Design and Implementation of Science Degree Program

UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

an Online MS In Regulatory for Working Professionals

James Polli, Paul Shapiro, and Andy Coop

University of Maryland, Baltimore, MD, United States

ABSTRACT

Objectives/intent. Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products. The objective was to design and implement an exclusively online Master of Science in Regulatory Science degree program for working professionals.

Methods/process. Institutional interests and capabilities focus on drug and biologics development and evaluation. Program design also considered target student audience, program objectives for students, curricular format, content delivery, and assessments, including individual and group projects.

Results/outcomes. The first cohort of students started in Spring 2014 and will graduate in Fall 2015. Recruitment for a third cohort (Fall 2015) has recently completed. Of the five courses that comprise the program, four have been taught at least once; one course is being taught for the first time in the Fall 2015 semester. Courses are delivered via Blackboard Learn™. Student retention (85%) has been excellent and attributed to flexibility of the program with respect to student time (e.g. pre-recorded lecture can be viewed anytime) and routine expectations across courses. Students report high value of group projects, which leverage internet-based communications. Student evaluations of the first four courses indicate favorable student learning experience [mean scores of 3.50(+/-0.11), 3.33(+/-0.14), 3.45(+/-0.11) and 3.18(+/-0.10) compared to all courses], although one course was negatively impacted by the shorter Summer semester. The first course was also certified by QualityMatters®.

Implications. An exclusively online Master of Science in Regulatory Science degree program for working professionals has been designed and largely implemented. Course assessments are on-going, including by QualityMatters®. Formal program assessment will start after graduation of the first cohort.

INTRODUCTION

- The University of Maryland sought to address the need for greater training in regulatory science (1), as well as to complement its research-intensive Center of Excellence in Regulatory Science and Innovation (CERSI) with a training program.

- The University of Maryland is seeking to have its regulatory science program courses be certified by QualityMatters®.

PROGRAM DESIGN ACTIVITIES

- **Scope and Courses**
  - The program was designed to achieve a science-driven understanding of the development and regulation of drugs and biologics.
  - The program consists of five 6-credit courses:
    - REGS 603 Drug, Biologic, and Device Regulation
    - REGS 614 Drug and Biologics Discovery
    - REGS 631 Drug and Biologics Development
    - REGS 621 Clinical Research
    - REGS 641 Regulated Products in the Marketplace

- **Blackboard Learn™**
  - The program was designed to be online and part-time, in targeting working professionals.

IMPLEMENTATION ACTIVITIES

- First cohort of students started in Spring 2014 and will graduate in Fall 2015.
  - A third cohort (Fall 2015) has recently enrolled.
- Four courses have been taught at least once.
  - One course is being taught for the first time in the Fall 2015.
- Student retention (85%) has been excellent.
  - High retention is attributed to flexibility of the program with respect to student time (e.g. pre-recorded lecture can be viewed anytime) and routine expectations across courses.
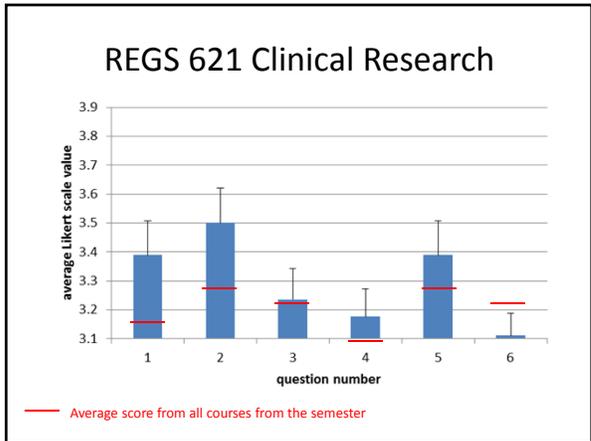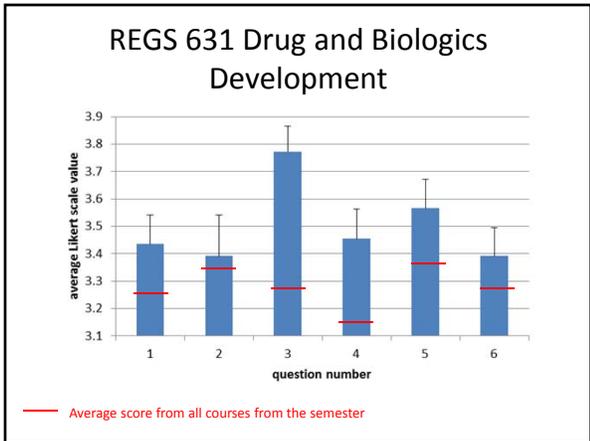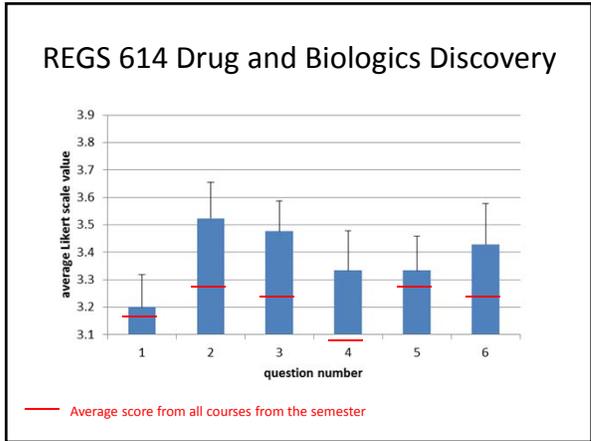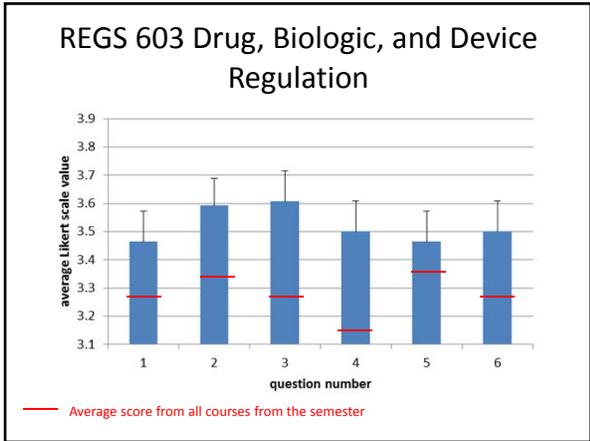
COURSE ASSESSMENT ACTIVITIES

- Student evaluations of each course are collected each semester at mid-point and at course end.
- Students report high value of group projects, which leverage internet-based communications.
- Student evaluations of the first four courses indicate favorable student learning experience [mean scores of 3.50(+/-0.11), 3.33(+/-0.14), 3.45(+/-0.11) and 3.18(+/-0.10) compared to all courses].
- One course was negatively impacted by the shorter Summer semester.
- The first course has been certified by QualityMatters®.

Student Evaluations of First Four Courses

- **Question 1**: The types of learning activities in this course were valuable to my understanding of the material.
- **Question 2**: I was challenged to apply the information in this course.
- **Question 3**: Graded assessments (including exams) related to the course objectives.
- **Question 4**: Graded assessments (including exams) accurately measured my understanding of the course content.
- **Question 5**: I understand how the material in this course contributed to my professional development.
- **Question 6**: I have achieved the stated course goals/expected outcomes.

- Students responded via a Likert scale [i.e. strongly agree, agree, disagree, and strongly disagree, with point values 4, 3, 2, and 1, respectively].
- Responses were compared to all courses that semester.
- **Result**: Student evaluations of the first four courses indicate favorable student learning experience.

REGS 603 Drug, Biologic, and Device Regulation

— Average score from all courses from the semester

REGS 614 Drug and Biologics Discovery

— Average score from all courses from the semester

REGS 631 Drug and Biologics Development

— Average score from all courses from the semester

REGS 621 Clinical Research

— Average score from all courses from the semester

CONCLUSION

- An exclusively online Master of Science in Regulatory Science degree program has been design and largely implemented for working professionals, with a focus on drug and biologics development and regulation.
- Student evaluations of the first four courses indicate favorable student learning experience.
- The first course in the program has been certified by QualityMatters®.
- Formal program assessment will start after graduation of the first cohort (i.e. Fall 2015).

References:

1. Steve Olson and Anne B. Claiborne, Rapporteurs. "Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary". National Academy of Sciences; Washington DC. 2012.