WHO Implementation Workshop: Characterization of Cell Banks for the Production of Biologicals

27 – 29 May 2013

Lijiang, China

AGENDA

(version dated on 13 Dec 2012)

Chair:
Rapporteur:

Day 1, Monday, 27 May 2013

Session 1	**Welcome and Introduction**
09:00 - 09:20	Opening remarks and welcome by host
09:20 - 09:40	Self-introduction; Announce of DOI assessment
09:40 - 09:50	WHO approach to evaluation of cell substrates
09:50 - 10:10	Objectives and expected outcomes of the workshop
10:10 - 10:30	Key issues to be addressed in the workshop
10:30 - 11:00	***Coffee break***
Session 2	**Cell banks used for production of biologicals**
11:00 - 11:30	Characterization of cell banks
11:30 - 12:00	WHO recommendations from 2010
12:00 - 12:30	Discussion and comments
12:30 - 13:30	***Lunch break***
Session 3	**Goals and basic principles for detecting microbial agents**
13:30 - 13:50	Overview and general considerations
13:50 - 14:10	Development of strategies for testing
14:10 - 14:30	Strategy developed to test cell substrates for viruses
14:30 - 15:30	Discussion and comments
15:30 - 16:00	***Coffee break***
Session 4	**Key issues in detection of microbial agents**
16:00 - 16:20	National regulatory authorities' experience from developing country

16:20 - 17:00	Manufacturers' experience on development of strategies and limitations in applying the strategies
17:00 - 17:30	Call for the comments from participants

Day 2, Tuesday, 28 May 2013

Session 5	**Case study 1:** Viruses to be screened - 3 cell line examples
09:00 - 09:30	Vero cell
09:30 - 10:00	CHO cell
09:30 - 10:30	Murine myeloma cells
10:30 - 11:00	***Coffee break***
11:00 - 12:00	Discussion
12:00 - 13:00	***Lunch break***
Session6	**Case study 2:** Understanding pros/cons of two strategies for testing
13:00 - 13:30	1st Strategy: MCB (exhaustive testing) + WCB (limited testing)
13:30 - 14:00	2nd Strategy: MCB (limited testing) + WCB (exhaustive testing)
14:00 - 15:30	Work in groups: Compare and contrast two strategies
15:30 - 16:00	***Coffee break***
16:00 - 17:30	Feedback from groups to all and Discussion
17:30 - 18:00	Summary of the case study outcomes
18:00 -	Evaluation of the Workshop (form to be filled in) - Chair

Day 3, Wednesday, 29 May 2013

Session 7	**Implementation of WHO Recommendations: Regulators' and manufacturers' perspectives**
09:00 - 10:30	National regulatory authorities' perspectives from developed/developing countries
10:30 - 11:00	***Coffee break***
11:00 - 12:30	Manufacturers' perspectives from International Federation of Pharmaceutical Manufacturers & Associations/ Developing countries Vaccine Manufacturers Network
12:30 - 13:00	Discussion
13:00	Close of open meeting
13:00 - 14:00	***Lunch break***

Session 8	**Closed session (regulators and participants without conflict of interest)**
14:00 - 15:30	Implementation plans: NRAs in different countries
15:30 - 16:00	***Coffee break***
16:00 - 16:30	Proposals for further improvements - Discussion
16:30 - 17:00	Summary of the Workshop
17:00	Close of meeting