Abstract

To protect our nation’s security, medical countermeasures must be developed to treat and prevent infections with microorganisms that threaten our nation’s health. Ten years ago the United States Department of Health and Human Services Food and Drug Administration (FDA) published the final rule for New Drug and Biological Drug Products: Evidence needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible (21 CFR Parts 314 and 601, Federal Register, May 31, 2012). The rule, which allows the equivalent of human phase III clinical trials to be performed in animal studies when the human studies are not ethical or feasible, is often cited as “The Animal Rule.” To date, only one draft FDA Guidance document has been published describing the approach of using a well characterized animal model to predict human response. Only five products have received approval via this rule. The Animal Rule requires compliance of these studies with the Good Laboratory Practice (GLP) regulations (21 CFR Part 58). Because of the highly infectious nature of the disease-causing agents, these studies are often performed in high or maximum (BSL3/4) biocontainment laboratories. The logistics of assuring accurate and reliable data as collected and transferred from a BSL3/4 laboratory; conducting the study under regulatory oversight; maintaining animal records equating to clinical case files; characterizing the disease-causing agent; and designing the appropriate study to satisfy the regulatory reviewers that the data are equivalent to the outcome in humans is challenging and complicated. The design and execution of these studies differ from a toxicology safety study as defined in the scope of the GLP regulations. In order to gain a better understanding of the complexities involved in executing these studies, the FDA and the University of Texas Medical Branch at Galveston (UTMB) are collaborating to design and implement a training program to cross educate sponsors, scientists, veterinarians, quality assurance personnel, regulators, reviewers, and policy-makers to enable the conduct of regulated studies for product approval via The Animal Rule.

Specific Aims

- Develop and Launch Beta (Pilot) Training 5-Day Class for Conduct of Regulated Studies in High/Maximum Containment Laboratories
- Develop and Launch On-line Basic GLP Training Modules
- Establish Plan for Training Program Sustainability

Instructional Design Model

ADDIE Model for Systematic Course Design

Analysis

- Gap Analysis
- Needs Assessment
- Target Audience

Design

- Course Topics
- Learning Objectives
- Faculty Assigned

Development

- Course Grid
- Content
- SME Review

Implementation

- Online Modules
- Pilot Course
- April 1-5, 2013

Evaluation

Learning Components

- Lectures
- Case Studies
- Interactive Homework
- BSL4 Mock Training Activities
- E-learning Modules
- Role Play Exercises
- Remote Lectures via Adobe Connect

Example of the E-learning Modules

1. FDA Product Overview Module
   - Online: Review, Statistics Tracking
2. FDA Introduction Module
   - Online: Review, Statistics Tracking
3. Sparse and Definitions Module
   - Online: Review, Statistics Tracking
4. Roles and Responsibilities Module
   - Online: Review, Statistics Tracking
5. Protocols, SOPs and Final Reports Module
   - Online: Review, Statistics Tracking
6. Good Documentation Practices and Retention Module
   - Online: Review, Statistics Tracking
7. Facilities Module
   - Online: Review, Statistics Tracking
8. Animal Care and Use Rule Module
   - Online: Review, Statistics Tracking
9. Text Control Article Module
   - Online: Review, Statistics Tracking
10. Equipment Module
    - Online: Review, Statistics Tracking
11. Instruments and Disposal Postizations Module
    - Online: Review, Statistics Tracking
12. FDA Final Assessment
    - Online: Review, Statistics Tracking

Conclusions

Evaluations of the pilot course are currently being analyzed to determine revisions necessary to improve course design and development. The next course is expected to occur in the Spring of 2014.

The learning measurement results have yielded the following conclusions:
- Cross education of participants has occurred;
- Pre-assessment scores were higher than expected due to pre-existing expert knowledge of participants;
- Participants from government, academia, and industry met the intended target audience;
- Pilot course increased the knowledge of subject matter experts;
- Pre-requisite On-line GLP modules provided to participants basic GLP principles that were foundational to the Pilot Course.

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