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| <i>Course Title</i> | Laboratory Quality Systems –SCSC 629 |
| <i>Term</i> | |
| <i>Meeting Location</i> | Online |
| <i>Credit Hours</i> | 3 |

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
- Validation of Analytical Procedures
- ISO Procedures and Implementation
- Laboratory Management

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.

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.)

Software is available to students at a discounted price through the Texas A&M Software Center, available at <http://software.tamu.edu>

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. Online slide presentations with audio for each module can be accessed from eCampus. The slides for each presentation will be provided as a .pdf file that can be downloaded and printed if needed.

Graded Assessments

Discussions (3)

There will be three 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. Ungraded discussions are also available and are a good way to communicate with other students to share ideas and insights or ask a question. However, if you need an immediate answer to a question, please send an email directly to tjh@otsc.tamu.edu

Homework Assignments (7)

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

Exams

There are no exams for this course.

Grading Policies

Discussions, homework and quizzes must be completed by the due date unless prior approval has been granted by the instructor. Your grades will be determined as follows:

70% of total grade = Homework assignments (7)

30% of total grade = Discussions (3)

A = $\geq 90\%$

B = $< 90\% \geq 80\%$

C = $< 80\% \geq 70\%$

D = $< 70\% \geq 60\%$

F = $< 60\%$

Course Schedule

| Topic | Assignments |
|--|--------------------------------------|
| Unit I - Laboratory Quality System Structure | |
| Laboratory Quality Systems-Overview ; Laboratory Standards | Self-Introduction; Discussion # 1 |
| ISO 17025 Requirements; Laboratory Accreditations | Homework #1 |
| Unit II- Laboratory Quality Control Techniques | |
| Quality Control Techniques The Big Three <ul style="list-style-type: none">• Traceability• Proficiency Testing• Uncertainty | Homework #2 |
| Quality Control Procedures <ul style="list-style-type: none">• Chain of Custody• Control of Non-conforming work Recording and Reporting for Quality Assurance | Homework #3 |
| Statistical Process Control | Homework #4 |
| Unit III – Method Validation | |
| Validation of Analytical Procedures | Homework #5 |
| Validation of Microbiological Procedures & Chemical Procedures, Spectroscopic Procedures and Rapid Methods | Homework #6 |
| Validation of Spectroscopic Procedures and Rapid Methods | Discussion #2 |
| Unit IV – Laboratory Quality Management | |
| Concept of Quality Management; Technology Strategy; Budgeting; Benchmarking | Homework #7 |
| Laboratory Networks ; Laboratory Safety; Risk Assessment | Discussion # 3 |

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. All student communication will be sent via TAMU email accounts (<http://gateway.tamu.edu>) unless you provide a preferred alternate email address.

Attendance and Make-up Policies

Due to the participatory nature of this online class, regular log-in to the eCampus is expected. Excused absences are subject to Texas A&M rules and guidelines. For more information, visit <http://student-rules.tamu.edu/rule07>. If an absence is excused, the instructor will either provide the student an opportunity to make up any quiz, exam, or other work that contributes to the final grade or provide a satisfactory alternative by a date agreed upon by the student and the instructor. The make-up work must be completed in a timeframe not to exceed 30 calendar days from the last day of the initial absence.

University Policies

The Americans with Disabilities Act (ADA) is a federal anti-discrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this legislation requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation for their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services at Student Services at the White Creek Complex on west campus, or call (979) 845-1637. For additional information, visit <http://disability.tamu.edu>

Information regarding Texas A&M's Accessibility Services can be found at <http://itaccessibility.tamu.edu>

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.

Academic Integrity

“An aggie does not lie, cheat, or steal or tolerate those who do.”

For more information about the Aggie Honor code, please visit <http://aggiehonor.tamu.edu>