Attachment 7
Supplemental Information – New certificate proposals
FS Executive Committee Review
October 29, 2019 Meeting
https://kstate.curriculog.com/agenda:831/form

Education

Sports Performance Coaching Certificate – New (https://kstate.curriculog.com/proposal:3865/form)

Rationale: The Coaching Endorsement program has existed in the College of Education over the last 25 years. The Endorsement program was not as robust nor in accordance with the Kansas State High School Activities Association or the National Federation for High School Sports guidelines. Updating the program from endorsement to certificate will reflect the KSHAA guidelines as a substitute or waiver of the American Coaching Effectiveness Program (ACEP), which is currently offered through the KSHSAA educational program.

The Coaching Certificate will also reflect the upgrades to the prefix, course numbers, and course names.

Impact (i.e. if this impacts another unit) – Statement should include the date when the head of a unit was contacted, and the response or lack of: No other academic unit will be impacted by this proposal.

Sports Performance Coaching Certificate

1) Purpose (clear and appropriate educational objective).

Coaching is one of the most exciting and lucrative industries today and years to come. A coach is one of the most influential people in the lives of young and professional student-athletes. The purpose for the Sports Performance Coaching certificate is to allow students to practice the foundations of coaching, coaching competencies, role play, learning the rules and procedures in the sport of coaching. A sport coach will learn how to apply coaching ethics and standards appropriately in all coaching situations. The well-trained coach is a multidimensional person, with a wide range of technical, communication, and interpersonal skills. Coaches are trained to coach student-athletes to compete at the highest levels as individuals and/or team members in specific sports. In the state of Kansas, the Kansas State High School Athletic Association (KSHSAA) as well as at the national levels, coaches who are not certified teachers and want to coach sports at any level, will need state certification to satisfy the requirements to coach. KSHSAA notes,

"with the requirement that all non-faculty interscholastic coaches in Kansas be trained prior to assuming coaching duties in their 2nd year, Human Kinetics and the NFHS are poised to assist the KSHSAA in reaching this goal (kshsaa.org)". The Sports Performance Coaching Certificate at Kansas State University will provide the required courses as approved by KSHSAA needed to be certified as a coach in the state of Kansas. According to *The Best Education Jobs, US News & World Report* (2019), sport coaching ranks fifth as the best education jobs behind high school teacher, teaching assistant, middle and elementary school teachers.

2) Evidence of demonstrated need or demand for proposed certificate

The evidence of demonstrated need or demand for the Sports Performance Coaching Certificate program is to prepare students to learn the basic skills needed to coach one or multiple sports and for students who desire to coach athletes and becoming a trained sport specific coach. The certificate will allow students to transition from the old program to the new program to continue their success as a future coach. The former coaching endorsement has had 56 completers in the last five years.

3) Requirements for the coaching certificate program are:

1. Students must complete the CPR/First Aid certificate and AED training as required by KHSAA upon completion of the certificate. In April 2019 the KSHSAA Board of Directors adopted a rule requiring any head or assistant coach/sponsor for any KSHSAA sanctioned activity be certified or trained in Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) administration (www.kshaa.org)
2. Minimum cumulative grade point average of 2.0 is required in courses applied to the Sports Performance Coach Certificate
3. All courses applied to the certificate will record letter grades for the courses
4. No more than 25% of total credit hours required for the certificate may be transfer credits

4) Desired outcomes for the coaching certificate program are:

1. Students will be able to identify and comprehend the ASEP (American Sports Education Program) coaching philosophy
2. Students will be able to understand the concept of goal setting and how it relates to ethical, and practical issues in coaching
3. Compare and contrast coaching styles and philosophies
4. Discuss coaching theory and principle of training
5. Demonstrate teaching component of sport skills
6. Describe the rules to the sports presented
7. Students will be able to read and evaluate sport rule books and codes of conduct
8. Identify the rules, mechanics and techniques of the officiating
9. Describe the financial components of officiating
10. Evaluate the performance of officials
11. Describe the legal responsibilities of a sports official

5) Assessment procedures

The courses in the certificate coaching program will be assessed by the following procedures:

- Performance assessment - evaluating student' knowledge, coaching and developmental skills;
- Authentic assessment - observing coaching experiences in "real-life" situations using knowledge and skills;
- Indirect assessment - student's reported perceptions of their own learning in different stages of the program;
- Formative assessment -how students are performing at different stages in coaching;
- Summative assessment - semester final evaluation of their achievements; and
- Embedded assessment - evidence of student learning outcomes obtained through assignments, research, KHSAA state testing, and the end point of the course.

6) Estimated budget and staff required

The courses for the Sports Performance Coach Certificate will be taught by the current faculty in the Department of Curriculum & Instruction in the College of Education and Health and Human Sciences, Department of Food, Nutrition, Dietetics & Health

7) Evidence of approval of their certificate program through internal academic channels.

Approval of the Sports Performance Coaching certificate program has been accepted in the College of Education, Department of Curriculum and Instruction, and the College of Health and Human Sciences, Department of Food, Nutrition, Dietetics & Health

Additional Information

The Sports Performance Coaching certificate is a credential (free-standing) certificate in the Department of Curriculum & Instruction in the College of Education. The certificate may be obtained by degree-seeking students at Kansas State University

All free-standing certificate programs will share the same admission process and criteria unless additional/higher criteria are specified by the department and college.

References

1. Kansas State High School Athletic Association (KSHAA). Kansas state high cchool activities association coaches education program. Retrieved from http://www.kshsaa.org/Public/General/ASEP.cfm
2. Human Kinetics (2019). American Sports Education Program. Retrieved from http://www.asep.com/asep_content/org/KSHSAA.cfm
3. US World News & Report (2019). Best education jobs. Retrieved from https://money.usnews.com/careers/best-jobs/sports-coach

~~Coaching Endorsement~~

The coaching endorsement is open to students who plan to coach at the high school level after graduation. The Kansas State High School Activities Association accepts the K-State College of Education coaching endorsement as a substitute for the American Coaching Effectiveness Program, which is currently offered through the KSHSAA educational program.

~~Questions about the coaching endorsement should be directed to the department of Curriculum and Instruction in 261 Bluemont Hall at (785) 532-5550.~~

Program requirements (~~10~~ credit hours)

Any student interested in the College of Education endorsement program should take the following hours of course work:

- ~~EDSEC 250 -~~ Scientific Principles of Coaching **Credits:** 3

~~EDSEC 587~~ Supervised Practicum for Athletic Coaches ~~(2)~~

- FNDH 320 - Care and Prevention of Athletic Injuries **Credits:** 3

~~One coaching and officiating class (2 credit hours)~~

Examples:

- ~~EDSEC 302 - Coaching and Officiating Basketball **Credits:** 2~~
- ~~EDSEC 305 - Coaching and Officiating Football **Credits:** 2~~
- ~~EDSEC 306 - Coaching and Officiating Volleyball **Credits:** 2~~

Sports Performing Coaching Certificate

The coaching endorsement is open to students who plan to coach at the high school level after graduation. The Kansas State High School Activities Association accepts the K-State College of Education coaching endorsement as a substitute for the American Coaching Effectiveness Program, which is currently offered through the KSHSAA educational program.

Program requirements (12 credit hours)

Any student interested in the College of Education endorsement program should take the following hours of course work:

EDCI 300 Principles of Coaching Sports Performance (3)

FNDH 320 Prevention and Recognition of Athletic Injuries (3)

EDCI 301 Coaching and Officiating Methodology (3)

EDCI 588 Supervised Practicum in Sports Performance (3)

Olathe (School of Applied and Interdisciplinary Studies)

Regulatory Affairs in Animal Health Graduate Certificate – New (https://kstate.curriculog.com/proposal:3737/form)

KANSAS STATE UNIVERSITY | Olathe

Regulatory Affairs in Animal Health Graduate Certificate
Updated 9.18.19

Title: Regulatory Affairs in Animal Health Graduate Certificate
Contact Name: Dr. Jackie Spears, Interim Dean and CEO, K-State Olathe
Contact Email address: jdspears@ksu.edu
Contact phone number: 913-307-7381

This application for a Regulatory Affairs in Animal Health Graduate Certificate has been organized based on Graduate Handbook Chapter 4, Section C.4.

Introduction

Provide a statement of the educational objectives, including student learning outcomes, if known.

A Regulatory Affairs in Animal Health Graduate Certificate is being proposed to meet a longstanding industry need in the animal health industry. Regulatory Affairs requires a specialized skill set, which combines the knowledge of animal science and veterinary medicine, with skill in navigating governmental processes and regulations. Students in the Graduate Certificate in Regulatory Affairs in Animal Health will be able to:

1. Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.
2. Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.
3. Synthesize regulatory requirements with effective business practices while operating in a compliant manner.

The Assessment of Student Learning Plan is in a separate attachment (***Attachment 1).***

Curriculum Overview

List the courses associated with the certificate including titles and course descriptions both for existing courses and any new courses that may be developed.

The Regulatory Affairs in Animal Health Graduate Certificate curriculum is 15 credit hours, which is comparable to other graduate certificates at Kansas State University. All of the courses proposed for the certificate can be applied to the Professional Science Master's degree, after a student is accepted to the Master's program. It is anticipated that the courses from the certificate will fulfill both PSM STEM and Professional Skills requirements. These courses can also be applied to other Master's programs such as the M.S. in Veterinary Biomedical Science.

AAI 840	Regulatory Aspects of Drug and Vaccine Development in the Animal Health Industry (2 cr)
AAI 841	Strategies in Preclinical and Clinical Research for Regulatory Affairs in Animal Health (2 cr)
AAI 842	Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health (2 cr)
AAI 843	Regulatory Development of Animal Pharmaceuticals – FDA (2 cr)
AAI 844	Regulatory Development of Animal Pesticides – EPA (2 cr)
AAI 845	Regulatory Development of Animal Biologicals and Diagnostics – USDA (2 cr)
STAT 703	Introduction to Statistical Methods for the Sciences (3 cr)

Course description for existing courses

AAI 840 Regulatory Aspects of Drug and Vaccine Development in the Animal Health Industry (2 cr.)

Faculty Member: Paige Adams

This course explores the topic of regulations associated with animal health product development and manufacturing. Topics for discussion will include an overview of the regulatory affairs process in the U.S. and other countries, drug and vaccine classifications and the approval process, GCP/GLP guidelines, drug and vaccine efficacy and safety testing, human and environmental safety issues, and future challenges and current industry needs. *(Course cross-listed - DMP 895)*

STAT 703 Introduction to Statistical Methods for the Sciences (3 cr.)

Instructor: Thomas Pawlowski

Statistical concepts and methods applied to experimental and survey research in the sciences; tests of hypotheses, parametric and rank tests; point estimation and confidence intervals; linear regression; correlation; one-way analysis of variance; contingency tables, chi-square tests.

Course descriptions for new courses

AAI 841 Strategies in Preclinical and Clinical Research for Regulatory Affairs in Animal Health (2 cr.)

Faculty Member: Ellen Lowery

In this course, students will review the history of regulations as well as gain an understanding of the integration of science into successful product approval outcomes. Students will learn how to achieve target claims for developing new products while ensuring safety. Students will also be introduced to the planning, design, and conduct of preclinical and clinical studies. The topics covered include protocol design and the evaluation and assessment of regulatory submissions. The course will consider practical issues in regulatory affairs.

AAI 842 Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health (2 cr.)

Faculty Member: Paige Adams

In this course, students will learn about the role of regulatory affairs in stewardship of animal health products. The topics covered include expected activities primarily post product approval, compliance, strategies for supply management, product life cycle management, risk management, and the role of industry in policy development. Communication with various stakeholders, including regulatory agencies, research and development, manufacturing, and marketing and sales are covered. The course will consider practical issues in regulatory affairs.

AAI 843 Regulatory Development of Animal Pharmaceuticals –FDA (2 cr.)

Faculty Member: Ellen Lowery

In this course, students will focus on the regulatory strategies that support product development and maintenance regulated by the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM). This includes product development strategies based on clinical and nonclinical data, key manufacturing and supply chain regulations, and post approval product life cycle management, including pharmacovigilance. Variances between food animal and non-food animal targets in developing regulatory strategies will be reviewed. Special topics, current topics and FDA enforcement actions will be covered.

AAI 844 Regulatory Development of Animal Pesticides – EPA (2 cr.)

Faculty Member: Ellen Lowery

In this course, students will focus on the regulatory strategies for the development of products deemed to be regulated by the Environmental Protection Agency (EPA). This course will focus on product development strategies, manufacturing and supply chain regulations, and post marketing product life cycle management, including pharmacovigilance. Environmental laws and risk assessment will also be covered.

AAI 845 Regulatory Development of Animal Biologicals and Diagnostics - USDA (2 cr.)

Faculty Member: Paige Adams

In this course, students will focus on the structure and detailed approach for developing animal biologicals and diagnostics regulated by the United States Department of Agriculture (USDA). Students will gain solid understanding of the critical pathway to successful product development, manufacturing, compliance, and product life cycle

management, including post marketing surveillance. The course also addresses adapting new technology to emerging and re-emerging diseases.

A spreadsheet of expected course sequencing is attached as a separate document (***Attachment 2***).

A statement of how the courses associated with the certificate will meet the stated educational objectives.

All of the proposed courses are connected to the proposed student learning outcomes.
Student Learning Outcome 1: Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA

Courses Proposed to Meet the Outcome:

1) AAI 842 Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health (2 cr)
2) AAI 843 Regulatory Development of Animal Pharmaceuticals – FDA (2 cr)
3) AAI 844 Regulatory Development of Animal Pesticides – EPA (2 cr)
4) AAI 845 Regulatory Development of Animal Biologicals and Diagnostics – USDA (2 cr)

Student Learning Outcome 2: Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.

Courses Proposed to Meet the Outcome:

1) AAI 840 Regulatory Aspects of Drug and Vaccine Development in the Animal Health Industry (2 cr)
2) AAI 841 Strategies in Preclinical and Clinical Research for Regulatory Affairs in Animal Health (2 cr)
3) STAT 703 Introduction to Statistical Methods for the Sciences (3 cr)

Student Learning Outcome 3: Synthesize regulatory requirements with effective business practices while operating in a compliant manner.

Courses Proposed to Meet the Outcome:

1) AAI 842 Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health (2 cr)
2) STAT 703 Introduction to Statistical Methods for the Sciences (3 cr)

<u>Statement of Need</u>
A statement of the need for the proposed certificate and the basis for such a need, supported by either externally or internally derived data.

Over a seven year period, K-State has collected market demand information to inform planning for academic and professional development programming. The findings have consistently reflected a clear and ongoing need for educational offerings focused on regulatory affairs in the

animal health industry. The graduate certificate will meet the need of industry professionals who are looking for regulatory affairs credentials.

Survey of Educational and Professional Development Needs in the Animal Health Corridor

In 2010, Vincent Amanor-Boadu, Associate Professor of Agribusiness Economics and Management at Kansas State University, and K. Renee Stoneman, Graduate Student of Agribusiness Economics, conducted a survey of industry needs in the Animal Health Corridor spanning from Columbia, MO to Manhattan, KS. Of the 446 industry responses to the survey, 177 respondents (40%) indicated interest in programming focused on "policy and regulations." The results show strong interest in "policy and regulations" programming at the graduate level (81 respondents) and bachelor level (62 respondents). The interest in "policy and regulations" education spanned from executives (34.5% of executive respondents) and mid-managers (39.3% of mid-manager respondents) to non-managers (42% of non-manager respondents).

Meetings with Industry

From 2012-2014, K-State Olathe met with industry representatives who consistently confirmed the need for educational opportunities that cover the following topics in regulatory affairs. Participating organizations: Boehringer Ingelheim, Merck Animal Health, Ceva, Expedite, Kansas City Area Life Sciences Institute (now BioNexus KC), and DuPont/Danisco.

- Policies and regulatory requirements for USDA, FDA, EPA, FAA, and DOT
- Global strategies including historical perspectives, social aspects, and methods to ensure safety
- GXP, validation, study design, and applied statistics, including requirements for different regulators

Regulatory Affairs Professional Development Events

Over the past two years, six professional development seminars focused on important topics in the field of regulatory affairs were held at K-State Olathe. The seminars covered a wide-range of subjects including: new technology implementation, data management, antibiotic stewardship and CRO-sponsor relationships. The average attendance of these events was 94. These seminars served to establish K-State Olathe as a convener of quality speakers and panelists from the world of regulatory affairs. It is anticipated that students for the certificate program will come from these attendees.

Regulatory Affairs Programming Interest Survey

In March of 2019, an interest survey for regulatory affairs programming was sent to attendees of the regulatory affairs seminars held at K-State Olathe, as well as to students, most of whom have already taken the AAI 840 *Regulatory Aspects of Drug and Vaccine Development in Animal Health Industry* course. The survey had 51 responses (35 students and 16 industry partners), and 41 responders expressed interest in taking additional graduate courses with topics related to regulatory affairs.

Industry Roundtable

In 2016, K-State Olathe invited industry representatives to a roundtable discussion focused on the educational needs of their employees. Of the 22 organizations, 14 indicated strong interest in programming focused on "regulatory aspects of drug and vaccine development in animal health." Interested organizations: Ceva, Bayer Crop Science, Bayer Animal Health, George Butler & Associates, Aratana, U.S. Food & Drug Administration, Kansas City Area Life Sciences Institute (now BioNexus KC), MRI Global, Merck Animal Health, Boehringer Ingelheim, Norbrook, Cardinal Health, and KC Animal Health Corridor.

Comparative/Locational Advantage

There are not any other animal health regulatory affairs graduate programs in the Kansas City area or in the region.

Certificate Administration

A description of the certificate program's administration, including coordinating/governing committees, additional requirements for membership on student supervisory committees if the certificate is linked with graduate degree programs, etc.

Administrative support for the Regulatory Affairs in Animal Health Graduate Certificate will be provided by the K-State Olathe campus, School of Applied and Interdisciplinary Studies. Dr. Jackie Spears, the interim Dean and CEO, provides academic leadership for all programs at the Olathe Campus. Additional administrative support is provided by the Olathe-based Academic Affairs unit which includes a Director of Student Services, Assistant Dean for Academic Support Services, and Program Coordinator for the Associate Dean. The Academic Affairs unit at the Olathe Campus will support recruitment, advising, and other student support activities for the Regulatory Affairs certificate students.

Estimated Budget

Estimated budget to support the certificate program;

Curriculum Development	$15,000 ($3,000 per course for five courses)
Visiting Lecturer Salaries	$15,000 ($3,000 per course for five courses each year)

Budget Narrative

The content of the regulatory affairs courses is unique and there are not any known academic experts with knowledge in all of the areas covered by the certificate. In order to build the courses and curriculum, Kansas State University-Olathe contracted for curriculum development support from known subject matter experts (SME) in each area. The SMEs were responsible for developing lectures outlines and case studies for the courses.

Instruction will be provided by existing full-time K-State faculty who are already supported by the University. Additional faculty support will be required for the delivery of all of the proposed courses for the Regulatory Affairs certificate. It is estimated that visiting lecturers at

approximately $3,000 per course will be recruited to provide agency specific context (FDA/EPA/USDA).

All expenses will be covered by revenue from tuition and Johnson County Education Research Triangle (JCERT) funds.

Faculty

The names of the faculty associated with or contributing to the certificate program, either by teaching one or more of the courses associated with the program or participating in the design of the curriculum.

Instructional Faculty:

Paige Adams, PhD, DVM, Research Assistant Professor, K-State Olathe (Non-Tenure Track) (Olathe-Based)

Gary Anderson, PhD, DVM, Professor, College of Veterinary Medicine (Tenured) (Olathe-Based)

Mike Apley, PhD, DVM, Professor, College of Veterinary Medicine (Tenured) (Manhattan-Based)

Ellen Lowery, PhD, DVM, MBA, Professor of Practice, K-State Olathe (Non-Tenure Track) (Olathe-Based)

Graduate Certificate Coordinator

Dr. Gary Anderson, Director, International Animal Health and Food Safety Institute
K-State Olathe, 170E ganders@vet.k-state.edu

Student Learning Outcomes and Assessment Plan

Student learning outcomes and assessment plan for the program.

The Student Learning Outcomes and Assessment Plan for the program is included with this proposal as ***Attachment 1***.

Endorsements

Endorsements from those academic units (including extension) whose students, courses, or programs could be impacted by the creation of the new graduate certificate.

Attachment 3: Support letter from Bonnie Rush, Interim Dean, College of Vet Med

Attachment 4: Support letter from Christopher Vahl, Department Head, Statistics

Sample Course Sequencing: Regulatory Affairs in Animal Health Graduate Certificate

When courses will be offered:		
Fall	Spring	Summer
AAI 840	AAI 841	AAI 843
AAI 844	AAI 842	
AAI 845		
STAT 703 (in-person in Fall, or online Sum/Spring)		

Sample Course Schedule:				
Fall 2019	Spring 2020	Summer 2020	Fall 2020	Spring 2021
AAI 840 (2 cr.)	AAI 841 (2 cr.)	AAI 843 (2 cr.)	AAI 844 (2 cr.)	AAI 842 (2 cr.)
STAT 703 (3 cr.)			AAI 845 (2 cr.)	

Course Titles:
STAT 703- Introduction to Statistical Methods for the Sciences (3 cr.)
AAI 840 - Regulatory Aspects of Drug and Vaccine Development in the Animal Health Industry (2 cr.)
AAI 841 - Strategies in Preclinical and Clinical Research for Regulatory Affairs in Animal Health (2 cr.)
AAI 842 - Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health (2 cr.)
AAI 843 - Regulatory Development of Animal Pharmaceuticals –FDA (2 cr.)
AAI 844 - Regulatory Development of Animal Pesticides – EPA (2 cr.)
AAI 845 - Regulatory Development of Animal Biologicals and Diagnostics - USDA (2 cr.)

Graduate School

Regulatory Affairs in Animal Health Graduate Certificate

School of Applied and Interdisciplinary Studies, K-State Olathe
Assessment of Student Learning Plan

A. College, Department, and Date

College: School of Applied and Interdisciplinary Studies
Department: School of Applied and Interdisciplinary Studies
Date: July 15, 2019

B. Contact Person(s) for the Assessment Plan

Contact Name: Dr. Jackie Spears, Interim Dean and CEO, K-State Olathe
Contact Email address: jdspears@ksu.edu
Contact phone number: 913-307-7381

C. Name of Proposed Degree Program

Regulatory Affairs in Animal Health Graduate Certificate

D. Assessment of Student Learning Three Year Plan

1. Student Learning Outcome(s)

a. Student learning outcomes for the program.

Upon successful completion of the Regulatory Affairs Graduate Certificate the students will be able to:

- Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.
- Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development
- Synthesize regulatory requirements with effective business practices while operating in a compliant manner.

b. Indicate at least three outcomes on the above list that will be assessed by the first mid-cycle review.

Each student learning outcome is equally important; therefore, all student learning outcomes will be assessed by the first mid-cycle review.

2. Assessment Strategies

How will each of the learning outcomes be assessed?

a. Direct Measures

All student learning outcomes will be assessed at the end of the certificate in the AAI 842: Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health course. This course will be the last course that students take in the certificate program. Students will be required to complete a final paper in the course, which incorporates all three learning outcomes. The student's final paper will be evaluated by the course instructor and at least one external regulatory affairs subject matter expert (advisory board members). The evaluation will be used for the course grade and for assessment purposes for the certificate.

Table 1. Direct Measure for Student Learning Outcomes

Student Learning Outcome	Direct Measure
1. Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.	1) Rubric used for final paper in AAI 842: Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health.
2. Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.	1) Rubric used for final paper in AAI 842: Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health.
3. Synthesize regulatory requirements with effective business practices while operating in a compliant manner.	1) Rubric used for final paper in AAI 842: Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics in Animal Health.

Table 2. Matrix of Learning Outcomes and Courses Where They Are Addressed

	Regulatory Aspects (840)	Preclinical & Clinical (841)	FDA (843)	EPA (844)	USDA (845)	Strategies in Stewardship (842)	Statistics (STAT 703)
Certificate SLOs							
1. Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.			X	X	X	X	
2. Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.	X	X					X
3. Synthesize regulatory requirements with effective business practices while operating in a compliant manner.						X	X
Graduate School Outcomes							
Knowledge	X	X	X	X	X	X	X
Skills						X	X

Attitudes & Professional Conduct						X	

b. Indirect Measures

At or near the completion of the certificate program, students will be sent a survey asking them to provide a self-assessment of their proficiency on the Student Learning Objectives.

c. Number of students included in the assessment

All students completing the certificate will be included in the assessment process.

d. Timetable

Direct Measures: Data from each of the measures will be compiled at the conclusion of each semester in an aggregate format by the Program Coordinator.

Indirect Measures: The completion surveys will be sent at or near the completion of the program, and complied by the Program Coordinator.

3. Results and Review of Student Learning Outcomes and Assessment Strategies

a. Describe the process the faculty will follow to review the results of assessment data.

The Program Coordinator will compile the assessment data, which will be reported and reviewed at least annually by the certificate faculty. The faculty will be asked to make recommendations for program and assessment revisions.

Regulatory Affairs Graduate Certificate Student Self-Assessment of Student Learning Outcomes (Indirect Assessment)

Please rate your learning related to the three Student Learning Outcomes, with 1 being the lowest level of proficiency and 3 being the highest.

- I am able to demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.
    - Why do you rate yourself at this level?
- I am able to Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.
    - Why do you rate yourself at this level?
- I am able to synthesize regulatory requirements with effective business practices while operating in a compliant manner.
    - Why do you rate yourself at this level?
- Describe how you may approach work demands differently as a result of this program.

Regulatory Affairs in Animal Health Graduate Certificate, AAI 842 Strategies in the Stewardship of Licensed Pharmaceuticals and Biologics, Final Paper (Revised 9/18/19 in response to feedback from the Graduate School Assessment and Review Committee)

Assessment of:
(SLO1) Demonstrate comprehensive understanding of the regulatory process and strategy for products approved by the FDA/EPA/USDA.
(SLO2) Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development.
(SLO3) Synthesize regulatory requirements with effective business practices while operating in a compliant manner.

Assignment:
Students will write a 15 – 20 page paper on a regulatory affairs topic in animal health approved by their instructor. The paper must integrate knowledge of the relevant regulations, quality assurance processes, clinical research, and related business practices. Possible topics/scenarios for student papers may include:

- Students may be asked to imagine that they are working at a company where a novel product is being developed that will go through the FDA or the USDA for approval. The student is responsible for shepherding the product through the approval process for the company. The student must explain in detail the processes and strategies involved for the agency, analyze the clinical research processes required, and explain the relevant

business practices and compliance concerns.

- Students may be asked to imagine that they are responsible for marketing for a major pharmaceutical company, and they are asked to develop a written presentation for the head of the company on the marketing strategy for three different products. The student must explain the relevant processes and strategies for all three agencies, analyze the clinical research processes required, and explain the relevant business and compliance concerns.

The student's final paper will be evaluated by the course instructor and at least one external regulatory affairs subject matter expert (advisory board members). The evaluation will be used for the course grade and for assessment purposes for the certificate. Successful completion of the final paper ranges from acceptable to exceptional and may depend on the student's prior experience with regulatory affairs.

Common Rubric used to assess the Regulatory Affairs in Animal Health Graduate Certificate

	Exceptional	**Proficient**	**Acceptable**	**Deficient**
Knowledge of Regulatory Processes and Strategy for Products Approved by FDA/EPA/USDA (SLO1) Related Graduate School Outcome: Knowledge Note – Need to decide # of agencies.	Integrates knowledge of processes and strategies for an agency or agencies in a way that is innovative and demonstrates deep understanding of the similarities and differences among the agencies.	Demonstrates knowledge of process and strategies for an agency or agencies in a way that shows clear understanding of each agency.	Demonstrates basic knowledge of the process and strategies, but lacks a clear understanding of an agency or agencies.	Knowledge of the processes and strategies of the agency or agencies is superficial.
Identify the extent to which clinical research protocols establish the efficacy and safety of products compliant with regulatory guidelines for product development. (SLO2)	Draws thoughtful conclusions and able to make sophisticated judgments regarding the role of clinical research in product development. Shows evidence of using quantitative analysis in	Able to make reasonable conclusions and judgements regarding the role of clinical research in product development. Shows awareness of applicability of quantitative analysis in drawing	Able to make plausible conclusions and judgments regarding the role of clinical research in product development. Shows some understanding of how quantitative analysis may aid in drawing	Conclusions and judgments regarding the role of clinical research in product development show a lack of logic or ability to connect critical pieces of information. No evidence of knowledge of how

Related Graduate School Outcome: Skills	drawing conclusions which are accepted by the relevant agency's requirements.	conclusions which are accepted by the relevant agency's requirements.	conclusions which are accepted by the relevant agency's requirements.	quantitative analysis can aid in drawing conclusions which are accepted by the relevant agency's requirements.
Synthesize regulatory requirements with effective business practices while operating in a compliant manner. (SLO3) Related Graduate School Outcome: Professional Conduct	Able to apply business practices and compliance requirements to a problem taking into consideration multiple contextual factors (e.g. ethical behavior, group dynamics, etc.).	Able to apply business practices and compliance requirements to a problem taking into consideration a number of contextual factors (e.g. ethical behavior, group dynamics, etc.)	Able to apply business practices and compliance requirements to a problem taking into consideration some of the relevant contextual factors (e.g. ethical behavior, group dynamics, etc.)	Limited ability to apply business practices and compliance requirements to a problem.
Sources and Writing	Demonstrates sophisticated use of high-quality and relevant sources which are appropriate for the related disciplines.	Demonstrates skillful use of high-quality and relevant sources which are appropriate for the related disciplines.	Demonstrates use of relevant sources which are appropriate for the related disciplines.	Does not use relevant sources or sources are not appropriate for the related disciplines.