Quality Management Systems

Training for professionals of the vaccine industry on Water, Air, Audit and clinical studies management for global supply.

30 May to 03rd June 2016 at Windsor Excelsior, Rio, Brazil.

DAY 1 – 30 May 2016 – Chair person: Prof. Dr. Germano Gehardt Filho		
	Topic : Water sytems	Speaker
8.00 -8.30 h	Registrations	Local organizer
8.30 -9.00 h	Opening remarks by Chair and Introductions	Prof. Dr. Germano Gerhardt Filho, President of FAP
9.00 - 9.30 h	DCVMN Global initiatives : impact of professional training for industry, train-the-trainers concept and quality management	Dr. S. Pagliusi DCVMN
9.30 - 10.00 h	General overview of Workshop Objectives. Group introduction. Group selection. Test 1 assessment	Dr. V. Maqueda
10.00 - 10.30	Coffee break	
10:30 – 12.30	Water for Injection / Purified Water: Main points to consider. Microbiological & Physicochemical Aspects – Methods – Design – Installation – WHO requirements.	Dr. V. Maqueda
12.30 - 13.30	Lunch break	
13.30 - 14.30	Case study analysis or Group Exercise: Identify design defects and evaluate impact	Participants
14.30 - 15.30	Presentation of Groups case study analysis. Summary & Guidance.	Participants
15.30 – 16.00	Coffee break	
16.30 - 17.30	Qualification of Water Systems. Routine monitoring - Selection of sample locations – Risk Assessment -.Case study analysis or Group Exercise: Out of Limits	Participants
17.30 - 18.00	Presentation of Groups case study analysis. Summary of findings and conclusions. Reading material selection.	Participants
18.00	adjourn	

DAY 2 Tuesday 31st May 2016		
Time	Topic : HVAC	Speaker
8.30 – 9.30	HVAC: Design – Classification – Qualification – WHO requirements	Dr. Maqueda
9.30 – 10.00	Environmental Monitoring: Viable and Total Particles - Selection of sample locations – Risk Assessment - Action & Alert Levels - Trends – Microbiological aspects. New pharmacopeia and WHO requirements.	Dr. Maqueda
10.00 – 10.30	Coffee break	
10.30 – 12.30	Case study analysis or Group Exercise: Identify design defects. Management of Environmental Monitoring Excursions.	Dr. Maqueda
12.30 – 13.30	Lunch	
13.30 – 14.30	Air control technology	D. Santos Munters
14.30 – 15.30	Presentation of Groups case study analysis. Summary of Main Points to consider & Guidance. Reading material selection.	Dr. Maqueda
15.30 – 16.00	Coffee	
16.00 – 17.00	Presentation of Groups case study analysis. Summary of Main Points to consider & Guidance. Reading material selection. (cont)	Participants
17.00 - 17.30	Q&A	
DAY 3 Wednesday 1stth June 2016		
Time	Topic : Audits	Speaker
8.30 – 9.30	Self-Inspection: Audit process, Auditing Skills, Audit Report, CAPA and Follow-ups. ISO 19011. External Supplier Audits. WHO requirements	Dr. Maqueda
9:30 – 10:30	Case studies – Audit situations & Examples. CAPA.	Dr. Maqueda
10.30 - 11.00	Coffee break	
11.00 - 12.30	Presentation of Groups case study analysis. Summary of positive & negative outcomes of audits	Dr. Maqueda
12.30 - 13-30	Lunch	
13.30 – 14.30	Recent advances in Microbiological monitoring of Water and Air in Biopharmaceutical environment.	Mr. M. Veltri of Merck Life Sciences

14.30 – 15.30	Summary of main points to consider of HVAC, E.M., Water for Pharmaceutical Use, Self-Inspection, and Supplier Qualification	Dr. Maqueda
15:30 - 16.00	Coffee break	
16.00 – 17.00h	Test 2	
17.00 -18.00	Q&A and conclusions	
18.00	adjourn	

DAY 4 Thursday 2nd June 2016		
Time	Topic : clinical studies management	Speaker
8.30 – 09.30	Clinical Research Overview Epi studies, Development phases (pre-clinical/phases I-IV, post-mkt surveillance, bridging) Informed Consent Form, Safety, National x International, Multicentric sites x Local studies.	Ms. A. Oliveira
9:30 – 10:00	Clinical Research Organization: Project Plan, Feasibility Investigator´s meeting, initiation visit, monitoring visit, close-out visit and Final Study Report	Ms. A. Oliveira
10.00- 10.30	Coffee break	
10.30 -11.30	Group discussion on challenges for clinical studies in Developing Countries: alignment with international standards and GCP	Group
11.30 -12.30	Randomization, Confidentiality, Trainings & Certifications, Update of study documentation, Source Document, e-CRF, Reports, ICF, Investigator Monitoring Process. Follow-up letter, safety, cold chain.	
12.30 -13.30	Lunch break	
13:30 – 15:30	GCP/ICH and FDA requirements overview. Quiz GCP/ICH	
15.30 – 16.00	Coffee break	
16.00 – 17.00	Regulatory Approvals Local (IEC, CONEP, ANVISA), International (IEC of Origin Country) Quality of Clinical Studies.	
17.00 -18.00	Inspection and Audit. Site Selection	

DAY 5 Friday 3rd June 2016		
Time	Topic	Speaker
8.30 – 10.00	The best possible clinical dossier	Dr. S. Nishioka
10.00 – 10.30	Coffee break	
10.30 – 11.30	Q&A and Test 2 assessment review	Dr. Victor Maqueda & Aldrey
11.30 – 12.30	Sharing experiences and Q&A	Participants
12.30 – 13.30	Lunch	
13.30 – 14.30	Case studies (anonymized)	Dr. Nishioka
14.30 – 15.30	Wrap up, Conclusions	Dr. Pagliusi
15.30 – 16.00	Coffee break	
16.00 – 17.00	Course certificates and feedback	
17.00	Adjourn	