EROMED

European Regulation of Medical Devices Seminars

# Seminar Content for Neurograft Project

| Monday, October 13th, 2014 | | | |
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| | 08.45 – 09.30 | Registration<br>Welcome & introductions | Sharon Kelly<br>NUIG |
| 1. | 09.30 – 10.00 | Objectives of Workshop<br>• Challenges facing the design and development of collagen based implants such as with combination devices<br>• Reasons for incorporating additional components to the collagen Share general principles of device/drug/cell combination product development with all participants | Abhay Pandit<br>NUIG |
| 2. | 10.00 – 10.45 | Update on Collagen: Regulatory requirements<br>• Current status<br>• Future directions | Carolyn Holladay<br>Vornia |
| | 10.45 – 11.00 | Coffee break/ Tour of NFB | |
| 3. | 11.00 – 11.45 | Regulatory Presentation:<br>• Data needed to support CE marking in the EU<br>• Compliance with all other Essential Requirements<br>• Risk Analysis – leading to Instructions for Use, ct etc<br>• Risk analysis and standards for animal-derived materials | John Webster<br>Obelis |
| 4. | 11.45 – 12.30 | Clinical Data To Support CE Marking<br>• Need for clinical investigation vs. clinical data<br>• Clinical Evidence to meet the essential requirements<br>• Clinical evaluations, when, why and how<br>• Clinical Investigations, when why and how<br>• Outline clinical protocol – what would the first study look like for devices containing animal derived material? | Edith Millan<br>NAMSA |
| | 12.30 – 13.45 | Lunch | |
| 5. | 13.45 – 14.15 | Biomaterials based approach for spinal cord regeneration | Aniket Kshirsagar<br>NUIG |
| 6. | 14.15 – 15.00 | Regulatory presentation:<br>• Impact of adding a medicinal substance – classification of combination products in the EU<br>• Data requirements for medicinal substances in medical device combination products<br>• Use of biological/biotechnological medicinal substances (blood/plasma-derived / recombinant proteins) | Alison Wilson<br>Celldata Services, on behalf of Obelis |



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| | 15.00 – 15.15 | Coffee Break/ Tour of NFB | |
| **7.** | 15.15 – 16.00 | Technical Aspects of ATMPs<br>• Background on GMP requirements for medicinal products (formal approval by Competent Authority, different from medical devices Quality Management Systems)<br>• EUTCD requirements<br>• Technical challenges for cell-based products, e.g., QC and sampling, release at risk, development of adequate potency assays, difficulties when trying to use animal models for human cells... | Ana Frias<br>Stemmatters |
| **8.** | 16.00 – 16.45 | Regulatory Presentation:<br>• Impact of adding cells – classification of cellular products in the EU<br>• Data requirements for ATMPs – first-in-man clinical trial<br>• Clinical trial approval process(v) | Alison Wilson<br>Celldata Services, on behalf of Obelis |
| **9.** | 16.45 – 17.30 | The Need For Clinical Evidence Post CE Marking:<br>• Collection of clinical evidence throughout the product lifecycle<br>• Post market clinical follows up.<br>• How to collate and collect the data and the key processes applicable. | Edith Millan<br>NAMSA |
| **10.** | 17.30 | Questions and Discussions | |

Directions to Biosciences Building in NUI Galway can be found at: http://www.nfb.ie/location



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