

Course Description

Quality systems and method development used within a laboratory; ensuring the integrity of procedures used in lab processes, chain of custody, information management, and international laboratory standards; regulatory requirements for laboratory operation; bio-security precautions; and laboratory management.

This course will address the following topics:

- Ensuring Validity and Reliability
- Laboratory Procedures
- Quality Assurance: Procedures, Tools, and Methods
- Laboratory Management

Prerequisite: None

Course Objectives

After completing this course, students will possess a practical knowledge of the standard laboratory practices and quality systems required to oversee a scientific laboratory's quality management program. This course is intended to equip the student with the breadth of knowledge needed to obtain laboratory data and results that are reliable, interpretable, repeatable, and defensible. Students will possess the capability to participate on a laboratory management team including budgeting and forming a technology strategy.

Instructor Information

Dr. Tim Herrman
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Course Tools

All course materials and activities will be presented using the eCampus Learning Management system, powered by Blackboard. Log into eCampus at <http://ecampus.tamu.edu> to gain access. Before you access course materials, please perform a Vista Browser Check by clicking on the Check Browser Support link to ensure compatibility.

Due to the participatory nature of this online class, regular log-in to the eCampus is expected.

Technical Requirements

To ensure successful participation, students must have access to:

- A computer that is less than 4 years old
- Microphone and speakers
- High-speed Internet connection (cable/DSL or better) and an updated browser
- Microsoft Word, PowerPoint, and Excel (2003-2013) or equivalent
- Plug-ins for course materials (e.g. [Adobe Reader](#), [Adobe Flash player](#), etc.)

Resource Materials

There are no required text books. Readings will be taken from reference materials including government publications and standards. Most readings will be available in eCampus in .pdf format. Other readings will be available online, with a hyperlink provided in eCampus. Weekly materials will be presented using a variety of formats, including online slide presentations, audio, and videos, which can be accessed from eCampus.

Graded Assessments

Discussions (2)

There will be two graded discussions held on the discussion forum in eCampus. Your responses to the questions posted to the discussion board will be evaluated and included in your final grade. If you need an immediate answer to a question, please send an email directly to tjh@otsc.tamu.edu

Homework Assignments (8)

There will be eight homework assignments to assess your understanding of course concepts.

Grading Policies

All classwork must be completed by the due date unless prior approval has been granted by the instructor. Your grades will be determined as follows:

20 points = Discussions (2)
80 points = Homework assignments (8)

A = ≥ 90 points
B = $< 90 \geq 80$ points
C = $< 80 \geq 70$ points
D = $< 70 \geq 60$ points
F = < 60 points

Instructor/Student Communication

Please send all emails to tjh@otsc.tamu.edu. I will not be using the eCampus Mail Tool. If you have a question about the material, please post it in the discussion board so that other students have the chance to respond to it and/or benefit from the answer. I will read the discussion board and will reply to messages when necessary.

Copyright

Course materials and all other materials generated and/or used during this course are copyrighted. As a result, you do not have the right to copy the course packets unless given explicit permission by the instructor.

Course Schedule

Week	Topic	Assignments	Due Date
<i>Memorial Day, Monday, May 29, 2017 – No class</i>			
Unit 1: Introduction to Quality Systems			
Week 1 (May 30 – June 4)	Laboratory Quality Systems – Overview	Self-Intro Discussion # 1	6/5/17
Week 2 (June 5 – 11)	Laboratory information Management; Reporting Results Sampling & Handling Evidence	Homework # 1	6/12/17
Unit 2: Validation of Analytical Procedures			
Week 3 (June 12 – 18)	ISO 17025 Framework and Accreditation; Documents and Records; SOPs	Homework # 2	6/19/17
Week 4 (June 19 – 25)	The Big Three: <ul style="list-style-type: none"> • Traceability • Proficiency Testing • Uncertainty 	Homework # 3	6/26/17
Week 5 (June 26 – July 2)	Quality Control Procedures: <ul style="list-style-type: none"> • Corrective Actions • Control of Non-Conforming Work • Instrument Calibration & Maintenance • Training 	Homework # 4	7/3/17
Unit 3: ISO Procedures and Implementation			
Week 6 (July 3 – 9)	Validation of Analytical Procedures: Microbiology	Homework # 5	7/10/17
Week 7 (July 10 – 16)	Validation of Analytical Procedures: Rapid Methods	Homework # 6	7/17/17
Week 8 (July 17 – 23)	Validation of Analytical Procedures: Instrumental	Homework # 7	7/24/17
Unit 4: Laboratory Management			
Week 9 (July 24 – 30)	Statistical Techniques	Homework # 8	7/31/17
Week 10 (July 31 – Aug 7)	Technology Strategy	Discussion # 2	8/7/17