Sociedad Española
Terapia Génica y Celular

ESGCT New EU regulations on Clinical trials and ATPs workshop

Friday 25 October 2013

Time	Topic	Speaker	
09.05	Introduction	*Robin Ali*	
Planning a clinical trial			
09.05	Planning an academic trial - the sponsor's perspective	*Kim Champion, PhD*	Regulatory Manager - Advanced Therapy Trials, UCL
Manufacturing of gene and cell products			
09:35	Production of vector and genetically modified stem cells	*Anne Galy*	Genethon
09:55	The role of QP in assessing ATMP	*Eleanor Berrie*	QP,Clinical BioManufacturing Facility, University of Oxford
Preclinical studies			
10:15	AAV gene therapy for haemophilia	*A. Nathwani*	
10:35	Lentiviral vector GT for beta-thalassemia	*G. Ferrari, TIGET*	
10:55	Gamma-retro and lentiviral vector GT for CGD	*M. Grez, Frankfurt*	
11:15	Discussion		
11:30	**Break**		
Clinical trials			
11:55	EU regulations for ATMP and clinical trials	*Lucia D'Apote,*	*CAT secretariat*
12:10	Ensuring GCP Compliance, Patient Safety and Data Integrity	*Kim Champion, PhD*	Regulatory Manager - Advanced Therapy Trials
Case Studies			
12:25	Glybera	*Harald Petry*	Uniqure
12:45	ChondroCelect	*Lydia Dorrego*	TiGenix
13:05	*Regulatory Challenges in Development of Lentiviral Ex Vivo Gene Therapy Products*	*Anne-Virginie Eggimann*	BlueBirdBio
13:45	*ATMP in the EU; The long and winding road*	*Sol Ruiz*	CAT, AEMPS
14:00	**Adjourn and lunch**		