EROMED

European Regulation of Medical Devices Seminars

Seminar Content for Neurograft Project

Thursday, December 11th, 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	Rachel Ronan 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 – 12:15	Technical discussion • Addition of IL37 • Additional of other medicinal substance	Rachel Ronan NUIG
5.	12:15 – 13:30	Lunch	
6.	13:30 – 14:15	Regulatory Presentation: • Impact of adding a medicinal substance – classification of combination products in the EU • Data requirements for medicinal substances in medical device combination products • Use of biological/biotechnological medicinal substances (blood/plasma-derived / recombinant proteins)	Alison Wilson Celldata Services, on behalf of Obelis
7.	14:15 – 15:00	Safety and Performance of ATMP Before First-in-Man Studies	Antoine Alves NAMSA

info@eromedseminars.com / cvpinto@stemmatters.com +32(0)488 1930 76

	15.00 – 15.15	Coffee Break	
8.	15:15 – 16:00	Regulatory Presentation: • Impact of adding cells – classification of cellular products in the EU • Data requirements for ATMPs – first-in-man clinical trial • Clinical trial approval process(v)	Alison Wilson Celldata Services, on behalf of Obelis
9.	16:00 – 16:45	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
10.	16.45 – 17.30	Pre-clinical testing of Combination Products	Antoine Alves NAMSA
11.	17.30	Questions and Discussions	

info@eromedseminars.com / cvpinto@stemmatters.com +32(0)488 1930 76