Biocompatibility for Medical Devices

20-21, November 2019
CCIB
Barcelona, Spain

ISO 10993: ARE YOU BIOCOMPATIBLE?

Tackle Testing Methods, Evaluations, Risk and Regulations with Competent Authority, Notified Body and Industry Guidance.

Hear practical advice and case studies from the best and brightest in biocompatibility:

Pieter Van de Vijver
Non-Clinical Assessor, Medical Devices
FAMHPS

Philippe Hasgall
Principal Scientist
ZIMMER BIOMET,
Switzerland

Anna Moeke-Knizhnik
Senior Manager, Biocompatibility
BIOTRONIK

James Moore, Ph.D.
Senior Scientist, Biocompatibility,
W.L. GORE & ASSOC. INC.,
USA

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#Biocompatibility

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PRE-CONFERENCE WORKSHOP • Monday, 18 November 2019

Instructor: **Philip Clay,** Director, **Chorley Consulting**

08:30 *Registration*

09:30 **Workshop introductions**

09:40 **An introduction to biocompatibility**

10:00 **Biocompatibility vs biological safety**

10:20 **ISO 10993: history, development, structure and content**

10:45 *Morning coffee and networking*

11:15 **Relationship between 10993 and 14971**

11:40 **Medical device categorization for biological risk assessment**

12:05 **Endpoints to be addressed in a biological risk assessment**

12:30 **Good Laboratory Practice**

12:55 **Chemical characterisation vs chemical information**

13:20 *Lunch*

14:20 **Extractables and leachables testing – when and why?**

14:45 **Risk assessment using E&L data**

15:10 **Medical Device Regulation safety requirements**

15:35 **Question & Answer session**

MAIN CONFERENCE • Wednesday, 20 November 2019

08:15 *Registration*

09:00 **Chair's opening remarks**

09:10 **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

Mollie Holter, Consultant & Owner, **MicroBio Consulting, LLC,** *USA*

09:45 **Competent Authority perspectives on biocompatibility**

- General requirement nr 1: "taking into consideration the state of the art" & biocompatibility: implications.
- Issues with the "margin of safety" concept
- Extracts: always the solution?
- Biocompatibility & clinical investigations: requirements, etc.

Pieter Van de Vijver, Non-Clinical Assessor, Medical Devices, **FAMHPS**

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

Christina Reufsteck, Product Specialist, **TÜV SÜD Product Service GmbH,** *Germany*

10:55 *Coffee and networking break*

11:25 **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

Philip Clay, Director, **Chorley Consulting**

11:55 **Spotlight session**

12:30 *Networking lunch*

14:00 **Physical and Chemical "information" vs "characterisation" – is there a difference?**

- Terminology in ISO 10993-1 and the MDR
- What is "chemical information" and is this different to "chemical characterisation"
- Physical information
- What chemical & physical data are needed for a risk assessment
- What will be expected by Notified Bodies

Henry Sibun, Director, **Henry Sibun Associates Ltd,** External Notified Body Reviewer/Lead Auditor, **TÜV SÜD Product Service,** *UK*

14:35 **Alternative techniques for determination of exhaustiveness (according to the FDIS of ISO 10933-18)**

Annelies Vertommen, Team Leader, Medical Device Chemical Characterisation Testing**, Nelson Labs NV**

15:10 *Afternoon networking refreshments*

15:40 **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?
- Understanding how to manage TTC: What should manufacturers do with the information?
- Best practice for handling unidentified substances coming out of testing

Anna Moeke-Knizhnik, Senior Manager Biocompatibility, **Biotronik**

16:15 **Linking ISO 10993-17 and ISO 10993-18**

- Assessing the status of ISO 10993-18 and clarifying the guidance surrounding chemical characterisation and toxicological risk assessment
- Understanding how the two parts link together

Jianfeng Hong, Senior Research Scientist & Chemistry Lab Manager, **Fresenius Kabi USA**

16:50 *Chair's closing remarks*

17:00 *End of conference day one*

08:30 *Registration*

09:00 **Chair's opening remarks**

09:10 **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
- Validation of skin irritation on 3D models to replace animal testing
- Latest developments in skin sensitization and perspectives for biomedical devices
- Assessing the need for positive materials with good human data to validate existing assays in vitro

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

09:45 **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
- Assessing the results of the Round Robin and demonstrating method consistency
- Lessons for industry

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

10:20 **Insights into in vitro Hemocompatibility testing according to ISO 10993-4**

- Blood and the coagulation system – brief introduction
- Recommended Hemocompatibility tests by ISO 10993-4
- Hemocompatibility evaluation of medical devices
- Hemolysis
- Coagulation and platelet activation
- Hematology
- Leukocyte activation and complement system
- Lab experience, data interpretation and border cases

Sonia Font Tellado, Study Director, **Eurofins**

10:55 *Morning Networking Refreshments*

11:25 **How to deal with cytotoxicity failures**

- Introduction to cytotoxicity testing
- Quantitative versus Qualitative cytotoxicity tests
- The flaw of ISO 10993-5 – Case study
- Reasons for failure
- Cytotoxicity failed – what next?

Philippe Hasgall, Principal Scientist, **Zimmer Biomet,** *Switzerland*

12:00 **Tests for local effects after implantation: Assessing the latest revisions for implantations**

- Understanding what is being updated and why
- Absorbable materials: what are the points to consider?
- How can industry prepare?
- Timelines

Christopher Parker, Associate Department Head In-Vivo Biocompatibility, **Toxikon** and member, ISO/TC 194/WG 10 Implantation working group, **Toxikon**

12:35 *Networking lunch*

14:05 **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?

James Moore Ph.D., Senior Scientist, Biocompatibility, **W.L. Gore & Assoc. Inc.,** *USA*

14:40 **Ensuring device biocompatibility by proper cleaning and sterilisation processes**

Gerhard Marini, Team Leader, Biocompatibility & Sterility, R&D Impl. Development, **MED-EL**

15:15 *Networking afternoon refreshments*

15:45 **Panel discussion: Harmonisation of IS0 10993 in EU, US and China**

- Assessing different interpretations of IS0 10993-2018 IN EU, US and China
- Understanding parallel regulatory requirements in EU, US and China
- Examining the extent to which biocompatibility requirements in EU, US and China can be harmonised

Wei Zhang, Senior Scientist, **Medtronic Technology Center – Greater China**
Mollie Holter, Consultant & Owner, **MicroBio Consulting, LLC,** *USA*

16:30 *End of Conference*

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