Quality Management Systems

Training for professionals of the vaccine industry in cooperation with International Vaccine Institute (IVI),

28 June to July 1st 2016, at Best Western Seoul Garden, South Korea.

DAY 1 – Tuesday 28th June 2016		
	Topic	Speaker
8.00 -8.30 h	Registration	Local organizer
8.30 -9.00 h	Opening remarks and Introductions Welcome remarks	IVI Executives Dr Y. Sohn DG of NIFDS
9.00 - 9.30 h	DCVMN Global initiatives	S. Pagliusi DCVMN
9.30 - 10.00 h	Train the trainers' approach introduction and Pre-test	DCVMN
10.00 - 10.30	Coffee break	
10.30 – 12.30	Quality by Design Concept	Dr. C.K.Lee Expert Senior Consultant
12.30 – 13.30	Lunch break	
13.30 – 14.30	GMP Facility Design for Vaccines	Dr. C.K.Lee Expert Senior Consultant
14.30 – 15.30	GMP Audits	Dr. C.K.Lee Expert Senior Consultant
15.30 – 16.00	Coffee break	
16.00 – 17.00	Turn-key solutions for vaccines Biosafety and production	Ms. O. Chandra
17.00 – 18.00	Q&A	All participants
18.00 – 19.00	Welcome reception	All participants

DAY 2 – Wednesday 29th June 2016		
Time	Topic	Speaker
8.30 – 9.30	Global registration of vaccines: regulatory remarks	N. Dellepiane, Regulatory expert consultant
9.30 – 10.30	Challenges and opportunities to global vaccines' registration	N. Dellepiane, Regulatory expert consultant
10.30 – 11.00	Coffee break	
11.00 - 12.00	Sharing experience on recent PQ Submission	Eubiologics
12.00 – 12.30	Q&A	All participants
12.30 - 13.30	Lunch break	
13.30 - 14.30	Prioritization and establishment of essential documents: group exercise	Working groups
14.30 - 15.30	Group discussions: Input from manufacturers groups on potential essential registration documents	Participants
15.30 – 16.00	Coffee break	
16.00 – 17.00	Feedback presentations from groups	Participants
17.00 - 17.30	Conclusion: Joint views on essential documents and prioritization	N. Dellepiane, Regulatory expert consultant
17.30 - 18.00	Q&A	

There will be opportunity for private consultations with the regulatory consultant in parallel sessions on day 3, to provide feedback on the topics discussed on Day 2, as well as on the list of documents for global registration. There are 8 slots available, please contact DCVMN secretariat if you wish to set an appointment.

DAY 3 – Thursday 30th June 2016		
Time	Topic	Speaker
8.30 – 9.30	Regulatory basics for facility design (WHO GMP): current GMP requirements	C. Bachoffen GMP consultant
9.30 - 10.30	Regulatory basics for facility design (WHO biosafety): biosafety requirements	C. Bachoffen GMP consultant
10.30 - 11.00	Coffee break.	
11.00 – 12.30	Case Study: Differences in the facility design philosophy / principles between Europe and Asia (presentation and discussion of examples for different design approaches)	C. Bachoffen GMP consultant
12.30 - 13-30	Lunch break	
13.30 – 15.00	Case study: Observations made by CB Consultancy during inspection of vaccine manufacturing facilities (discussion of interesting examples regarding violation of GMP / biosafety requirements; solutions for remediation of the observations)	C. Bachoffen GMP consultant
15.00 – 16.00	Observations by using a thorough "quality by design" approach and risk assessments performed as an interactive exercise together with the audience;	C. Bachoffen GMP consultant
16.00 – 16.30	Coffee break	
16.30 – 17.30h	Cont. Exercise on previous sessions	C. Bachoffen GMP consultant
17.30 -18.00	Q&A	
18.00	adjourn	

In parallel sessions there will be opportunity for private consultations with the regulatory consultant to provide feedback on the topics discussed on Day 2, as well as on the list of documents for global registration. There are 8 slots available, please contact DCVMN secretariat if you wish to set an appointment.

DAY 4 – Friday 1st July 2016		
Time	Topic	Speaker
8.30 – 10.30	Steps, structure and organization of a facility design, planning and construction project (structured approach: Project definition (URS), conceptual and basic design, detailed design, construction, commissioning)	C. Bachoffen GMP consultant
10.30- 11.00	Coffee break	
11.00 -12.30	Quality management and "quality by design" activities which are performed during a facility design, planning and construction project (risk assessments, design review, design qualification, critical review and approval stops, controlled implementation of project changes, controlled remediation of errors and defects)	C.Bachoffen GMP consultant
12.30 -13.30	Lunch break	
13.30 – 15.00	Q&A, closure of the training.	C. Bachoffen GMP consultant
15.00 -15.30	Wrap up, test2 and feedback	DCVMN secretariat
15.30 – 16.00	Coffee break	
16.00 – 17.30	Q&A adjourn	All participants