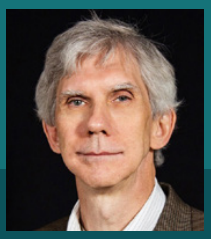
Biocompatibility for Medical Devices US

October 24 - 25, 2019
JW Marriott Chicago,
Chicago, IL

NAVIGATE THE EVOLVING BIOCOMPATIBILITY LANDSCAPE FOR MEDICAL DEVICES

Get To Grips With ISO 10993, The Risk-Based Approach, Chemical Characterization, and Toxicological Risk Assessment, Amidst Global Regulatory Change

Hear from leading industry experts including



Kelly P. Coleman, Ph.D
DABT, ERT, RAC - Distinguished Toxicologist, Technical Fellow, Bakken Fellow, MEDTRONIC PLC, *USA*

Taryn Meade
Senior R&D Biocompatibility Engineer, FRESENIUS KABI

Beau Rollins
Director, Quality Services, CONVATEC

Deanna Porter
Senior Principle Biocompatibility Scientist, ABBOTT

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PRE-CONFERENCE WORKSHOP • Wednesday, October 23, 2019

An Introduction to Biocompatibility

9:00 *Registration*

10:00 **An introduction to medical devices**
Xiaoling Dai, Medtronic

10:10 **An introduction to biocompatibility**

10:20 **Biocompatibility vs biological safety**

10:40 **ISO 10993 history and development**

11:00 *Morning coffee*

11:20 **ISO 10993 structure and content**

11:40 **Relationship between 10993 and 14971**

12:00 **Medical device categorization for biological risk assessment**

12:20 **Endpoints to be addressed in a biological risk assessment**

12:40 **Good Laboratory Practice**

13:00 *Lunch*

14:00 **Chemical characterisation vs chemical information**

14:20 **Physical Characterization**

14:40 *Afternoon refreshments*

15:00 **Extractables and leachables testing – when and why?**

15:20 **Risk assessment using E&L data**

15:40 **Medical Device Regulation safety requirements**

16:00 *End of workshop*

MAIN CONFERENCE • Thursday, October 24, 2019

8:15 *Registration*

9:00 **Chair's Opening Remarks**

9:10 **ISO10993-2018 – 1: General Updates and Recent Changes**
- Assessing the recent changes to ISO 10993-2018
- Examining why the changes have been made
- Success strategies for complying with ISO 10993-1
- Harmonisation of ISO 10993-1 under the EU
- Directives and Regulations

Beau Rollins, Director, Quality Services, **ConvaTec**

9:45 **Assessing the Impact of the MDR on Biocompatibility Testing**
- Examining the key differences between the MDD and MDR for biocompatibility testing
- Understanding the requirements for carrying out chemical characterisation and toxicology assessments for devices already on the market
- Rationalising the product portfolio and assessing which products to keep and which to remove
- Best practice for industry

Karen Sargis, Biocompatibility Manager, **ICU Medical**

10:20 **Notified Body Perspective on Biocompatibility**
- Discussing the common biocompatibility pitfalls in industry and how they can be avoided
- Chemical characterisation: What is needed?
- MDR & biocompatibility

10:55 *Coffee and Networking Break*

11:25 **Assessing the Status of ISO 10993-18 and Clarifying the Guidance Surrounding Chemical Characterization and Toxicological Risk Assessment**
- Strategies for conducting chemical characterizations for medical devices
- Translating state of the art extractables and leachables testing
- Lessons learned in carrying out chemical characterizations

Ted Heise, Vice President Regulatory and Clinical Services, **MED Institute**

12:00 **ISO 10993-17: Establishment of Allowable Limits for Leachable Substances: Status and Best Practice**
- Assessing the current requirements for leachable substances in biocompatibility
- Extraction tests in toxicological evaluation: what are the criteria for deciding whether to carry out the tests?
- What's the best way to proceed to assess the toxicity?
- How to ensure compliance with MDR, CFDA and FDA
- Understanding how to manage TTC: What should manufacturers do with the information?
- Best practice for handling unidentified substances coming out of testing
- Examining the steps to take if you can't perform extractables and leachables tests

Ron Brown, Toxicologist, **Risk Science Consortium, LLC**

12:35 **Pitfalls of Extractable and Leachable Testing, the Curse of Tentatively Identified and Unknown Compounds**

Thor Rollins, Director of Toxicology and E&L Consulting, **Nelson Labs**

1:05 *Networking Lunch*

2:35 **Assessing Alternatives to Animal Testing: Changing the Paradigm from in vivo to in vitro Toxicology**
- Examining alternative available methods to predict biocompatibility
- Strategies for demonstrating the value of in vitro methods to predict biocompatibility
- Communication, training and education: Strategies for gaining stakeholder and regulator buy-in for in vitro testing
- Balancing increased requirements with the move from animal testing – when can it be avoided?
- When is literature enough?

Kelly P. Coleman, Ph.D., DABT, ERT, RAC - Distinguished Toxicologist, Technical Fellow, Bakken Fellow, **Medtronic plc,** *USA*

3:10 **Examining the Latest Developments in Skin Sensitisation and Irritation Testing**
- Validation of skin irritation on 3D models to replace animal testing
- Assessing how far away the industry is from having positive materials with good human data
- Assessing the need for good human data to validate existing assays in vitro
- Defining the right strategy for sensitisation and irritation testing
- Materials are on the market with no complaints/PMS requirements

Christian Pellevoisin, Scientific Director, **Episkin Academy**

3:45 *Afternoon Networking Refreshments*

4:20 **Success Strategies to Demonstrate Good Biocompatibility**

Niranjan Goud, Senior Scientist, Toxicology and Biocompatibility, **Cook Medical**

5:00 **PANEL DISCUSSION: Harmonisation of ISO 10993 in EU, US and APAC**
- Assessing different interpretations of ISO 10993-2018 IN EU, US and APAC
- Understanding parallel regulatory requirements in EU, US and APAC
- Examining the extent to which biocompatibility requirements in EU, US and APAC can be harmonised

Niranjan Goud, Senior Scientist, Toxicology and Biocompatibility, **Cook Medical**
Beau Rollins, Director, Quality Services, **ConvaTec**
Kent Grove, Principle Biocompatibility Scientist, **Abbott**

17:45 *End of Conference Day One*

8:30 *Registration*

9:00 **Chair's Opening Remarks**

9:10 **Taking a Risk-Based Approach to Biocompatibility Testing**

- Understanding why a risk-based approach is being encouraged
- What needs to be submitted to authorities? How should the table be incorporated into submissions?
- Evaluating which tests are appropriate for your medical device
- What are the challenges and opportunities associated with the table?

Deanna Porter, Senior Principle Biocompatibility Scientist, **Abbott**

9:45 **Spotlight session**

10:20 **Examining the evolving role of chemistry in biocompatibility of medical devices**

- "Difference" and clarification between material characterization and chemical characterization
- Evolving roles of material/chemical characterization in device biocompatibility evaluation since 1980's
- Analytical instrumentation advances over last 15 years
- Roles and differences of chemical characterization testing vs. biological testing in biocompatibility evaluation today
- Challenges in analytical chemistry in quantitation and identification of unknowns with upcoming updated ISO10993-part 18

Dr. Jianwei Li, Senior Chemistry Manager/Medtronic Technical Fellow, **Medtronic, Inc.**

10:55 *Morning networking refreshments*

11:25 **Outsourcing chemical characterisations studies: challenges and opportunities**

- Finding a qualified lab that can carry out chemical characterisation
- How can test labs ensure a harmonised approach?
- What are some of the challenges with outsourcing chemical characterisation?

Taryn Meade, Senior R&D Biocompatibility Engineer, **Fresenius Kabi**

11:55 **Spotlight Session**

12:30 *Networking Lunch*

1:30 **Hemocompatibility Testing of Medical Devices ISO 10993 Part 4 Overview and Recent Changes to the Standard**

- What is hemocompatibility?
- Changes to ISO 10993-4:2017:
- New and revised definitions
- New and revised Tables
- New and revised Annexes
- Recommended hemocompatibility tests and methods
- Principles to follow when setting up hemocompatibility assays
- In vitro thrombogenicity test alternatives to large animal thrombogenicity testing: Case Studies

Michael F. Wolf, Scientist, Technical Fellow, and Bakken Fellow Corporate Technology and Innovation, **Medtronic Inc**

Anita Sawyer, Biocompatibility Expert **(ISO, ASTM, USP), (ISO, ASTM, USP)**

2:35 *Networking afternoon refreshments*

3:05 **Abbott case study: Thrombogenicity Testing and the High Failure Rate**

- Developing an in vitro blood loop and comparative against animal models
- Examining why the in vitro blood loop was developed
- An update on the Round Robin and demonstrating method consistency
- Lessons for industry

Kent Grove, Principle Biocompatibility Scientist, **Abbott**

3:10 **Ensuring device biocompatibility by proper cleaning and sterilisation processes**

- Sharing best practice for validating cleaning and sterilisation process with respect to device biocompatibility
- Overcoming challenges associated with cleaning and sterilisation processes
- Risk management applied to cleaning and sterilisation processes
- Cleaning and sterilisation process changes

Stephanie Volk, Senior Corporate Sterilization and Biocompatibility Specialis3, **ConvaTec**

3:45 *Chair's Closing Remarks*

3:55 *Close of Conference*

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