One and a Half Day In-Person Seminar

Biocompatibility Testing for Medical Devices

By: **Mike Colvin Ph.D**, Medical Device Technical Adviser/Consultant

Location: Boston, MA | June 13-14, 2019

SPEAKER

Mike Colvin Ph.D, Medical Device Technical Adviser/Consultant

Mike has over 30 years' experience developing medical devices and systems. Over his career he has been in charge of safety & efficacy testing and Regulatory & Clinical strategies. He has also served as a technical advisor/consultant in the medical device industry for over 25 years, giving him exposure to both large medical device companies and startups.

Mike has taught college for over 25 years and has contributed/participated on many domestic and international technical committees. He holds a Ph.D. in Physical Chemistry from the University of Southern California/California Institute of Tech

LEARNING OBJECTIVES

After completing this seminar, participants should be familiar with the full scope of ISO 10993-1, including the current version. The topics covered will include:

- Gain a deeper understanding of global regulatory expectations for biological safety.
- Know how to review reports for accurate data and work with a laboratory when unexpected results are reported.
- Understand evaluating complexities for drug/device combination devices.
- Familiarization with calculating allowable limits for cancer, chemical mixtures, and assessment of unidentified chemicals.
- Experience working application with real life examples to calculate allowable limits, experience testing errors and how to mitigate them, and then manage a device from concept to market clearance.
- Gain knowledge on the principles of toxicology, FDA consensus standards, and Good Laboratory Practices.
- Learn the difference between evaluation and testing. Recognize when testing is absolutely necessary and how to avoid unnecessary test-ing.

COURSE DESCRIPTION

The medical device field is one of the most heavily regulated industries, for obvious reasons. Medical devices are an important tool in efforts to improve patient care and treatment outcomes. Learn how to achieve more successful biocompatibility testing outcomes by attending this seminar.

Biocompatibility testing is in the spotlight with regulatory bodies – especially with the recent release of the updated European MDRs and the FDA's Guidance document on ISO 10993-1. It is essential for medical device manufacturers to have an understanding of the current landscape for biocompatibility testing while keeping an eye on the future trends that will affect future requirements. This seminar will discuss the recent changes to regulatory documents and standards and how they will impact the overall biocompatibility assessment of medical devices.

Attendees will understand and apply ISO 10993-1 and the FDA Guidance on its use. They will know how to use the ISO documents to locate information that you need.

Understand what tests to select and how to choose among various options.

By attending this seminar, attendees will get answers of these questions:

- When is testing not the only option?
- Understand how to apply Materials characterization, and more importantly learn how to use the information to understand biological safety?
- Understand ISO 14971 and how to use it?
- Learn how to use ISO 10993-1 as a tool for hazard identification?
- Learn how to develop a program that guides your device on the regulatory path and reduces your time to market?
- Practice how to execute your plan from development to completion and how to schedule and document the implementation of your biocompatibility plan.?

AGENDA

Day One (8:30 AM - 4:30 PM)

08.30 AM - 08.59 AM: Registration and Meet & Greet.

09.00 AM - 10.00 AM:

- Seminar outline
- History of Biocompatibility testing

10.00 AM - 11.00 AM: ISO 10993-1

- The general principles governing the biological evaluation of medical devices within a risk management process;
- The general categorization of devices based on the nature and duration of their contact with the body;
- The evaluation of existing relevant data from all sources;
- The identification of gaps in the available data set on the basis of a risk analysis;
- The identification of additional data sets necessary to analyse the biological safety of the medical device;
- The assessment of the biological safety of the medical device.

11.00 AM - 12.00 PM: FDA & 10993-1

- ODE Final Biocompatibility Guidance Use of ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Published: June 16, 2016

12.00 PM - 01.00 PM: Lunch

01.00 PM - 02.00 PM: ISO 14971-Risk Assessment

- Have risks been designed out if possible?
- Have manufacturers shown that risks have been reduced as much as possible?
- Have manufacturers conducted a risk benefit analysis for all risks?
- Have residual risks been incorrectly reduced by warnings placed on IFUs or provided in training?

02.00 PM - 03.00 PM: Developing a Biological Safety Plan

- Biological Safety: More than just Test Data
- Leverage information that is known about the constituents of the device
- Identify and characterize biological and toxicological hazards associated with the medical device product in an effort to characterize risk
- Define a plan for ensuring biological safety
- Explain how your company uses the requirements of ISO 109931:2003 to assure biological safety

03.00 PM - 04.00 PM: Chemical Testing: Extractables & Leachables

- Regulators are concerned with substances migrating from different materials (polymers, metals, glass etc.) which patients may be exposed to through many different routes of administration.
- Extractables studies
- Leachables studies
- Analytical Techniques for Extractables and Leachables
- What do the results tell you?

04.00 PM - 04.30 PM: Good laboratory practices

- What are they? How do they apply?

Day Two (8:30 AM - 12:30 PM)

08.30 AM - 10.00 AM: ISO 10993-17 Allowable Limits

- Approach for setting tolerable intake (TI) values for chemical compounds released from medical device materials based on the method described in the standard
- Practical advice is provided on how to derive both non-cancer and cancer-based TI values

10.00 PM - 12.00 PM: Biocompatibility Endpoints-Testing

- Use of ISO 10993-1 and the FDA-modified matrix (Attachment A) to determine the relevant biocompatibility endpoints for an evaluation
- General biocompatibility testing considerations, including test article preparation
- Specific considerations for the following testing: cytotoxicity, sensitization, hemocompatibility, pyrogenicity, implantation, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and degradation assessments
- Chemical assessment recommendations
- Considerations for labeling devices as "-free"

12.00 PM - 12.30 PM: Seminar wrap up

WHO WILL BENEFIT

- Consultants
- Technical advisors
- Product Managers
- Laboratory Managers
- Process Development and System Engineers
- Research, Design and Manufacturing Engineers
- Regulatory Affairs and Quality Assurance Professionals
- Microbiologists and Chemists involved in the evaluation of Medical Devices