



Instructors:

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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; laboratory management.

Student Credit Hours: 3

Prerequisites: None

Course Goals

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.

Key Topics

This course will address the following topics:

- Ensuring Validity and Reliability
- Validation of Analytical Procedures
- ISO Procedures and Implementation
- Laboratory Management

Course Tools

All course materials and activities will be presented using the Blackboard Learning Management System. You access Blackboard by logging into <http://ecampus.tamu.edu>
Before you access course materials, please perform Vista Browser Check by clicking on the Check Browser Support link.



Technology & Software Requirements

To ensure successful participation, students must have access to:

- A computer that is less than 4 years old;
- High-speed Internet connection (cable/DSL or better) & updated browser;
- Office software such as Microsoft Word, PowerPoint & Excel or equivalent;
- Common plug-ins (e.g., Adobe Reader, Flash Player, virus protection, etc.);
- Microphone and speakers; and
- CD/DVD player/burner.

Software Requirements:

Students must have access to a PC with Excel 2003-2013 (available at <https://software.tamu.edu>)

Class Readings

Readings are taken from reference materials such as government publications and standards. Most readings are available in .pdf format on the course Web site. Other readings are available online, with a hyperlink provided in Blackboard. You may request a free print copy of the FAO Quality Assurance for Animal Feed Analysis Laboratories manual by sending email to your instructor with a physical mailing address. Local students may pick up a copy from the Office of the Texas State Chemist, [445 Agronomy Road](#), College Station, TX.

Lecture Presentations

Weekly materials will be presented using a variety of formats, including online slide presentations, audio, and videos.

Discussions

Course discussions facilitate class communication and understanding of topics. If you need an immediate answer to a specific question, please e-mail your instructors directly at susie@otsc.tamu.edu or tjh@otsc.tamu.edu.

Homework Assignments

Homework assignments assess your understanding of concepts throughout the course.

Exams

A midterm and final exam will be administered through the course management system.

Grading

Your grades will be determined as follows:

Homework	60% of total grade
Exams	30% of total grade
Discussions	10% of total grade

A	$\geq 90\%$
B	$<90\% \geq 80\%$
C	$<80\% \geq 70\%$
D	$<70\% \geq 60\%$
F	$<60\%$



Grading Policy

Class assignments and exams must be completed on the dates set by the instructor on the course website unless prior approval has been granted by the instructor.

Attendance, Homework and Make-up Exam Policy

Due to the participatory nature of this Web-based class, regular log-in to the course Web site is expected. Excused absences are subject to TAMU rules and guidelines please see: <http://student-rules.tamu.edu/rule07> for details.

Instructor/Student Communication

Please send all e-mails to susie@otsc.tamu.edu or tjh@otsc.tamu.edu. The instructors will not use the Blackboard Mail Tool. All student communication will be sent via TAMU email accounts (<http://gateway.tamu.edu>) unless you provide a preferred email address.

Post any questions you have about the material to the discussion board so other students can respond to it and/or benefit from the ensuing discussion. The instructors will read the discussion board and reply to messages when necessary.

University Policies

American Disability Act (ADA)

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 of their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services, in Cain Hall, Room B118, or call 845-1637. For additional information visit <http://disability.tamu.edu>.

Copyright

Course packets and all other materials generated and/or used during this course are copyrighted. Because these materials are copyrighted, you do not have the right to copy the course packets, unless the instructor expressly grants permission.

Academic Integrity Statement

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

For more information, read the Honor Council Rules and Procedures at <http://student-rules.tamu.edu/aggiecode>

Course Schedule

Week	Topic	Assignments
Unit I - Introduction to Quality Systems		
1	Laboratory Quality Systems-Overview Using Statistical Procedures to Analyze Laboratory Data	Self-Introduction Discussion topic
2	Using Statistical Procedures to Analyze Laboratory Data, cont.	Homework 1 (Statistics)
Unit II Validation of Analytical Procedures		
3	Validation of Analytical Procedures: Microbiology	Homework 2 (AOAC)
4	Validation of Analytical Procedures: Rapid Methods	Homework 3 (MPAES) Discussion topic
5	Validation of Analytical Procedures: Instrumental	Midterm
Unit III – ISO Procedures and Implementation		
6	ISO 17025 Framework and Accreditation	Homework 4 (Standard Operating Procedure)
7	Traceability, Proficiency Testing, & Uncertainty	Discussion topic
8	Quality Control Procedures	Homework 5 (Corrective/ Preventative actions for non-conforming work)

Unit IV – Laboratory Management

9	Laboratory Management Principles Research Compliance Technology Strategy	Homework 6 (Capital Budgeting)
10	Reporting Results Sampling & Handling Evidence Laboratory Information Management	Final Exam Discussion topic