

DCVMN-UNICEF-VINS Bioproducts Workshop:
Supply Chain Management and Internal/ External Audit
3-7 April 2017, Radisson Hitec City, Hyderabad, India

DAY 1, Monday 3 th April 2017- Welcome and Introduction		
Time	Topic	Speaker
8h30 – 9h00	Welcome and introduction	Siddarth Daga, Executive Director VINS Bioproducts
9h00 – 9h30	DCVMN introduction	DCVMN
9h30 – 10h00	Test 1	
10h00 – 10h30	Coffee break	
10h30 – 12h00	<ul style="list-style-type: none"> - Background of Universal Immunization Program (UIP) including milestones, target beneficiaries, immunization schedule. - Immunization supply chain in public sector in India: levels of stores, distribution of vaccines, open vial policy, alternate vaccine delivery and national centers for cold chain. 	<p>Dr. Satish Gupta, UNICEF India</p> <p>Dr. Akshay Misra and Dr. Mainak Chatterjee, Government of India (GoI) National Cold Chain and Vaccines Resource Center (NCCVRC)</p>
12h30 – 13h30	Lunch	
13h30 – 14h30	Quality assurance for supply chain (cEVM assessments)	UNICEF India/ GoI NCCVRC
14h30 – 15h30	Conduction of Immunization Session (service delivery)	UNICEF India/ GoI NCCVRC
15h30 – 16h00	Coffee break	
16h00 – 17h30	<ul style="list-style-type: none"> - Adverse event following immunization and immunization waste management - Capacity building of immunization managers and health workers - Management Information Systems (MIS). This will include National Cold Chain MIS and Electronic Vaccine Intelligence Network (eVIN) 	UNICEF India/ GoI NCCVRC
18h00	Welcome reception	

DAY 2, Tuesday 4 th April 2017- Self-Inspection		
Time	Topic	Speaker
8h30 – 9h00	General overview of Workshop objectives and methodology.	Victor Maqueda
9h00 – 10h00	Audits: a low priority activity to show regulators or an effective tool for continuous improvement?	Victor Maqueda
10h00 – 10h30	Coffee break	
10h30 – 12h30	Audits as a component of QMS. Regulatory requirements. First, Second and Third party audits. Advanced concepts and strategies. Audit process. Audit Plan. Auditor selection & qualification. Typical setbacks during audits. Categorization of findings. Exit meeting.	Victor Maqueda
12h30 – 13h30	Lunch	
13h30 – 14h30	Effective Monitoring of vaccine cold chain – GMP Aspects	Ajit Tamhane, Lisaline (Temptime partner)
14h30 – 15h30	Case study analysis: audit plan preparation on different key topics (e.g. data integrity, VVM).	Victor Maqueda
15h30 – 16h00	Coffee break	
16h00 – 17h30	Presentation of group case study analysis. Summary of main points to consider & guidance.	Victor Maqueda
17h30	Adjourn	

DAY 3, Wednesday 5 th April 2017- Self-Inspection		
Time	Topic	Speaker
8h30 – 10h00	Key practical aspects of CAPA: Firefighter or Preventive CAPA mode? Do you measure the performance of your CAPA system? Does your CAPA need a CAPA?	Victor Maqueda
10h00 – 10h30	Coffee break	
10h30 – 12h30	Auditing Skills. Practical & friendly-user audit reports for companies and regulators. ISO 19011.	Victor Maqueda

12h30 – 13h30	Lunch	
13h30 – 14h30	Recent advances in Microbiological monitoring of Water and Air in vaccine manufacturing environment	Parag Vachhani, Merck
14h30 – 15h30	Manage actual audit situations (case study group analysis / Role-playing on aseptic processing, utilities).	Victor Maqueda
15h30 – 16h00	Coffee break	
16h00 – 17h30	Presentation of group conclusions. Summary of main points to consider & guidance.	Victor Maqueda
17h30	Adjourn	

DAY 4, Thursday 6 th April 2017- External Audit		
Time	Topic	Speaker
8h30 – 10h00	External Supplier Audits. Regulatory requirements. Supplier Qualification Program.	Victor Maqueda
10h00 – 10h30	Coffee break	
10h30 – 12h30	Sterilization & Lab services Auditing.	Victor Maqueda
12h30 – 13h30	Lunch	
13h30 – 14h45	BiOZEEN's Approach in process equipment design to meet guidelines of regulatory authorities	Dr. Daniel Cardoso
14h45 – 15h30	Audit plan & checklist preparation based on case studies of vaccine production (group discussion)	
15h30 – 16h00	Coffee break	
16h00 – 17h30	Group presentation of audit plans. Summary of positive & negative outcomes of audit plans (open discussion)	Victor Maqueda
17h30	Adjourn	

DAY 5, Friday 7 th April 2017- Internal Audits		
Time	Topic	Speaker
8h30 – 10h00	Audit situations based on the vaccine case studies. Auditing Skills (group analysis / Role-playing).	Victor Maqueda
10h00 – 10h30	Coffee break	
10h30 – 12h00	Brief report preparation – findings categorization (group work and Discussion)	Victor Maqueda
12h00 – 12h30	Test 2	
12h30 – 13h30	Lunch	
13h30 – 15h30	Audit report presentation	Victor Maqueda
15h30 – 16h00	Coffee break	
16h00 – 17h30	Test review, Q&A and summary	Victor Maqueda
17h30	Adjourn	