



American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

Regulatory Perspective of the “Animal Rule”

To be presented by

Laine Peyton Myers, PhD

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Senior Toxicologist

Division of Antiviral Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research (CDER), US FDA

Thursday, April 12, 2018

****New venue**:** **CCACC HQ, 9366 Gaither Rd. “1st Floor Music Room”,
Gaithersburg, MD 20877**

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:50 PM – Program

8:50 – 9:00 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public –

\$5: [non-ASQ members](#) to cover pizza/drink cost;

Free: ASQ members, current job-seekers, CCACC volunteers/employees/members, veterans, senior citizens, past speakers, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, NTMUADC members, CKUAADC members, NTHUAADC members, NJTUAADC members, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, and all Tai-Chi classes students in Metropolitan DC.

Registration Deadline: Please register by ***Thursday noon, April 12, 2018.***

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Cars: From I-270 (N or S bound): Take Exit 8 onto Shady Grove Dr. Drive toward east and turn left onto Gaither Rd. The building is on your left after passing a stop sign.
By Metro rail: Exit at the Red Line Shady Grove Station.

Summary

The “Animal Rule” is a regulatory pathway to approve products that cannot be studied in humans due to ethical or feasibility issues. The many of these products are bioterrorism agents (e.g., Smallpox, Anthrax, various nerve agents) that would not be possible to investigate via the normal development of a standard clinical trial. Therefore, animal models are developed by the Sponsor and evaluated by the Agency to meet various criteria to determine if they are an adequate surrogate efficacy model for the human disease. Due to interspecies differences, there are many challenges that the Agency and stakeholders have to overcome during the development of medical countermeasures for the “Animal Rule”.

In this presentation, Dr. Myers will introduce the concept of the “Animal Rule” and provide examples of various related development programs. Dr. Myers will point out the differences and similarities between “Animal Rule” and standard drug development programs. Dr. Myers will mainly focus on viral pathogens that fall under the Animal Rule but the concepts can apply across a host of development paradigms.

Speaker

Dr. Laine Peyton Myers is a **Senior Pharmacology/Toxicology reviewer** for antiviral products at the US FDA CDER. Dr. Myers received his PhD in immunotoxicology from LSU Health Sciences Center in 2003, and was a postdoctoral fellow at NIOSH from 2003–2006. He joined the US FDA as a Pharm/Tox drug reviewer in 2006, and has experience in multiple divisions, including: antivirals, oncology, and reproductive/bone products. Dr. Myers has served on multiple US FDA Pharm/Tox subcommittees and is the current **chair** of the CDER Immunotoxicology subcommittee.

He also serves in several professional Societies and is the **Past-President** of the Immunotoxicology Specialty Section in the Society of Toxicology. Dr. Myers has helped to organize multiple scientific sessions at various professional societies including SOT, DIA, and ACT. He is currently one of the Agency experts on the “animal rule” at the FDA with a specialty in antiviral products.

This event is cosponsored by Chinese Culture and Community Service Center, Inc. (CCACC, www.ccacc-dc.org), NTU Alumni Association DC Chapter (www.ntuaadc.org), and Chinese American Professionals Association of Metropolitan Washington, DC (www.capadc.org).

