International Symposium on GMP for Biological Products

Seoul, Republic of Korea
18 September 2018

AGENDA

(Draft 23 August 2018)

Opening Session	**Welcome and Introduction**	
09:00 - 09:30	Registration	
09:30 - 09:35	Opening remarks	Sunhee LEE (DG of NIFDS, MFDS)
09:35 - 09:40	Group photo	
Session 1	**WHO GMP Guidelines for Biological Products**	
09:40 - 10:10	Main principles and overview of revision of WHO GMP guidelines for biological products	Dianliang LEI (WHO)
10:10 - 10:40	Personnel, starting materials, seed lot, cell bank system	Victor MAQUEDA (WHO)
10:40 - 11:10	Premise, production, and campaign production	Mohamed REFAAT (WHO)
11:10 - 11:40	QC, Use of animals and documentation	Anil CHAWLA (WHO)
11:40 - 13:10	**Lunch break**	
13:10 - 13:40	WHO- PQ experience on on-site audit	Mustapha CHAFAI (WHO)
Session 2	**Biosafety issues on GMP for Biological Products**	
13:40 - 14:10	Harmonization of GMP & Biosafety regulations with special regard to facility Design	Chung Keel LEE (MFDS)
14:10 - 14:40	Regulatory Perspective of Biosafety on GMP	Jaeho JUNG (MFDS)
14:40 - 15:10	Consideration for Biosafety on Polio Vaccine Manufacturing Facility	Hyun Seok YEO (LG Chemical)
15:10 - 15:40	**Coffee break**	
Session 3	**GMP for advanced therapy medicinal products**	
15:40 - 16:10	EU GMP guidelines for advanced therapy medicinal products (ATMP)	Kyoungphil Byun (Asan Medical Center)
Session 4	**Panel Discussion**	
16:10 - 17:10	Panel Discussion	Facilitator: Chung Keel LEE (MFDS)
Closing Session		
17:10 – 17:20	Closing Remarks	Kyungwon SEO (NIFDS)