EROMED

European Regulation of Medical Devices Seminars

Seminar Content for Neurograft Project

Monday, October 13th, 2014			
	09.00 – 09.30	Welcome, introductions & courses objectives	ALL
1.	09.30 – 10.00	Objectives of Workshop • Challenges facing the design and development of collagen based implants such as with combination devices • Reasons for incorporating additional components to the collagen Share general principles of device/drug/cell combination product development with all participants	Abhay Pandit NUIG
2.	10.00 – 10.45	Update on Collagen: Regulatory requirements • Current status • Future directions	Carolyn Holladay Vornia
	10.45 – 11.00	Coffee break	
3.	11.00 – 11.45	Regulatory Presentation: • Data needed to support CE marking in the EU • Compliance with all other Essential Requirements • Risk Analysis – leading to Instructions for Use, ct etc • Risk analysis and standards for animal-derived materials	John Webster Obelis
4.	11.45 – 12.30	Clinical Data To Support CE Marking • Need for clinical investigation vs. clinical data • Clinical Evidence to meet the essential requirements • Clinical evaluations, when, why and how • Clinical Investigations, when why and how • Outline clinical protocol – what would the first study look like for devices containing animal derived material?	Janette Benaddi NAMSA
	12.30 – 13.45	Lunch	
5.	13.45 – 14.15	Technical discussion • Addition of IL37 • Additional of other medicinal substance	Aniket Kshirsagar NUIG
6.	14.15 – 15.00	Regulatory Presentation: • Regulation of cell-based products in the EU covering introduction to the ATMP Regulation • Combination of cells with medical devices - unregulated combinations, cell-processing and separation devices, and combined and non-combined ATMPs • Examples of combined ATMPs • Data requirements for first-in-man clinical trial with an ATMP such as Neurograft (structural repair tissue engineering product)	Alison Wilson Celldata Services, on behalf of Obelis

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	15.00 – 15.15	Coffee Break	
7.	15.15 – 16.00	Technical Aspects of ATMPs • Background on GMP requirements for medicinal products (formal approval by Competent Authority, different from medical devices Quality Management Systems) • EUTCD requirements • 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...	Rui A. Sousa Stemmatters
8.	16.00 – 16.45	Regulatory Presentation: • Impact of adding cells – classification of cellular products in the EU • Data requirements for ATMPs – first-in-man clinical trial • GXP requirements • Clinical trial approval process(v)	Alison Wilson Celldata Services, on behalf of Obelis
9.	16.45 – 17.30	The Need For Clinical Evidence Post CE Marking: • Collection of clinical evidence throughout the product lifecycle • Post market clinical follows up. • How to collate and collect the data and the key processes applicable.	Janette Benaddi NAMSA
10.	17.30	Questions and Discussions	

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