranged in an NIH format (an atypical and confusing format) and poorly written. The UW IRB application is unnecessarily confused and not representative of commercial IRBs or most academic medical centers.

5.2.4. Suggestions for improvement:

The primary suggestion is outlined in section 5.5 of this document. This rearrangement of the course structure would reduce the hours dedicated to this material and provide it in a logical order that avoids the need for retrospective education.

A co-instructor for this material would allow a second perspective on the material covered and if the co-instructor comes from a non-academic environment, this may help with the bias shown against industry.

A change in guest lecturers and a broadening of the source of these guest lecturers beyond the University of Washington will help provide a broader perspective in instruction.

I also suggest a change to the final assignment to use a newer clinical study protocol and a modification to include multiple IRBs representing a variety of IRB types.

5.3. Clinical Trials 2 - Hammond

5.3.1. General Description of the Class

This class is the second in the three-part series on clinical trials. It is taught in the winter of the first year and is a combined class with certificate students. The stated description of this class is: This course outlines the work of carrying out a clinical trial. The complex work of study initiation, the issues of site and data managements, the preparation of the final report and study close-out are covered, as well as the myriad details that control the study conduct.

The intent of this class is to cover protocol design, regulatory submissions to the FDA, data management, monitoring, marketing and PR. The material is covered in 10 weekly 3-hour sessions. The lecturing is all done by David Hammond and no guest lecturers are used. In the first year of

this evaluation, the students were assigned to groups and each group presented a presentation on a significant clinical study. In the second year of this evaluation, the student presentation was dropped and one class on Case Report Form (or data form) design was flipped with a pre-recorded lecture and an in-class work session that involved the construction of case report forms. In addition, an Instructional Assistant was added and one of extra lecture sessions was filled by the IA.

The students complete 4 short homework assignments, 2 short (2-3 page) papers and 1 long (5-7 page) paper.

5.3.2. Strengths

As I am the instructor for this class, these strengths and weaknesses come from student comments during the end-of-class review and the student evaluations.

- The instructor has a strong background in the material covered and having worked in multiple positions for both the sponsor and clinical study site is able to provide a varied perspective.
- His lectures include numerous anecdotes and real-life examples that emphasize the material covered in class.
- He frequently jokes and is establishes a comfortable classroom environment.
- As he does the lectures, he is able to answer questions about all of the material.
- At the beginning of each class, he reviews the previous material to ensure that we understand.

5.3.3. Weaknesses

- The instructor often speaks quickly and for students who don't speak English as a primary language it can be confusing.
- The instructor does not use any guest lecturers and listening to one speaker for the entire quarter can be tedious.
- The instructor sometimes spends too much time reviewing the previous session's material.
- The instructor focuses too much on medical devices and corporate sponsors
- His jokes can be distracting from the necessary material in the class

5.3.4. Suggestions for improvement:

A better integration of this material with the other quarters of the clinical trials certificate would distribute the material in a manner that is more consistent with the regular progression of a clinical trial. A proposed redistribution of the courses is discussed in Section 5.5

To address the issues regarding a focus on medical devices and the lack of guest lecturers, this course should either introduce a co-instructor with a complimentary background in pharmaceuticals or increase the use of guest lecturers with pharmaceutical background.

The instructor has, since the comments on the speed of his lectures and time spent reviewing the prior quarters, made adjustments to his lecture style to address these issues.

5.4. Clinical Trials 3 – Hayashi/Hammond

5.4.1. General Description of the Class

This is the third quarter of the Clinical Trials series. This quarter is taught by Eric Hayashi and Dave Hammond, each teaching 5 sessions. The five sessions led by Dave Hammond focus on project management for clinical trials. This includes areas such as metrics for projects, start-up and shut down phases, disaster management and recruitment prediction.

The five sessions led by Eric Hayashi focus on business aspects around clinical trials such as budgets and break-even analyses, negotiations, meetings, managing staff, sales, and resumes and job seeking information.

The five sessions led by Dave Hammond are all taught by the instructor. The five sessions led by Eric Hayashi utilize guest speakers for three whole sessions and half of a fourth.

In this class, the students complete 6 HW assignments and 1 5-page paper.

5.4.2. Strengths

As I am one of the two instructors in this class, the comments regarding my portion of the program will be based on student comments from the student surveys and in-class debrief. The discussion of Eric Hayashi's portion will be based on my observations.

Regarding the business of clinical trials, the instructor brings a varied, but relevant background having managed a site maintenance organization and a central lab service. In earlier quarters the students had complained about the relevance of this material, as it does not easily related to clinical trials, but Eric has made an effort over the last few years to explain that relevance to

the students and the comments regarding this have decreased. Eric uses many guest speakers who bring a varied background (former police detective, HR trainer, recruiter). The material on Break-Even analysis was useful.

Regarding project management and clinical trials, the students identified the following strengths:

- The material on Gantt Charts was very useful
- The creation of the plans (Data Management, monitoring) as group work worked well.
- Dave is engaging/entertaining/enthusiastic and knowledgeable

5.4.3. Weaknesses

The quarter is currently broken into two 5-week pieces. These pieces are blended together and the quarter jumps back and forth between the two pieces and it can be confusing for the students. A consistent 5-week set of courses would make the material easier to follow and more consistent. The past presentations on sales and business development have not worked well and should be removed in favor of another topic.

The course suffers from the blend of certificate and MS students (discussed in section 5.12) and the certificate students do not get as much attention paid to work submitted.

The high usage of guest lecturers by Eric Hayashi does not allow the instructor as much ability to follow-up and answer questions at later class sessions, plus Eric has more material he could directly present.

5.4.4. Suggestions for improvement:

A better integration of this material with the other quarters of the clinical trials certificate would distribute the material in a manner that is more consistent with the regular progression of a clinical trial. A proposed redistribution of the courses is discussed in Section 5.5

Dave Hammond should increase the number of guest lecturers used in his portion of the course and Eric Hayashi should reduce the number of guest speakers in his section.

The blending of the two sections of the third quarter leads to confusion and decreases the continuity in the material presented. These distinct sections should be done in 5 consecutive class sessions.

5.5. Global review of the clinical trials certificate

The Clinical Trials Courses differ from the Regulatory Affairs Courses in that each quarter has a different lead instructor who is responsible for the material and testing. In the Regulatory Affairs series, the same primary instructors lead all three quarters.

With the differing instructors, the quarters are not well integrated and the material covered does not follow a single logical, temporal progression. This is primarily due to the differing areas of expertise of the instructors. In the tables below, I proposed an updated flow of data, the elimination of some lectures I felt to be duplicative or unnecessary and the inclusion of some information that helps us better match the certification examinations from ACRP and SoCRA.

Class Session	Overall Topic	
1	History/Ethics	Class Basics, FDA History, FDA's Phased Approach to Drug Testing
2		Human Subjects Protection Regulations, Case Study Discussion,
3	FDA Overview	Bringing a product to market, Sponsor Types, Academic v. Industry Research
4	Regulatory	GCPs, Medical Device Regulations
5		Regulatory Pathways, IND/IDE/NDA/PMA/510k
6	International Considerations	Clinical Trials OUS
7	Protocol Design	Types of clinical trials, Clinical Protocol Design, elements of the protocol
8		Statistical Concepts and Study Design
9	Project Management	Principles of Project Management
10	Budgets / Contracts	Financial Management Tools, Budget Concepts
11		The Art of Negotiation
12		Contracts & Financial Forecasting
13	IRB / Consent	Informed Consent and Consent Forms, Conflict of Interest
14		IRB perspectives on advertising and recruitment, Mock IRB Meetings
15	CRFs	Case Report Forms, Data Mgmt, EDC
16	Other Documents	Plans, SOPs, Study Manual, DSMC/CEC/AEAC
17	Investigational Product / Lab Samples	Labeling, Preparation, Storage
18	Sites & CROs	Outsourcing & Ancillary Documents, Site Selection
19		Study Set-Up, Site Operations, Preparing the Project
20	Study Start-up	Investigator Meetings, Start-up Visits, Investigational Product Tracking
21		Managing Yourself & Others
22	Screening	Initiating Screening/Screening Activities/Recruitment planning
23	Trial Master File	Contents, Management, Auditing

24	Project Management	Project Maintenance & Disaster Planning
25		Interim monitoring, close-out
26		Clinical Reports, Safety Reports, NDA
27	Project Close-out	Project Close-out
28		Business Presentations
29		Marketing, PR, OPDP
30	The Real World	What it's really like out there/Voices from the Trenches

5.6. Regulatory Affairs 1, 2, 3 – Hazlet

5.6.1. General Description of the Class

While this class is actually three separate sessions held over the Fall, Winter and Spring quarters of the student's first year, the class instructors and format remain the same and so the entire regulatory affairs series will be reviewed together. In this class, I conduct two guest lectures a year and grade the student homework. I attended this class as a student in the autumn of 2011 and the winter and spring of 2012.

The Regulatory Affairs Series, taught by Tom Hazlet and Martha Feldman (first year of the evaluation) and Daina Graham (second year of the evaluation) is 3 credits per quarter. I was never able to observe Daina Graham as an instructor in this class. The class is taught for 10 sessions that are each 3 hours long. The regulatory affairs classes follow a logical progression starting with a basic review of the regulations, a discussion of pre-approval activities such as clinical research and INDs and IDEs. The program then moves to the winter quarter with a focus on quality systems and finally into the spring quarter with a review of post-market activities, such as recalls and marketing.

At the beginning of the first quarter, the students are placed into groups of five or six students and assigned a drug and a medical device. These groups are a mix of graduate students and certificate students. This combination of student types leads to some conflict (this is discussed in a later section in this document). The groups then complete a set of 5 or 6 homework assignments in each quarter that focus on their products. In addition, at the end of each quarter, the student groups do a presentation on their products that reflects the stage of the course. For example, at the end of quarter 1, the students discuss the clinical trials being conducted on their products, while at the end of quarter 2, they may discuss quality system issues that arise from the manufacturing. The students also complete a series of short quizzes online. In addition, the graduate students have a large project that spans three quarters. They select a section of the regulations, propose a change, and then write a 10-page paper discussing the change, the reason for the change,

the potential impact of the proposed change and the potential negotiations that may arise from the proposed change.

At the end of the winter quarter and the spring quarter, the students take field trips to a drug manufacturer (typically ICOS CMC) and a device manufacturer (most recently, Philips Medical).

Nearly 70% of the classroom sessions are done by guest lecturers. Several of these guest lecturers return in later quarters, but most do not.

5.6.2. Strengths

The class does a good job covering a vast area of information in a structured manner. The fact that the instructors and class structure are consistent from quarter to quarter, helps the students maintain focus as they are not dealing with new instructional styles and expectations each quarter. The regulatory affairs series has been done for a number of years and the rough edges have been smoothed off and polished.

Several of the guest lecturers recruited by the UW are outstanding and bring excellent real-world experience to the classroom.

The tours of the drug facility and the device manufacturer are always well received by the students.

I felt that the long-term project completed by the students over the three quarters was fascinating, but my opinion was not echoed by several of the students in my cohort.

5.6.3. Weaknesses

Despite the high quality of some of the guest lecturers, there is a heavy reliance on these guests who, as discussed later in this document, often duplicate information and are unavailable to students at later points when questions arise over homework or quiz questions and the students and instructors are left to rely on the slide sets and their own memories. This has been addressed, somewhat, with the recording of most class sessions using Tegrity. However, a recording is not a substitute for access to the guest.

The graduate students and certificate students are grouped together, which can cause a conflict in terms of the student motivation.

There have been complaints in the previous quarters that the homework assignments were confusing and did not align well with the topics covered in class. Over the last two years, these assignments have been rewritten and realigned with the lectures and the students have complained less about this issue.

Many students found the requirements for the long-term project confusing and often expressed a wish that there was a chance to meet with Dr. Hazlet one-on-one to discuss the project.

5.6.4. Suggestions for improvement

I suggest a reduction in the number of guest lecturers that are used for this program. The percentage of the course that is conducted by guest lecturers should be 50% or less. This provides the instructors to bookend the guest presentations with context and review and reduces the number of presentations about which the students may have difficulty with follow-up.

I also suggest that the student groups be divided by student type with graduate students grouped together. This should reduce the conflict on the student motivation and need for grades.

I would finally suggest that in the initial weeks of the first quarter that the instructors set time, immediately before or after class to meet with each student and discuss their long-term project to ensure that the students are aware of the requirements and have a plan for its completion.

5.7. Introduction to Technical Writing – Teal

5.7.1. General Description of the Class

Technical Writing is a 3-credit course taught by Dr. Karen Teal and typically taken in the second quarter of the first year of the program. During my tenure as a first-year student (winter 2012), the course was taught on six Saturdays, five hours per session. It has since moved to 10 sessions on Thursday evenings for three hours per session. The course is described as "The course presents up-to-date information and strategies for effective technical communication within the medical product industries. It addresses the appropriate and correct use of the English language, information design, and the use of computer technology in producing professional documents. It also emphasizes communicating technical information to a variety of stakeholders. "

The course is taught primarily by Dr. Teal with a single guest lecture by an expert in XML. The students submit writing samples of various lengths including the response to a warning letter.

The Class of 2014 will take an additional technical writing class, Advanced Technical Writing. As this class was not a requirement for the Class of 2013, it will not be reviewed in his document.

5.7.2. Strengths

This class teaches necessary basic writing skills, focusing on common failures for writers such as over use of the passive voice and run on sentences. There is also a focus on basic punctuation and document structure.

It is difficult to teach writing skills to a set of graduate students with varying levels of competency in the English language and skill at writing. Dr. Teal's class structure allows her to focus on advanced areas of writing with students who do not need a primer on punctuation, but allows for some relatively elementary correction of poor writing practices.

After having taught students before and after the completion of this class, I found that the written assignments showed marked improvement. My own writing improved greatly after completing this class.

The students are given extensive written feedback on each piece that is invaluable in the student's progress in writing.

5.7.3. Weaknesses

The earliest lectures contained instructions on writing that directly conflicted with those presented in Skills for the Regulatory Professional.

The instructor, Dr. Teal, has little regulatory experience, so the writing skills taught are general and are not necessarily specific to the field of regulatory affairs. Some of the instruction given to the students about avoiding the passive voice and writing specificity into the documentation is counter to the common practices in the industry.

The writing assignments could have been more representative of the types of documents a student would be required to complete on the job.

5.7.4. Suggestions for improvement:

The primary suggestion for improvement is the introduction of a co-instructor that can provide the regulatory experience to supplement Dr. Teal's experience in teaching writing. This co-instructor could help steer the assignments and writing styles to those best suited for the field.

A second suggestion for improvement was to move away from the Saturday 5-hour sessions. This has already been accomplished.

5.8. Advanced Medical Products Regulation 1 & 2 – Feagin

5.8.1. General Description of the Class

This was a series of two classes for the class of 2013, but has been changed to a single class for the class of 2014. These classes were taught by Jean Feagin, for seven weeks for three hours a week. I attended these classes in the fall of 2012 and the winter of 2013. The course descriptions for the two sessions were: Provides an in-depth exploration of regulatory issues primarily related to non-clinical and clinical aspects of medical product development." and "Provides an in-depth exploration of regulatory issues primarily related to manufacturing, post-marketing concerns, and FDA interactions." While the descriptions varied, the classes were fairly similar in their layout. The first session involved five sessions with various guest lecturers and two sessions dedicated to student presentations at the end of the quarter. The second session involved five sessions dedicated to various guest lecturers, two sessions for the mock FDA meetings. One session was for student preparation and one was for the actual meetings. Of the 10 sessions dedicated to lectures, one half of one session was completed by Dr. Feagin; guest lecturers, including 3 ½ sessions done by me, did the remaining 9 1/2.

The topics of these lectures varied from global health to usability studies to the construction of a protocol to alternate study designs to software to FDASIA.

The students submitted homework assignments, were graded on class participation, and for their efforts in the student presentations and FDA meetings.

The original purpose of this class was to provide an opportunity for deeper evaluation of topics discussed in other class sessions, new topics in regulatory affairs and topics that were beyond the clinical trials and regulatory affairs series in scope.

5.8.2. Strengths

This class' stated purpose gives it a broad spectrum of materials and topics that could be covered in any given class session and the class did span a broad set of topics and varied between pharmaceutical and medical device issues fairly successfully. Some of the guest lectures and their speakers were outstanding and would not have been available had a greater commitment than a single evening been required.

The class allowed potential instructors an opportunity to come speak to a group of students without the program making a full quarter commitment.

The FDA meetings conducted in the second quarter were an excellent use of class time and a well-designed opportunity for the students to experience a reasonable simulation of an activity typical of regulatory affairs professionals.

5.8.3. Weaknesses

Guest lecturers account for 95% of the material presented in the class meaning that these lecturers are unavailable for follow-up after the completion of the class session or a rehash of materials if questions arise. This also means that the HW, often generated by the guest lecturer, is graded by the instructor who may not be as familiar with the material and have difficulty if the student's answer varies from that provided by the guest lecturer. Or, if the guest lecturer does not provide HW questions, the instructor is left to generate homework herself based on her understanding of the material.

The high usage of guest lecturers means that the material jumps drastically from session to session based on the availability of the guest lecturers. With the high likelihood that a guest lecturer may have to change his/her schedule at the last minute, the schedule is chaotic and topics often feel like they are selected not because of their importance, but instead because an individual is available to discuss them on a particular date. The instructor's inability to cover key topics herself when a guest lecturer is unavailable makes this reliance on guest lecturers a greater weakness. The quality of the guest lecturers varies greatly and while several were good, many were poor either repeating information provided earlier in the program or simply lacking in presentation skills.

In the first quarter, two sessions of seven were assigned to student presentations. These sessions were primarily focused on old topics (biosimilars) and were more an evaluation of the student's presentation skills than the content of presentation. This topic (presentation skills) is amply covered in other quarters and seems an unnecessary use such a high-percentage of the available class sessions.

5.8.4. Suggestions for improvement:

As of the Class of 2014, this course is reduced from two quarters to one quarter. This reduction in class sessions will, per a discussion with the instructor, result in the elimination of the student presentations, but the FDA meetings will be kept. This reduction also means that the instructor is only responsible for six lecture sessions and will allow the weeding of poor guest lecturers.

A second suggestion is that the course's lectures follow a theme or concept instead of bouncing from topic to topic. While this will limit the exposure of a

certain class to new material, it will allow greater cohesion of the sessions and provide greater value in the topic chosen.

I suggest that a co-instructor with greater regulatory experience be assigned to assist Dr. Feagin in helping the lectures coalesce and in the creation and grading of HW.

5.9. International Regulatory Affairs – Hammond

5.9.1. General Description of the Class

International Regulatory Affairs is a 3-credit hour class taught by David Hammond. It is typically taken in the fall of the second year of the BRAMS program and has only students who are in the BRAMS program. The online description of the class is "The course content will focus on the regulatory processes of industrialized markets, but it is also designed to address evolving issues in emerging markets. By the end of the course, students should have a thorough understanding of the history behind international regulatory harmonization and the role this has played in solving current challenges and providing opportunities under the current climate of global trade and medical products regulation." The intention of the class is to select several countries beyond the US and discuss the regulatory systems and clinical trials processes for each country. The countries that are selected are common ones for product development (Canada, Australia, Japan, UK, and China) or prime examples of countries in different stages of regulatory development (Singapore, New Zealand). Due to the sheer volume of material, the class moves quickly and often covers regions at a high-level. The students also select a country, not otherwise covered in the class, and do a presentation on that country.

The class is taught primarily by David Hammond with guest lecturers accounting for 30% of the classroom time. The students complete five short homework assignments, a regulatory strategy memo and presentation on a country not covered in class, a spreadsheet of regulatory requirements and a final examination reviewing the materials in the class.

As the author of this document teaches this class, the strengths and weaknesses listed below are based on comments gathered from current and former students and the instructor's own evaluation of his strengths and weaknesses.

5.9.2. Strengths

This class provides a broad overview of a number of countries and focuses on the key countries most likely to be encountered by the student in his/her career in regulatory affairs.

The class covers regulatory approvals and clinical trial requirements for the countries discussed.

The instructor has personal experience in most of these countries and can provide real-life anecdotes about working in each.

The instructor does most of the teaching and is able to discuss issues and answer questions at later follow-up sessions.

5.9.3. Weaknesses

The class doesn't cover enough countries and the time for the class should be increased.

The instructor has experience in medical devices and the course lectures focus primarily on that product type.

The instructor does not spend time on Brazil or Russia.

The instructor does not spend much time on the marketing requirements for these OUS locations.

The instructor goes very quickly through large amounts of material.

Some of the guest lecturers do not provide a benefit to the class.

5.9.4. Suggestions for improvement:

The instructor needs to expand the pool of guest lecturers to focus on additional countries and pharmaceuticals. A co-instructor may also be able to assist with this expansion of teaching. The material to be covered in the class is significant and flipping class sessions may help with better time usage and allow the instructor time to better answer student questions about the countries.

This class will be reviewed during the spring quarter of 2013 and redesigned using the principles of Understanding by Design and this redesign may address several of the issues documented.

5.10. Medical Risk Analysis and Management – Loboda

5.10.1. General Description of the Class

Medical Risk Analysis and Management is a three-credit class taught by Raisa Loboda. It is typically taken by students in the winter of the second

year of the program and is populated by graduate students; I completed this class in the winter of 2013. The online description of the class is "Risk analysis, management and communication are increasingly important tools for medical products manufacturers both in the United States and internationally. Recent U.S. Food and Drug Administration and International Committee on Harmonization initiatives emphasize risk management in product development, manufacturing and marketing. This course will impart principles and applications of risk management methods in the design, manufacturing and marketing of medical products." The class focuses on the principles behind risk management and assessment and the tools (Fault Tree Analysis, FMEA) used by professionals in the field. The class focuses primarily on medical devices and software with two sessions dedicated to pharmaceuticals and biologics. Raisa does approximately 40% of the lectures herself and uses guest lecturers for the rest.

The students complete 3 quizzes, an online final examination, select a product recall and write a paper on the recall and the risk analysis, and do two written homework assignments on risk management in pharmaceuticals.

5.10.2. Strengths

The instructor of the class, Raisa Loboda, is engaging and entertaining. This class is the only one in the program directly focused on quality systems and related topics and the students find the material new and challenging. While the class relies heavily on guest lecturers, Raisa has sufficient experience to be able to discuss their topics if questions arise at later points. The material that is presented can be instantly transferred to real world use and the tools taught are reinforced through the final assignment on the product recall.

5.10.3. Weaknesses

The pharmaceutical/biologics portion of the class is weak with half of it duplicating material covered in the clinical trials' series. It seems to be almost an afterthought, included in the class to document coverage of both drugs and devices. There is an overuse of online quizzes that often have difficultly worded questions that frustrate the students. There was a syllabus provided at the beginning of the quarter with a list of HW assignments that was not followed causing confusion among the students. The student presentations use up two class sessions or 20% of the classroom time.

5.10.4. Suggestions for improvement:

Removing the pharmaceutical/biologics portion of the class would allow for more time to be spent on the medical device portion where the material was more in depth and relevant. The types of assignments should be modified to better handle the types of questions asked in the HW. A new instructor will be taking over the class in the winter of 2014 and a reassessment of the class, under this instructor, should be conducted.

5.11. Statistical Basis of Quality Assurance for Regulated Industries – Magee

5.11.1. General Description of the Class

Statistical Basis of Quality Assurance for Regulated Industries is the final three credit class taught by Sara Magee. It is currently taught in the final quarter of the second year of the BRAMS Program, but there is a plan to move it to the autumn quarter of the second year of the program. Due to a scheduling issue (a conflict with my teaching responsibilities for the spring quarter of the clinical trials program), I was forced to miss 50% of the class sessions. However, this allowed me to evaluate the current tools for distance learning (Tegrity).

This class is described on the BRAMS website as: This course reinforces the vocabulary and major concepts in statistics, and introduces methods used in medical products industries regulated by the U.S. Food and Drug Administration. This class was broken down into 10, 3-hour sessions. The class sessions were taught partially by Sara Magee and partially by guest lecturers. Most class sessions involved both Sara and the guest lecturer presenting.

There were nearly weekly quizzes, homework conducted in groups, and a final group presentation on a single statistical analysis project.

The class did not delve deeply into statistical calculation, but more into the application of statistical methodology to difference situations in medical devices and pharmaceuticals and the value of using these tools to monitor product quality.

5.11.2. Strengths

Overall, the class is very well done. The class has several strengths including the experience of the instructor, Sara Magee, and her ability to provide real-world examples to secure the class material with the students.

She breaks the students into groups for homework completion. This allows the students flexibility, as the group submits a single HW assignment and the participation of each group member is managed by the group. With most of the students having a full-time job and other extra-curricular responsibilities, this system worked very well for me and for all students interviewed on this issue.

Her combination of guest lecturers, bookended by her instruction, helps explain the material presented by the guest lecturer and put it in perspective for the students.

5.11.3. Weaknesses

The class has weakly quizzes. The quiz questions are often confusing in their wording and cause frustration among the students. The follow-up discussions on these quizzes in class were often frustrating and didn't help the students determine how to better answer the quiz questions.

The class has a strong focus on pharmaceuticals (this would make sense, as the instructor's background is primarily in drugs), but has only a little focus on medical devices (primarily added by guest lecturers).

This class is at the very end of the program. At this point, the students have lost a fair amount of focus, many are dealing with wrapping up their practicums and looking forward to the completion of the program. The attendance in this class has been mediocre, much of it, I believe due to senioritis.

This class has a bit of overlap with the clinical trials program when it comes to statistics and clinical trials and some overlap with the risk management class.

5.11.4. Suggestions for improvement:

The first suggestion for improvement has already been implemented; I would suggest a move from the final quarter of the program to a point earlier in BRAMS. This has been accomplished.

The second suggestion, as with many of the classes in the BRAMS program, is the addition of a co-instructor to cover material from a different perspective from that of the current instructor. I would suggest an instructor with a medical device background.

A third suggestion is to reconsider the use or design of the quizzes in this class. I think that quizzes can be used to reinforce important points, but that it would be helpful to have an independent individual review the questions and determine if the wording is understandable to someone other than the quiz creator.

5.11.5. Remote Learning:

As stated earlier, I was forced to attend 5 class sessions remotely. This remote learning was conducted through a review of the slides and listening to the Tegrity recordings for this class.

Unfortunately, this worked very poorly for this class. This was not due to a failure with the Tegrity technology. When recorded, the Tegrity system tended to work fairly well. However, there were a few issues:

- When students spoke in class or asked questions, the microphones used were not capable of picking up the question or comment.
- Several guest lecturers were unwilling to be recorded
- In post-recorded sessions, I was unable to ask questions of the lecturers on comments that were unclear or conflicted with my current understanding

The slide sets were designed for in-class presentation, meaning that they were designed as cues, but not complete in their content and not useful for review without an accompanying recording.

This reinforces my plan in section 6.2 for a move to distance learning. Simply recording current presentations and posting through Tegrity is inadequate for making the classes available remotely. The manner of presentation, in-class discussion and provision of slides or other material should be redone while considering that the lecture will not be conducted face-to-face. As we re-evaluate each class for consistency and clarity, we should also consider the need to make the material usable outside of a standard classroom environment.

5.12. Practicum - Feagin

5.12.1. General Description of the Class

The practicum project is the capstone project for students in this program. Each students is required to complete a practicum project that takes approximately 270 hours and is worth 9 credits (20% of the total credits required for graduation). Practicum projects are typically completed at the site of a biotechnology company or similar group. The project, selected by the company, is a defined set of work with a defined deliverable at its completion. Past projects have included regulatory strategy documents for new products, 510k submissions for medical devices or pediatric investigational plans for the EMA. The practicum project must be in a related field, must be approved by the practicum director and must not be something that the student has done before or is doing as a part of their

daily work activities. The practicum is described online as “The Biomedical Regulatory Affairs practicum provides a practical experience to ensure that students can shepherd new medical products (drug, device and biologic) through regulatory, clinical and quality assurance aspects. Each student will work on a project of his/her choice under the guidance of the Practicum Director. Students refine their work as they progress in the program and produce a final report. Although course work is completed independently, students are required to participate in group presentation sessions. These sessions provide an opportunity to share knowledge among peers, hone communication and presentation skills, and be evaluated by cohort members and instructors.

Course faculty members and the Practicum Director will communicate with practicum students and preceptors regularly to assess progress and student-practicum site harmony, and to be available for problem resolution.

To facilitate student work, the Practicum Director will focus on the following:

- Development, maintenance of and updating of affiliation agreements with practicum sites
- Student advising
- Development and maintenance of student progress and practicum site evaluation data set
- Development and scheduling of mentoring encounters

To successfully complete the practicum, the student must:

- Prepare periodic progress reports (to be submitted to the Practicum Director)
- Deliver a presentation about the project to the class
- Prepare a final report to be submitted to and evaluated by the Practicum Director who, along with the student, will determine the length and format of the report.”

There have been issues around the confidentiality of the work to be completed and in those cases, a separate document is completed for the practicum project that is either redacted or discusses the process around the completion of the work task.

The practicum is managed by Jean Feagin, but also by a practicum preceptor. The practicum preceptor is an individual at the sponsoring

organization that works with the student on the work product. The confidential work product is not provided to Dr. Feagin. The preceptor provides a review of the student's efforts and the quality of his/her work. The student begins the process with a short proposal, followed by a work plan, followed by quarterly progress reports, followed by a final submission and finally by a presentation on their project to an audience.

As this document is my practicum and it has not been conducted in the normal manner, my discussion of this class is based on discussions with current and former students, faculty and preceptors and my attendance at final practicum presentations.

As this project is a large portion of the credits allotted, covers several quarters of the program and can be quite stressful, this particular element of the class has several strengths and many weaknesses.

5.12.2. Strengths

This practicum project is often the best opportunity for a student to gain real-world experience while participating in the program. The classwork often strives to provide realistic examples and simulations of real-world scenarios, but within the confines of the classroom, it is impossible to truly replicate a realistic experience.

The Practicum provides an opportunity for students to get introduced to local biotech companies. Many students come into this program with no experience with biotechnology and wish to pursue a job in this field for the education is finished. This practicum has placed several students at the practicum sites and allowed for a higher employment rate among our graduates.

Experience of the practicum allows the students to provide useful skills on the resumes. Biotech employers often look beyond education to work experience gathered and these particular projects allow the students to provide that sort of experience to potential employers.

A capstone or practicum project is a requirement among most of the Masters of Science in biomedical regulatory affairs programs in the United States. Our practicum project allows us to stay competitive with these other programs.

Despite some of the weaknesses discussed below, the students often talk about the benefit of having an opportunity to utilize the classroom knowledge in a real-world situation. Despite some of the complications of frustrations the students may have experienced, they find this real world experience allows them the opportunity to realize how much they have learned in this program.

5.12.3. Weaknesses

There have been several issues identified with the practicum projects and the process for their completion.

Timelines for documents not married to the reality of project timelines. There is a requirement for students to submit a series of documents in order starting with a brief proposal, followed by a workplan, followed by progress reports and a final document. The proposal has often required multiple submissions and corrections with the accompanying timelines for these review cycles stretching to four or six weeks. The underlying projects at the practicum sites are on corporate timelines and must progress based on the company's needs. As is often the case, the work on the project begins while the brief proposal is still being negotiated and the workplan has not been cleared or even created. This puts the student in the precarious position of completing work on an unapproved work plan and then retrospectively completing the documentation to no real value.

Projects that stop before completion. In the world of biotechnology, projects are often begun and then abandoned when only partially completed. If a project used for a practicum stops at an early stage without much work invested, the loss to the student is minimal, but if the project has progressed for several weeks before being ceased, the student may have invested a large number of hours on a practicum that can't be completed as the company has pulled its investment of time and personnel. Currently, the student is simply told that he/she must start again on a new practicum.

Delays in communications and responses and the value of the reviews provided. As related to the first weakness, there have been delays in communications and responses between the practicum director and the students that put these projects at risk. Sometimes a company is willing to wait to begin the project until the practicum documentation has been completed, unfortunately, these long delays result in frustration at the practicum sites which put in peril the current practicum and the willingness of the practicum site to handle further practicum projects.

Student presentations and classmate participation. At the end of the practicum project, the students do a presentation on their practicum project to some faculty and to interested classmates. The issue around these presentations has been a lack of student participation in the audience. The new first year students often attend the first one or two presentations of the second year students to gather perspective on the practicum projects, but the attendance of the first year students after the first two presentations and the attendance of the second year students at any of the presentations has waned greatly since the outset of the practicum program decreasing the value of the practicum presentations. While it has been argued that there is value in providing the students with experience presenting before an audience, the

students will have done at least eight presentations at this point in the BRAMS program.

Lack of clarity in the requirements for each submission. The students have complained that there is a lack of clarity in the requirements for the length and content of the documents to be submitted at each stage in the practicum process. This leads to documents being sent back to students, not for content, but for structure causing the delays in documents that lead to timeline issues for the students and the sponsors of the practicums.

Inability of the practicum program/credit requirements to deal with shifting project timelines and financial aid requirements. The nature of the projects used for practicums is that they will shift from quarter to quarter as the company changes its timelines. Unfortunately, if a student has signed up for two credits of practicum and the project is delayed by two-three months, the student is unable to conduct the planned activities for the practicum in that quarter and the practicum instructor is unable to give the student a grade for the work to be done. Ungraded credits impact a student's ability to get financial aid and may jeopardize the ability of the student to continue in the program.

5.12.4. Suggestions for improvement

Timelines for documents not married to the reality of project timelines. To improve this situation, the review and return of documents must be accelerated. The reviews must also allow the students to begin the next stage of document creation when the review of the previous stage is not about addressing content, but structure and grammar. To accelerate the process, the practicum director may need to include co-instructors or designated reviewers and allow those reviewers to act independently of the practicum director so as to avoid the review bottleneck of a single reviewer. The reviewers must provide responses within defined time periods with no slippage.

Projects that stop before completion. To improve this situation, the practicum process must involve an alternate pathway and work product for projects that stop before completion. In the case that a student is engaged in a practicum project that stops early, the student and the practicum director can negotiate a work product that covers the efforts completed to date and covers an adequate number of hours to meet the credit requirements.

Delays in communications and responses and the value of the reviews provided. This is similar to the first suggestion for improvement. To accelerate the process and improve the quality of the responses provided, the practicum director may need to include co-instructors or designated reviewers

and allow those reviewers to act independently of the practicum director so as to avoid the review bottleneck of a single reviewer.

Student presentations and classmate participation. There are three potential solutions for this weakness. The student presentations can be done in a manner that requires student participation. The situation could remain unchanged and we accept that the student participation will remain low. The student presentations could be discontinued

Lack of clarity in the requirements for each submission. The instructions and presentation provided to the students at the beginning of the practicum project should be review and amended. A current or former practicum student could come in and provide examples of materials that were approved by the practicum project.

Inability of the practicum program/credit requirements to deal with shifting project timelines and financial aid requirements. The practicum project process must be amended to allow the students to slide the work from quarter to quarter to account for the slippage in the work to be completed for the practicum project.

5.13. Global Issues with certificate and BRAMS students

The certificates in clinical trials and regulatory affairs existed for nearly a decade before BRAMS was created, the certificates form a key segment of the courses to be covered for the BRAMS student, and many students who have advanced degree, who have no interest in additional academic credentials or who have limited time or budget for further education find the material presented in the certificate program to be adequate to advance their career or make a career change. As the certificate students are graded on their attendance and participation, but not on the assignments that are submitted, there is often a motivation gap for group or solo projects for these certificate students. The graduate students are graded on the completion of the homework assignments, projects, and class participation and there have been incidents of conflict between the certificate and graduate students when they are combined on group projects and the students have different levels of motivation or necessity. This difference has caused conflict on group work and in the homework completed for both the clinical trials and regulatory affairs classes.

6. Overall plan for BRAMS

6.1. Harmonization of teaching methodologies and student evaluation

Every instructor brings an individualized style of teaching and a personal history with the subject matter to the classroom. These aspects, often reflected on in the student evaluations and comments, greatly separate the successful instructors from those who instructor scores lag or with whom the students express frustration. The majority of the instructors in this program are experts in their field of instruction, but have had minimal training or guidance on how to handle a classroom, construct an effective syllabus, design homework or tests that adequately test knowledge or assess the understanding of the students. This leads to classroom workloads that vary greatly in complexity and required effort and this variation can make it difficult for the students to anticipate the instructor's needs.

A unique aspect of the BRAMS program compared to other graduate programs in regulatory affairs is the faculty. Many programs rely on professionals that have retired from the field which increases their availability, but utilizing people at this stage of their career affects the length of their tenure with the program and the relevance of their experience. Most of the faculty involved in this program are employed outside the UW in a career related to regulatory affairs and teach in the BRAMS program as a second job. This dual employment can cause stress for these instructors and cause instructors to consider leaving the program. Providing these instructors with assistance in planning their classes and providing ongoing feedback will likely help normalize the student experience from class to class and likely increase the job satisfaction of the instructors involved in the BRAMS program.

As a part of the ongoing development of the BRAMS program and its faculty, I propose that, in addition to the review of the student evaluation metrics, that three steps be taken to help with this harmonization and the development of our current faculty. The first step is a change in the frequency and focus of the faculty meetings. Currently, there is a single meeting focused on high level topics regarding the program, but I suggest that a second meeting be conducted that is designed for an in-depth review of the content of each class and the assigned workload to work on harmonization. The second step would be in-class observation of the instructors as they teach and a discussion of what is working and possibilities for change. The final step would be encouraging the faculty to utilize the services available to instructors, such as the Faculty Academy. Many of the faculty are unaware that these services exist.

6.2. A move to distance learning

When reviewing the current landscape of graduate programs in regulatory affairs, approximately a third of these programs offer remote education, or the opportunity to take the classes remotely. In addition, there has been a move to distance and remote education across the University of Washington and universities in the US at large. This is extremely prevalent in the realm of

professional graduate degrees (e.g. the MBA) designed for people who are currently working and seeking further education that fits a normal 40-hour work week.

The BRAMS program is designed for a similar population. Many of our students are currently working a full-time job. Our courses are on weeknights and occasionally on weekend days. Some of the program material (recorded lectures and slide sets) can be accessed remotely, but the courses are not designed for remote education. The current use of this material is for students who are unable to attend a particular class or wish to review a class lecture.

There are two large potential audiences for distance learning and the BRAMS program. Large portions of the United States are not physically close to a university offering a similar program and are served only by remote education and these areas could be served by a distance learning BRAMS program. The other substantial audience is the international market. There have been inquiries from outside the US about a need for education on the US regulatory system.

A move to distance learning is more complicated than simply recording the current lectures and posting them on a website. We must evaluate how the material in each class is presented, how the current group work would be handled and how the students are given an opportunity to interact with the instructors. While we work toward the harmonization and evaluation of the courses discussed in section 6.1, this would be an opportunity to consider the restructuring of the classes for better presentation remotely. This cannot be an instantaneous process, but should be a goal for the program over the next two or three years.

6.3. Summary of program-wide issues and a closure plan

Throughout this review, I have identified overlaps in materials taught, gaps to national certification examinations and places where the instruction could be improved or changed to address my observations and student concerns. In this section, I identify the largest issues and a four step plan to address these gaps, overlaps and improvements. The issues identified within the practicum are distinct and not included in this summary.

The biggest issues found during my review were:

- An overuse of guest lecturers that left the students unable to follow-up and the instructors unable to answer questions about the material presented during the guest lecturers presentation.
- Material that is presented, sometimes with conflicting information, in multiple classes by multiple instructors
- Too many student presentation that eliminates time better dedicated to classroom instruction

- A need for broader viewpoints when covering topics
- Blending of certificate and graduate students in the same class
- A non-sequential arrangement of the class materials in the Clinical Trials classes

6.3.1. Guest Lecturers and Student Follow-up

The usage of guest lecturers bring both positive and negative aspects to a class. These guest lecturers can assist with the need for a broader viewpoint (as discussed in section 6.3.4) and can bring wonderful real world experience, but also have numerous faults. The guest lecturers, as they are not privy to the previous presentations done by other lecturers, often repeat information previously presented to the students. The guest lecturers are often unaware of the stage of education of the students in the program and the presentations are too complex or too simple for the level of discourse appropriate for the students. The guest lecturers are often only brought to class once to do a particular presentation, but are then unavailable to the students for follow-up. While many of the guests leave contact information, the students may not be comfortable contacting the guest lecturer of their own accord to ask questions. In addition, if a HW assignment is generated based on that particular guest lecturer's presentation, the student may be at a loss for questions generated while completing the assignment.

I suggest that the use of guest lecturers constitute no more than 50% of the available class sessions. This allows the instructors time to preface and summarize their presentations during the following sessions. This will also reduce the number of topics covered about which the instructor may be unable to answer questions. I also suggest that the instructors take greater care in reviewing the proposed presentation with the guest lecturer prior to the class session to remove the unnecessary or repetitive material and to ensure that the presentation is appropriate to the students. It would also be preferable if the same guest lecturers could be used for multiple sessions in a quarter as that will provide the students opportunities to follow-up and allow the guest lecturers more familiarity with the class and to adjust his or her teaching style appropriately.

6.3.2. Duplicated Material

The first step is outlined in section 6.1 of this document where I suggest that a program-wide meeting be held to evaluate and harmonize teaching standards. This meeting can also be used to evaluate the materials taught program wide to identify places where material is being taught multiple times. Some repetition of information is important for adult learners, but too much repetition leads to boredom and a perception that the program is poorly organized.

6.3.3. Student Presentations

Experience doing presentations before peers is important for students in this or any professional program. However, in my review of the classes in the BRAMS program, a high percentage of the classroom sessions are dedicated to student presentations, reducing the time available for classroom instruction. I suggest that no more than 15% of a single class' time be used for student presentations (1.5 sessions in a 3 credit class and 1 session in a 2 credit class). In addition, during the review proposed in section 6.3.2, I would suggest reviewing the overall number of class sessions dedicated to student presentations and determining the impact on available time for the presentation of more material.

6.3.4. Broad viewpoints in class

In a counterpoint to instructors who rely heavily on guest lecturers, classes in which the instructor does the majority of the lecturing, there is a risk that the viewpoint expressed is limited that guided by the instructor's scope of experience. For example, an instructor whose experience is limited to medical devices may neglect topics relevant to pharmaceuticals or biologics or an instructor whose experience is academic may be unable to discuss elements relevant to industry. It is important that each instructor consider these other perspectives. Identifying shortcomings in an your own teaching may be difficult and so I suggest that the use of co-instructors or the observation and feedback suggested in section 6.1 as it may help an instructor identify these weaknesses.

6.3.5. Increased use of metrics

As discussed in section 4.5 above, the program collects a review of the class and instructor at the end of the quarter. This data can form a simple way to help an instructor evaluate his or her performance in a class or help the BRAMS program spot trends or triggers that may signal when a change is needed in the conduct of a course. I've recommended that there be a more systematic review of the student surveys and the creation of triggers that will recommend the program review the situation and, if necessary, institute corrective and preventative actions to rectify the underlying situation.

6.3.6. Blending of Certificate and Graduate Students

As discussed in section 5.13, the clinical trials courses and the biomedical regulatory affairs series are a blended class of certificate and graduate students. The proportion of students in the certificate vs. the master's program varies from year to year, but there a significant number of students representing both groups.

There are several possible solutions for this schism between the student groups.

- Separate the students on projects or homework groups into certificate and graduate groups
- Require that the certificate students complete homework and move from attendance to Pass/Fail based on work completed
- Separate the students into two separate classes
- Provide additional course time for the graduate students alone

The simplest solution is to separate the students by certificate and graduate student, but this has a unique complication. The students who are enrolled as only certificate students often have as much or more experience in the field than those participating in the BRAMS program and separating the students deprives the graduate students of exposure to those in the certificate who bring real-world experience to the class.

Moving all the students to a graded situation puts an increased burden on the instructors, doubling the grading required and this change would have to be consistent across all quarters of both the clinical trials and regulatory affairs series.

The students could be separated into two separate classes, but as the material to be taught to both is the same, this is waste of instructor time and class resources.

Providing additional course time for the graduate students alone would allow for in-depth discussion of topics that may not have gotten as much attention in the larger class and it would allow the instructor greater time to interact with the graduate students. This would require an increase in the number of credits assigned to each class, adding cost to the students and requiring a greater time commitment from the instructor.

The least disruptive of these suggestions and the one that damages the class dynamics least is a move to grading the work of the certificate students and moving them beyond attendance and participation to pass each quarter of the certificate.

6.3.7. Non sequential material in the Clinical Trials coursework

Due to the segmentation of the quarters in the clinical trials courses, the material presented does not follow a logical order. An amendment to the schedule of these classes is suggested in Section 5.5 of this document.

7. Understanding by Design

7.1. What is Understanding by Design

Understanding by Design is a methodology for designing classroom materials that relies on what Wiggins and McTighe call "backward design" (also known as "backwards planning"). This is the opposite of what is felt to be the traditional process for curriculum planning that starts with activities and plans the curriculum around those activities as opposed to identifying learning goals and planning toward that particular goal. This 'backward design' of beginning with a goal and planning the curriculum, choosing activities and designing the necessary materials to reach that goal is the point of UbD®.[1]

According to Understanding by Design, this 'Backward Design' is developed in three stages.

Stage 1 starts with educators identifying the desired results of their students by establishing the overall goal of the lessons by using content standards, common core or state standards. In addition, UbD's stage 1 defines "Students will understand that..." and lists essential questions that will guide the learner to understanding. Stage 1 also focuses on identifying "what students will know" and most importantly "what students will be able to do".

Stage 2 is about how to assess the students and their understanding. Teachers plan performance tasks and evidence of understanding. Performance tasks determine what the students will demonstrate in the unit and what evidence will prove their understanding. This can include self-reflections and self-assessments on learning.

Stage 3 is the development of learning activities that will lead students to your desired results[2]

7.1.1. Teaching for understanding

Another central idea of UbD is "Teaching for understanding." This understanding should be seen in the course design and teacher and student attitudes. Coherent curriculum design (as suggested in section 6.1), which will lead to clear distinctions between big ideas and essential questions. Teachers should tell students about big ideas and essential questions, performance requirements, and evaluative criteria at the beginning of the unit or course. Students should be able to describe the goals (big ideas and essential questions) and performance requirements of the unit or course. The learning environment should have high

[1] Hammond, G. Multiple methods of assessment. Red River College. Retrieved 5/12/2013.
[2] Wiggins and McTighe (2006). *Understanding by Design*. Pearson: Merrill Prentice Hall. p. 24. ISBN 0-13-195084-3.

expectations and incentives for all students to come to understand the big ideas and answer the essential questions.[3]

7.2. Deconstruction and Recreation of International Regulatory Affairs

As part of an independent study in the spring of 2013, I re-evaluated my International Regulatory Affairs class using the ideas in Understanding by Design and under the guidance of Dr. Steve Kerr from the School of Education at UW. I completed the standard UbD worksheets to establish my course understandings and then assessed how those understandings could best be taught and evaluated. Below are the conclusions I reached and my plan for their implementation.

7.2.1. Be able to identify the differences between the FDA's regulations and procedures and those in each country reviewed in the class

Understandings:

The differences/similarities between the FDA & the competent authorities for other countries

Essential Questions:

How does each country differ from/behave similarly to the FDA in terms of device/drug approvals, marketing, clinical trials

Students will know:

A basic regulatory comparison between the FDA and each core country

Students will be able to:

Make their own comparisons to the FDA from other countries

Performance Tasks:

Student Country Worksheets

Other Evidence:

In class discussion/development of the table of comparisons

Learning plan:

At the end of each lecture on a new country, review with a table of comparisons to the FDA and other countries studied

In the slide sets for each country, include comparison slides to the FDA

[3] McTighe, J. and Seif, E. (2002) Indicators of Teaching for Understanding. TTL Academies.

7.2.2. Be able to appropriately select countries based on regulatory needs

Understandings:

Different products have different regulatory paths and that these regulatory paths benefit from the regulatory systems within these different countries

Essential Questions:

What criteria does the regulatory pathway review most need?

What countries best fit the regulatory pathway needs of the product?

Students will know:

How to select a regulatory pathway based on different criteria

Students will be able to:

Outline a basic by-country regulatory pathway

Performance Tasks:

Take a product and sketch a regulatory pathway with explanations for the choices

Determine the key criteria for selecting a regulatory pathway from the project description

Other evidence:

In class discussions

Learning Activities:

In class regulatory path determination

Chart of countries and advantages/disadvantages to each

Final examination with a choice of regulatory pathway

7.2.3. Be able to research a new country's regulations and appropriately summarize

Understandings:

A systematic approach to reviewing a country's regulations

Essential questions:

Where do I look for the regulations/guidance documents for a country?

What information is important?

Students will know:

Where to look for regulations

What to include in a review of a country's regulations

Students will be able to:

Research the basic regulatory requirements of a new country

Performance tasks:

Complete 5 country worksheets that summarize the regulatory requirements

Memo on 1 country

Other evidence:

Class presentation on their country

Learning activities:

Lecture on researching new countries

Walk through of Germany/Practice researching a country using Germany

Discuss differences between Germany & US

7.2.4. Know regulatory structures for major countries: Canada, UK, China, Japan, Australia, Select EU countries

Understandings:

Each country possesses own set of regulations, many are similar, but have distinct difference.

How to compare to US

Essential questions:

What is/are the:

- Overarching law
- Device regulatory structure
- Drug regulatory structure
- Clinical Trial pathway
- Marketing requirements

Students will know:

Regulatory structures for Canada, UK, China, Japan, Australia, EU

Students will be able to:

Competently discuss the listed countries

Performance tasks:

Quiz Questions on each country

Make a student represent the basics to the class

Other evidence:

In class discussion/comparison charts

Learning activities:

In class lectures on each individual country

Progressive comparison chart in class

Rehash of basics by student of the previous country's material

7.2.5. Plan for amending the current program to meet these goals:

Create country worksheets for templates for reviewing the regulatory structure for each country

Amend each country's presentation to include comparison slides to US regulations

Create a slide set on researching a country and setting up a regulatory strategy

Write a final examination that involves setting up regulatory pathways for multiple countries

Set up template for in class comparison table

Setup template for student review of the previous week

8. Conclusion

The Masters degree in Biomedical Regulatory Affairs or BRAMS program grew out of a pair of post-graduate certificates over 5 years ago. As a young program, BRAMS has quickly added faculty and coursework and it was time for a comprehensive review of the program to ensure that it has maintained quality and student satisfaction. In this document, I reviewed BRAMS against outside

measures such as the national certifying exams and other master's degrees in regulatory affairs. I also reviewed the program from inside through my own observations over the last two years and a review of the student feedback at the end of each quarter.

During the external comparison, the BRAMS program compares quite well. The program covers all of the material listed as key to completed the RAC examination and almost all of the material required for the CCRP, CCRA and CCRC examinations. The suggestions made in this document for minor adjustments to the clinical trial series can cover those minor gaps.

The BRAMS program also compares well to similar graduate programs in regulatory affairs. Our cost and duration are similar and the material covered in BRAMS program is equivalent to the curricula of the programs reviewed. Our practicum project is fairly similar to the internships and capstone projects that are required in the masters' programs nationwide. Our curriculum has a greater emphasis on clinical trials, international regulatory affairs, pharmaceuticals and medical devices, and technical writing than many of these comparative programs. I have suggested a look to distance learning to expand our potential student base and to keep in step with a move made by other graduate regulatory affairs programs.

During the internal comparison, I attended each class in the program (for which I was not an instructor) and provided my personal assessment, as well as, comments from classmates and the cohorts before and after mine. These evaluations showed that each class had strengths and areas for improvement. Many of these areas, such as repetition of material, overuse of guest lecturers and an excess of student presentation were found across all classes.

I also looked to the study surveys to create tracking metrics to evaluate the long-term metrics for instructor evaluation. While, in most cases, the metrics indicate fairly steady scores with quarterly variations, there were trends that indicated higher or lower performance with certain instructors. I proposed a greater utilization of these metrics for long-term tracking and for guidance on the best application of time and resources for program improvements.

Biomedical Regulatory Affairs is a career field that has weathered the economic downturn fairly successfully and regions, such as the State of Washington with its Life Sciences Discovery Fund, have chosen biotechnology as a field for growth and investment. While there currently many positions in the field that require only a 4-year degree, there is a growing trend that requires a graduate degree for promotion within biotech organizations. At this point, there are only a few programs offering these graduate degrees in regulatory affairs and the need for graduates in this field is likely going to increase. With small investment and some minor changes suggested within this document, the BRAMS program

should see continued growth and provide an educational avenue for a field in need of well-educated professionals.