2012 KFDA Workshop on the Advanced Therapy Products

Date : November 7- 9, 2012

Place : Samjung Hotel, Gangnam-Gu, Seoul, Republic of Korea

Participants: Government agencies, Industries and Academic Institutes (day 1 and 2)

Sponsor: Korea Food and Drug Administration

No Registration Fee

<Program (Draft) >

	Time	Title	Speaker
Day1 Nov. 7 (Wed.)	**09:20-09:50**	Registration	
	09:50-10:00	Welcoming Remarks	Dr. Jeong Seok Lee (Director General, Biopharmaceutical & Herbal Medicine Bureau, KFDA)
	10:00 - 11:40	Statistical methods and principles for clinical trials Q&A	Dr. Chung Mo Nam (Younsei University College of Medicine)
	11:40 -13:00	*Lunch (* Invited luncheon for Speakers at Mari Hall (1st floor)*	
	13:00 -14:40	Design for early phase clinical trials : Variable factors to consider Q&A	Dr. Kyoung Soo Lim (Seoul National University College of Medicine & Hospital)
	14;40 - 16:20	Preparing for regulatory inspection of clinical trials-a sponsor perspective Q&A	Dr. Keun Su Bang (LG Life Sciences Co.)
	16:20 -16:40	*Refreshment Break*	
	16:40 -18:00	TBD: Presentation on xenotransplantation Q&A	Dr. Stewart Jessamine (Group Manager, Medsafe Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand)
	18:00 -	*Closing Remarks*	
Day2 Nov. 8 (Thu.)	09:00 -10:30	Regulation of Cell Therapy Products in the United States	Dr. Keith Wonnacott (Chief, Cellular Therapies Branch, Office of Cellular, Tissue, and Gene Therapies CBER, US FDA)
	10:30-12:00	TBD : Presentation on the Reflection Paper on Stem Cell Therapy of EU EMA	Dr. Menezes Ferreira (Assessor, National Authority of Medicines and Health Products, Portugal Member of the Committee for Advanced Therapies (Alternate) and of the Biologics and Cell Therapy working Parties, EU EMA)

	12:00 -13:20	*Lunch (* Invited luncheon for Speakers at Japanese Restaurant (2nd floor))*	
	13:20 -13:50	Guideline on the Cell Therapies GMP	Mr. Joon-Su Shin (Director, Biopharmaceutical Quality Management Division, KFDA)
	13;50 - 15:10	Regulatory Trends on the Cell Therapies GMP in USA	Mr. Alan Moore (Vice President, Testing and Cell Services, WuXi AppTec, Inc.)
	15:10 -15:30	*Refreshment Break*	
	15:30 -16:50	Regulatory Trends on the Cell Therapies GMP in Europe	Mr. Dominic M WALL (Operation director, Center for Blood Cell Therapies, Peter MacCallum Cancer Centre)
	16:50 -17:20	GMP Experiences from Industry	Dr. Suh, Dong-sam (Ph D. RMS Division, SewonCellontech Co., Ltd)
	17:20 -17:30	*Refreshment Break*	
	17:30 -18:00	*Panel Discussion and Q&A*	Panel : Speakers and KFDA Staff
	18:00 -	*Closing Address*	
Day3 Nov. 9 (Fri.)	*Satellite 1 : Closed Meeting 1*		
	09:00 -12:00	On cell therapy products, tissue-engineered products and xenotransplantation for participants from regulatory authority	Cell and Gene Therapy Products Division(KFDA)
	12:00 -13:00	Lunch	
	Satellite 2 : Closed Meeting 2		
	13:00 - 17:00	PMDA Point of view: Development and Approval of Biosimilar Products in Japan	Recombinant Protein Products Division(KFDA)