Building Continuity by Partnering with Regulatory Operations

**Regulatory Operations** provides an in-depth understanding of specific critical regulations and guidance in implementing a productive laboratory quality system to PIs and their staff who plan to support or conduct regulated studies. The ORNcS Regulatory Operations functional core includes an Operations Director, Quality Assurance Unit, Records Retention Management, and an Information Analyst.

**Fundamentals of a quality system** encompasses policies, processes, and procedures necessary to manage and improve work practices that will ultimately lead to better research development. It provides standardization in establishing:

- standard operating procedures,
- good documentation practices,
- personnel training files,
- equipment records,
- monitoring activities,
- identifying system improvement aligned with industry best practices.

Establishing a quality system is the essence of good science, it ensures reproducibility, reconstructability, and compliance with set standards.

**Quality Assurance Unit (QAU)** is an independent integral unit responsible for monitoring approved regulated studies to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in compliance with US FDA Good Laboratory Practices regulations, Quality Agreements, and/or other applicable requirements at UTMB. QAU also provides support and guidance to establish or improve existing laboratory quality systems’ infrastructure.

ORNcS has the capability of providing assistance in:

- implementation and maintenance of a quality system,
- evaluating existing quality systems,
- developing standard operating procedures (SOP),
- retaining and distributing departmental SOPs,
- equipment validation,
- establishing personnel training records.

**Records Retention Management** is designed to provide control over records from the time of their creation or receipt to their ultimate disposition. All records created or received by ORNcS are maintained and disposed of in accordance to GLP regulations and Texas state law.

Our archive facility offers:

- limited and controlled access,
- temperature and humidity controlled and monitored,
- inventory maintained on database,
- electronic imaging of reports and data.

ORNcS offers free training courses that harmonize the interaction between study administration and technical support. In promoting quality systems, ORNcS expands educational outreach in the areas of:

- GLP Basic Training*
- GLP Refresher Training
- Good Documentation Practices*
- Implementing a Quality System
- Internal QAU Audits
- How to Survive an FDA GLP Audit
- Writing Effective SOPs*
- Equipment Validation
- Customized training.

*Most popular classes (see back)

ORNcS utilizes a robust **MasterControl** Electronic Document Management Systems (MCEDMS) that automates and effectively manages document control processes and ensure compliance with GLP regulations and the predicate rule. ORNcS extends MCEDMS to other areas to improve internal processes related to SOP review, approval, and distribution. We also offer SOP training on performance of CheckSums for electronic datasets.

ORNcS builds continuity by partnering with faculty and staff to achieve compliance. ORNcS provides strong scientific and regulatory experience, which allows faculty and staff to evaluate and meet the challenges of today’s regulatory environment. ORNcS facilitates training and awareness on current and evolving best industry practices.

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Most Popular Classes

Title: Laboratory Safety & Good Laboratory Practices  
Course No.: CTPS 6108  
Course Length: 8 hours  
Credit Hours: 1

Course Overview: This course is designed to prepare postdoctoral scholars and advanced graduate students with basic tools and information about biomedical laboratory safety and the FDA’s Good Laboratory Practices (GLP) regulations, codified under Title 21 Part 58 of the Code of Federal Regulations.

Course Objectives:
Discuss UTMB laboratory policies, develop safe lab processes and procedures, including emergency procedures, safely handle chemicals in the lab, develop inventory tracking and storage procedures for hazardous chemicals, identify regulatory agencies and their policies regarding lab safety, identify potential hazards in the lab and develop procedures for correcting them, develop hazardous waste disposal procedures, including segregating different types of lab materials, identify the scope and applicability of the GLP regulations as applied to preclinical studies and product development, apply the GLP regulations to efficacy studies in accordance with the FDA’s Animal Rule and subsequent Guidance for Industry of Animal Models, identify and understand the consequences of documentation errors, apply the principles of equipment validation, understand the differences between a basic research laboratory and a regulated study, understand the differences between protocols and standard operating procedures.

Title: Good Documentation Practices  
Course Length: 1 hour

Course Overview: If you didn’t document it, you didn’t do it! Good Documentation Practices are essential tools in working in a regulated and non-regulated research environment. The expectations and your defined quality system will be largely the same regardless of the regulatory environment you face. This course is structured to be interactive, and will include plenty of opportunities for questions and discussions. Topics to be covered include the importance of good documentation practices, how to correct errors and omissions in data entry, how to sign, date and label data and records, how to complete documentation such as data collection forms and how to attach raw data to forms and lab notebooks.

Course Objectives: Upon completion, participants will gain essential knowledge in the areas of proper documentation entries and error correction procedures via physical and electronic copies.

Title: The Importance of Writing Effective Standard Operating Procedures  
Course Length: 1 hour

Course Overview: Standard Operating Procedures (SOPs) are essential tools for the clinical and research industries. SOPs outline responsibilities, guidelines, implementation procedures, approaches, and ensure consistency within an organization. This course provides an interactive and comprehensive introduction to designing, writing, implementing, revising, and updating of SOPs.

Course Objectives: Upon completion of this course the attendees will understand how to effectively and efficiently write SOPs, identify who should be involved in the development of SOPs, implement training of SOPs, identify many of the pitfalls associated with using SOPs as well as assign appropriate length and structure when writing new SOPs.