The face-to-face course offered a unique opportunity for members of the regulatory and scientific communities to solve complex issues in an interactive educational environment. Each year, the course reached capacity and a subsequent waiting list for the next year’s course is initiated a year in advance. Evaluation results have been consistently positive and participants have indicated that they will apply knowledge learned during the course and the newfound knowledge will result in the improvement of patient/public health outcomes. In 2015, 96% of respondents indicated they would like to attend the course again in the future; repeat course attendance has been documented. From 2013 to 2017, eight additional products have been approved through the Animal Rule pathway.

**Learning Objectives**

1. Identify the regulatory expectations of executing Animal Rule studies in maximum containment laboratories.
2. Describe conditions that may impact the quality and integrity of the data.
3. Outline the course impact on the Medical Countermeasure (MCM) community.

**Background**

Medical countermeasures (MCMs) are developed to prevent and/or treat infections against microbial agents that threaten human health. To facilitate MCM development, 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 603, Federal Register, May 31, 2010), the rule, which allows the equivalent of human phase II clinical trials to be performed in animal studies when human studies are not ethical or feasible, is often cited as the “Animal Rule.” The Animal Rule recommends compliance with the Good Laboratory Practice (GLP) regulations (21 CFR Part 58) to the extent practical. Because of the high risk, lethality, and potentially highly infectious nature of the disease-causing agents that fall under the purview of the Animal Rule, these studies are often performed in high or moderate (BSL3/4) containment laboratories. The logistics of sourcing accurate and reliable data are collected and transferred from BSL3/4 laboratories, conducting the study under regulatory oversight and meeting FDA expectations for characterizing the animal disease model(s) are challenging and complicated. Only four products were approved in the ten year period following publication of the final rule for MCM development to prevent and/or treat infections.

**Methods**

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 collaborated to train the MCM community to promote data quality and integrity in maximum containment laboratories. The logistics of sourcing accurate and reliable data are collected and transferred from BSL3/4 laboratories, conducting the training program included a five day face-to-face course in addition to an on-line course module covering the GLP regulations and the roles and responsibilities of Institutional Animal Care and Use Committees (IACUC). The mock BSL-4 laboratory was included as part of the course.

**Course Structure**

**Online Education**

- Pre-requisite Knowledge: GLP, IACUC

**Course Dates**

- April 27-May 1, 2015
- April 25-29, 2016
- April 24-28, 2017
- April 24-28, 2018

**Course Agenda**

- **Day 1:** Welcome and Introduction to the FDA Animal Rule Guidance Document, Good Laboratory Practice (GCP) Basic Training, Global Good Laboratory Practice (GCP) (on-line), Good Clinical Practice (GCP) Basic Training (on-line), Good Laboratory Practice (GCP) Refresher Training (on-line), Good Clinical Practice (GCP) Refresher Training (on-line)
- **Day 2:** Animal Rule Program Overview, Animal Rule Regulatory Pieces, GLP regulations, Good documentation practices, Animal Rule Regulatory Pieces
- **Day 3:** Regulatory Considerations for the MTM Environment (Site visit to a working BSL-4 laboratory), Animal Rule Regulatory Pieces, Regulatory Considerations for the MTM Environment, Regulatory Considerations for the MTM Environment (Site visit to a working BSL-4 laboratory), Animal Rule Regulatory Pieces
- **Day 4:** Face-to-Face Course Evaluation Results 2013-2017
- **Day 5:** Face-to-Face Course Evaluation Results 2013-2017

**Face-to-Face Course Comments**

- "The collection of knowledge from the government and industry compiled for this course is unparalleled. For those who work with developing MCMs this is the most relevant training course that I have ever seen!"
- "I think it is valuable for policy makers to understand the limitations associated with high containment environments and for sponsors to understand the key issues that drive policy making in the MCM mission space”

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**References**

- "Cost Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible (on-line)"
- "Another Drug Development, Biological Drug Product, Evidence needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible (on-line)"
- "Product Approval Development Under the Animal Rule Guidance Document for Industry (on-line)"
- "The Product Approval Development Under the Animal Rule Guidance Document for Industry was released as a final document in October, 2013 (HHS, FDA, 2015)"
- "Course Expansion (2017-2022)"
- "On June 26, 2017 the FDA announced their intention to accept and consider a single source application for an award to UTMB that allows for the continuation and expansion of this education program. During the next grant funding cycle (2017-2022), the education program will continue to support the goal of providing a robust, collaborative educational program using problem-based learning techniques designed to bring researchers and regulators together to educate each other on the challenges related to nonclinical and clinical trial studies conducted in maximum containment environments and to identify solutions that are acceptable from both scientific and regulatory perspectives. The expansion of the training program, to include Good Clinical Practice to maintain data quality in barrier serving settings, will include expansion of the on-line course curriculum in order to deliver on-demand distance education to meet the needs of infectious disease outbreaks. Proposed courses will include:"
  - Achieving Data Quality and Integrity in Maximum Containment Laboratories (F2F)
  - Achieving Data Quality and Integrity in Clinical Trials That Involve High Containment Species (F2F)
  - Good Laboratory Practice (GLP) Basic Training (on-line)
  - Good Laboratory Practice (GLP) Refresher Training (on-line)
  - Good Clinical Practice (GCP) Basic Training (on-line)"

**Conclusion**

Based on the attendance numbers, diversity of participation (by affiliation and area of expertise), evaluation results, and the number of products approved via the Animal Rule pathway, the course has been successful at achieving the objective of cross-educating the MCM community to promote data quality and integrity in maximum containment laboratories.