Informa Life Sciences' 7th Annual

Biocompatibility Testing and Evaluations for Medical Devices

8-9 December 2015
Radisson Blu Royal Hotel, Dublin, Ireland

Latest ISO 10993 updates and practical industry feedback into effective risk management and regulatory compliance for biocompatibility testing and evaluations

Keynote Speakers

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

Barbara Musi, *Senior Research Scientist, Toxicology & Biocompatibility, Life Science & Operations, Medical Products R&D,* **Baxter,** Sweden

Tim Morley, *Senior Director Preclinical Research,* **Smith & Nephew,** UK

Anna Moeke-Knizhnik, *Senior Manager Biocompatibility,* **BIOTRONIK,** Germany

Full speaker faculty inside...

- ✔ **Comprehensive ISO 10993 update** including latest status and revisions
- ✔ **Notified Body advice and feedback** on best strategies for biocompatibility submissions
- ✔ Sharing experiences with **justifications for biocompatibility test selections and exemptions**
- ✔ Explore the **chemical characterisation risk assessment approach and ISO 10993-18**
- ✔ Understand the current status of **revision for ISO 10993-4 on blood compatibility**

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"Excellent opportunity to interact with people from different areas to gain experience and knowledge"

Speaker 2014, Medtronic

CONFERENCE DAY ONE: TUESDAY 8 DECEMBER 2015

08.30 Conference registration

09.00 Opening remarks from the Chair

Recent and Upcoming Changes to ISO 10993

09.10 **Understanding the latest status and updates to ISO 10993**

ISO 10993 UPDATE

- Reviewing latest key updates and changes to ISO 10993, including:
  - Revision of ISO 10993-1 and the risk management process
  - Latest status of ISO 10993-4 blood compatibility revision and round robin
  - Revision of ISO 10993-5 and round robin on cytotoxicity test methods

Barbara Musi, Senior Research Scientist, Toxicology & Biocompatibility, Life Science & Operations, Medical Products R&D, **Baxter,** Sweden

Notified Body Advice and Feedback

09.45 **Notified Body perspective: Best strategies for successful biocompatibility submissions**

NOTIFIED BODY

- Understanding what needs to be included in a biocompatibility submission
- Reviewing examples of successful and unsuccessful biocompatibility submissions
- Overcoming key pitfalls experienced when completing biocompatibility submissions
- Exploring the extent to which Notified Bodies are accepting *in vitro* tests to replace *in vivo* testing and expectations for use of *in vitro* tests

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

10.20 **Biocompatibility and quality systems: Notified Body audits**

NOTIFIED BODY

- Manufacturer and Notified Body roles and responsibilities
- Biocompatibility as part of a Quality Management System Process
- Processes for design, change, documentation and post market surveillance
- Common non-conformities at Notified Body audits

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

10.55 Networking and morning coffee

11.25 **Notified Bodies Panel Discussion: Overcoming common pitfalls with biocompatibility submissions to ensure regulatory approval**

- What are the common pitfalls and how can these be overcome?
- What is expected to be included in biocompatibility submissions?
- Discussing case examples of successful and unsuccessful biocompatibility submissions

Led by:
Christina Reufsteck, Product Specialist, **TÜV SÜD Product Service GmbH,** Germany
Henry Sibun, Director, **Henry Sibun Associates Ltd,** and External Notified Body Reviewer/Lead Auditor for **TÜV SÜD Product Service GmbH,** UK

In Vivo Testing and *In Vitro* Alternatives

12.00 **Clarifying when *in vivo* testing is necessary and choosing the right animal models**

- Practically choosing the right animal model suitable for specific biocompatibility tests
- Outlining the pros and cons of different animal models for specific studies
- Determining which animal models have been successful and which have been unsuccessful in the past
- Highlighting progress with alternative *in vitro* testing and where this can be applied to replace *in vivo* testing

Brigitte von Rechenberg, Head of Musculoskeletal Research Unit, **Equine Hospital, Vetsuisse Faculty, University Zurich,** Switzerland

12.35 Networking lunch

13.35 **Exploring alternative *in vitro* test methods available to reduce *in vivo* biocompatibility testing**

- Determining whether there are any upcoming new *in vitro* methods to replace *in vivo* testing
- Outlining whether any *in vitro* tests are available as in vivo alternatives for sensitisation and irritation
- Reviewing the acceptance of *in vitro* alternatives by the regulatory authorities
- Examining key advantages and limitations of *in vitro* testing

Deanna Porter, Manager, Global Biocompatibility, **St. Jude Medical,** USA

Justifications for Biocompatibility Test Selections and Exemptions

14.10 **Best practice for justifications for biocompatibility test selections and exemptions**

- Exploring the guidance available for justifying exemptions of biocompatibility testing
- Practical advice on reporting justifications for biocompatibility test exemptions
- Reviewing whether exempting a particular test can be justified based on other data from other tests
- Outlining Notified Body expectations for justifications of biocompatibility test selections and exemptions

Sam Martin, Director, **TRCPL** and Consultant in BioMedical Technology Regulatory and Clinical Affairs, UK

14.45 **Interactive Experience Exchange: Sharing experiences with justifications for biocompatibility test selections and exemptions**

This session provides attendees with the chance to share their questions and knowledge in a highly interactive environment. Attendees will be split into small groups to share experiences and solutions to common problems in an informal environment.

Sam Martin, Director, **TRCPL** and Consultant in BioMedical Technology Regulatory and Clinical Affairs, UK

15.20 Networking and afternoon tea

15.50 **Understanding how a simple device can lead to a complicated biocompatibility assessment**

- How to approach the biocompatibility assessment for a multi-component device

Björn Lundgren, Head, Preclinical Development, **Galderma,** Sweden

Drug Device Combination Products and Reusable Medical Devices

16.25 **Exploring biocompatibility testing and evaluation considerations for Drug Device Combination Products (DDCPs)**

- Assessing the regulatory requirements for biocompatibility testing and evaluations applicable for DDCPs and borderline products
- Reviewing how to test the drug and device components as a complete final product
- Reviewing the similarity and difference between biocompatibility testing of final device product and drug leachables study into drug product from device

Jianwei Li, Sr. Chemistry Manager/Medtronic Technical Fellow, **Medtronic, Inc.,** USA

17.00 **Validation of reusable medical devices**

- General definition of reusability, cleanliness and sterilisability
- Regulatory requirements for reusable medical devices based on ISO 17664 and ISO 17665 series
- Possible grouping of medical devices for steam sterilisation validation
- Validation strategies for steam sterilisation cycles

Daniel Herber, Project Sr. Microbiologist, **Zimmer Biomet,** Switzerland

17.35 End of conference day one

"Latest updates from the industry on biocompatibility testing and excellent opportunities to network"

Delegate 2014, Baxter

CONFERENCE DAY TWO: WEDNESDAY 9 DECEMBER 2015

09.00 Opening remarks from the Chair

Chemical Characterisation and Allowable Limits for Leachable Substances

09.10 **Understanding and practically applying ISO 10993-17 allowable limits for leachable substances**
- Determining how ISO 10993-17 is practically applied during leachable evaluation
- Practical examples of leachable testing strategies for biocompatibility
- Understanding whether risk assessment must still be carried out on leachables present in trace amounts
- Exploring different software tools available for toxicological evaluation of leachables
- Evaluating key differences in what the FDA accepts for leachable studies compared to Europe

Taylor Builee, Toxicologist Scientist Level III, Material Science Department, **DePuy Synthes Companies of Johnson and Johnson,** USA

09.45 **Navigating and implementing ISO 10993-17 for leachable substances**
- Practically applying ISO 10993-17 during leachable evaluation
- Exploring leachable testing strategies for biocompatibility

Please see the website for further details – www.informa-ls.com/biocompatibility

Anna Moeke-Knizhnik, Senior Manager Biocompatibility, **BIOTRONIK,** Germany

10.20 **Exploring the chemical characterisation risk assessment approach and complying with ISO 10993-18**
- Reviewing how to successfully implement the chemical characterisation risk assessment approach
- Sharing experience with overcoming challenges or lack of clarity with ISO 10993-18
- Understanding and meeting expectations from the Notified Bodies and authorities
- Outlining how chemical characterisation can reduce animal testing and form a solid basis to justify why certain tests are exempted
- Clarifying how the results from chemical characterisation should be interpreted and applied

Tim Morley, Senior Director Preclinical Research, **Smith & Nephew,** UK

10.55 Networking and morning coffee

11.25 **Practically complying with ISO 10993-18 and understanding the chemical characterisation risk assessment approach**
- Experience with implementing the chemical characterisation risk assessment approach
- Practically meeting expectations from the Notified Bodies and authorities
- Determining how chemical characterisation can be used to justify why certain tests are exempted
- Interpreting and applying results from chemical characterisation

Gerardine Drummond, Senior Quality Engineer – Biocompatibility, **Medtronic,** Ireland

12.00 **Understanding material characterisation to ensure biocompatibility for orthopaedic medical devices with the focus of CE mark**
- Biological evaluation based upon risk management
- Material characterisation – general principles
- Test strategies for reduced testing

Jan Peeters, Primary Designated Engineer (PDE), **UL MDT,** Germany

Spotlight session
Raise your corporate profile by sponsoring or exhibiting at Informa Life Sciences' Biocompatibility Testing and Evaluations for Medical Devices. For details on speaking in this session or other sponsorship opportunities at this conference, please contact **Linda Cole, Tel: +44 (0) 20 7017 6631, Email: linda.cole@informa.com**

12.35 Networking lunch

13.35 **Use of extractable and simulated studies to chemically characterise a new device – specific highlight on compliance to ISO 10993 parts 17 and 18**
- Constructing a biological evaluation program
- Designing the test plan
- Test results – toxicological evaluation
- Clarifying how the results from chemical characterisation should be interpreted and applied

Cécile Frolet, WW Product Safety Manager, **BD,** France

ISO 10993-4: Blood Compatibility

14.10 **Understanding the current status of revision of ISO 10993-4 on blood compatibility and successful strategies for haemocompatibility testing and evaluations**
- Clarifying the latest status of, and modifications to, ISO 10993-4, effects on blood, proposed revision
- Discussion of ISO/TC 194 WG 9 Haemolysis Round Robin evaluation
- Examples of successful haemocompatibility tests carried out in compliance with ISO 10993-4
- Practical advice for selecting appropriate testing conditions

Anita Sawyer, Manager, Biological Sciences and Biocompatibility Standards, Corporate Preclinical Development and Toxicology, **BD,** USA

Biological Effects Testing Failures and Failure Investigations

14.45 **Understanding what to do when you get biological effects testing failures and failure investigations**
- What types of tests are more likely to exhibit failures and why?
- Why following proper procedures with regards to the biocompatibility assessment approach is so important
- What to do when you get a failure
- Leveraging the health based risk assessment
- Understanding the clinical relevance of your failure

Logan Peterson, DABT, CQE, Sr. Biomedical Eng., Biocompatibility R&D, **Bard Access Systems,** USA

15.20 Networking and afternoon tea

Cleaning and Sterilisation Considerations and Biocompatibility

15.50 **Ensuring device biocompatibility by proper cleaning and sterilisation processes**
- Sharing best practice for validating cleaning and sterilisation processes 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

Gerhard Marini, Manager, Sterilisation and Biocompatibility, **MED-EL,** Austria

Outsourcing and Working with Suppliers

16.25 **Practical advice on working successfully with contract laboratories and service suppliers for biocompatibility testing**

Please see the website for further details – www.informa-ls.com/biocompatibility

Lise Lyck, Senior Biosafety Specialist, **Coloplast A/S,** Denmark

17.00 End of conference

"Catch new updates and ideas on ISO 10993 for biocompatibility"

Delegate 2014, Baxter

PRE-CONFERENCE WORKSHOP (X) **MONDAY 7 DECEMBER 2015**

Registration is at 13:00 for a 14:00 start. The workshop will finish no later than 20:00. Workshop documents, refreshments and an evening meal will be provided

Practical Application of Risk Management for Biocompatibility Testing and Evaluations

This interactive workshop session will provide a comprehensive insight into practically implementing biocompatibility risk management in the design process. Attendees will have the opportunity to discuss and share best strategies for incorporating risk assessment into biocompatibility testing and evaluations and key challenges associated with ISO 10993-1.

Topics to be discussed include:
- Effectively incorporating risk management into biocompatibility testing, considering both ISO 10993 and ISO 14971
- Determining how to effectively tie in biocompatibility testing into the design process
- Risk management and biocompatibility testing: the importance of design process and process design
- Outlining how incorporating risk management into biocompatibility testing programmes can reduce additional testing required
- Clarifying which risks the device has, including from known information and where there are gaps in knowledge

Extractable and leachable study of infusion and transfusion parenteral products at Fresenius Kabi

Interactive discussion session: Sharing risk management strategies for biocompatibility testing and evaluations
- Which successful strategies have been used to incorporate risk management into testing and evaluations?

Please see the website for further details – www.informa-ls.com/biocompatibility

Led by:
Dr. Kamran Avary, Medical Device Consultant, Germany
Giuliano Rigo, Quality Engineer, Extremity Fixation, **Orthofix,** Italy
Gerhard Marini, Manager, Sterilisation and Biocompatibility, **MED-EL,** Austria
Jianfeng Hong, Sr. Research Scientist / Chemistry Lab Manager, **Fresenius Kabi,** USA

EVENING SEMINAR (S) **TUESDAY 8 DECEMBER 2015**

Registration is at 18:00 for an 18:15 start. The seminar will finish no later than 20:30. Seminar documents and an evening networking dinner will be provided.

Exploring Global Interpretations of ISO 10993

Interpretations of ISO 10993 can vary in different regions and in order to remain compliant and ensure a successful global strategy, it is essential to be aware of these variations. This interactive seminar session will provide a thorough insight into practically managing biocompatibility testing in a global environment.
Regions to focus on include China, Japan, South Korea and Taiwan.

Topics to be discussed include:
- Reviewing global regulatory requirements for biocompatibility testing and different interpretations of ISO 10993
- Determining the extent to which ISO 10993 is accepted globally and the degree of harmonisation
- Outlining how global ISO 10993 interpretations compare to Europe and the US
- Exploring how to take global requirements into account when developing a worldwide biocompatibility strategy for submissions
- Assessing specific additional testing requirements to be carried out within certain countries

Please see the website for further details – www.informa-ls.com/biocompatibility

Led by:
Barbara Musi, Senior Research Scientist, Toxicology & Biocompatibility, Life Science & Operations, Medical Products R&D, **Baxter,** Sweden
Jen Lee, Scientist II, Science & Technology, **St. Jude Medical,** USA
Anita Sawyer, Manager, Biological Sciences and Biocompatibility Standards, Corporate Preclinical Development and Toxicology, **BD,** USA

POST-CONFERENCE WORKSHOP (Y) **THURSDAY 10 DECEMBER 2015**

Registration is at 08:30 for a 09:00 start. The workshop will finish no later than 15:00. Workshop documents, refreshments and lunch will be provided.

Successfully Managing Change Control and Impact on Biocompatibility Testing and Evaluations

This highly interactive workshop session will delve into successfully managing change control, focusing on changes in product, material, processing or manufacturing site.

Topics to be discussed include:
- Reviewing the extent to which guidance is available for change control
- Sharing experiences on how to deal with day-to-day material changes on the biological evaluation of a medical device
- Understanding whether all tests must be repeated if only a small change is made
- Assessing documentation requirements for change control
- Practically complying with Notified Body and authority expectations for change control
- Overcoming the challenge when a vendor changes device materials or processes and justifying not testing for minor changes

Please see the website for further details – www.informa-ls.com/biocompatibility

Led by:
Sam Martin, Director, **TRCPL** and Consultant in BioMedical Technology Regulatory and Clinical Affairs, UK

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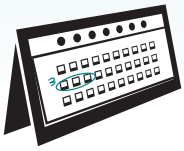
The Conference



2 days
2 parallel conferences

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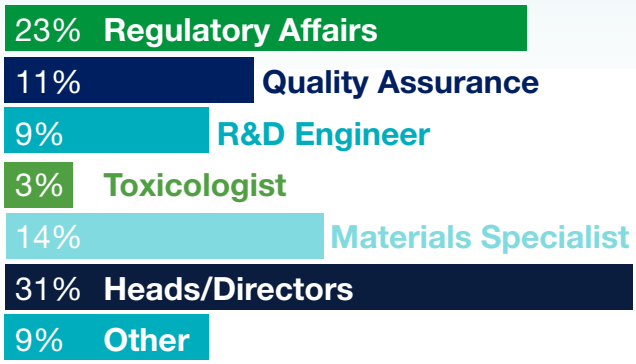
5 Interactive Sessions

120+ attendees

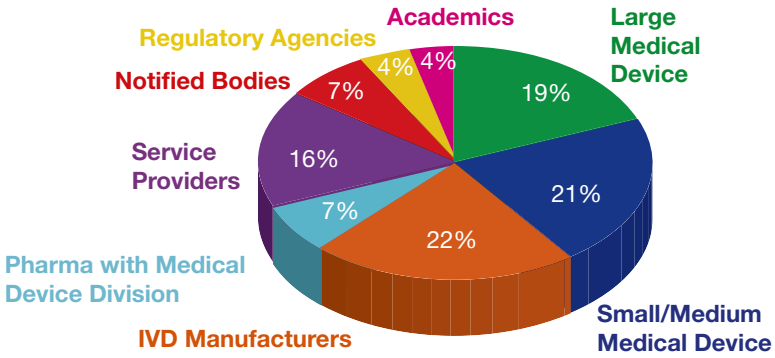
Networking



"The conference provides an excellent opportunity to interact with people from different areas to gain experience and knowledge"

Speaker 2014, Medtronic

What companies did 2014 attendees come from?



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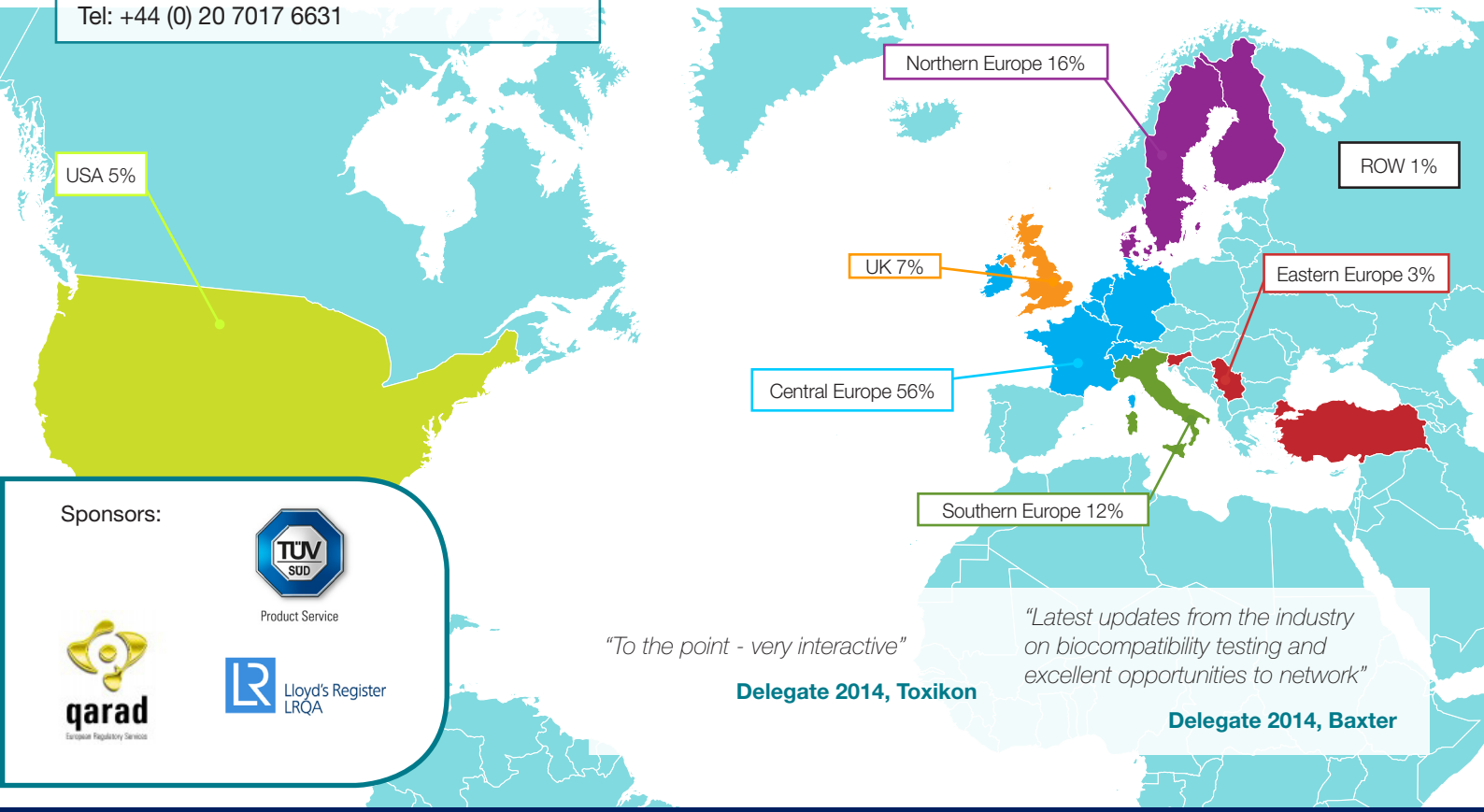
Where did 2014 delegates come from?



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"To the point - very interactive"

Delegate 2014, Toxikon

"Latest updates from the industry on biocompatibility testing and excellent opportunities to network"

Delegate 2014, Baxter

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Please select your pre OR post conference workshop:

❑ Pre-Conference Workshop (X): Practical Application of Risk Management for Biocompatibility Testing and Evaluations (Monday 7th December 2015)

❑ Post-Conference Workshop (Y): Successfully Managing Change Control and Impact on Biocompatibility Testing and Evaluations (Thursday 10th December 2015)

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