Tentative DRAFT Agenda for discussion
Quality Management

Training for professionals of the vaccine industry
Hyderabad 18-22 May 2015

Day 1	
Train the trainers approach – Dr. I. Walther	
8 :30	Registrations
9:00	Welcome and Introductions: New DCVMN Initiatives
9:15	Pre-training evaluation test
9:30	Introduction to Training situations – experiences in life What did you like – what did you dislike?
	Group work
	Collection of subjects by trainer Q&A
10 :00	Coffee break
10 :30	Requirements for adult training - What is specific in adult learning
	Training tools for trainers
	Speaking in front of a group - Exercise
12:30	Lunch break
13:30	How to prepare a training programme: potential conflicts and how to approach
15:00	Presentation of exercise tasks
	Preparation of short presentations Q&A
	Short presentations by volunteer participants
16:00	Coffee break
16:30*	Vaccine process development upstream Vaccine process development downstream
18:00	Adjourn and Welcome reception
Day 2	
Qualification & Validation – Dr. I. Walther	
8:00	Regulatory requirements and validation master plan
9:00	User Requirement Specifications and Functional Design Specifications
10:00	Coffee break
10:30	Design Qualification
12:30	lunch break
13:30	Factory Acceptance Test / Site Acceptance Test
14:30	Installation Qualification / Operational Qualification / Performance Qualification
16:00	Coffee break
16:30*	Cleaning Process validation (M. Payne/Pattnaik)
17:00*	Case studies Q&A
18 :00	Adjourn
Day 3 (parallel sessions)	

Qualification & Validation (cont) – Dr. I. Walther OR Quality Systems by S.Williams		
8:00	Process validation	How does a QS fit together? Regulatory requirements Management of Deviations/Investigations and CAPA
10:00	coffee break	
10:30	Practical exercises related to qualification	Practical exercises related to deviations/CAPA
11:30	WHO PQ updates by Webinar (TBC)	WHO PQ updates by webinar (TBC)
12.30	lunch break	
13.30	Cleaning validation	Change Management and Equipment Qualification
14:30	Practical exercises	Practical Exercises
16:00	Coffee break	
16:30*	Process economy, Facility design and Group work	Practical exercises related to change management and equipment qualification
18:00	Adjourn	
Day 4		
Fundamental Quality Systems – S. Williams		
8:00	Controlling contamination in a Biologics Facility – key regulator expectations and Risk Management	
10:00	Coffee break	
10:30	Qualifying Suppliers: Supplier Assurance Programs	
12:30	Lunch break	
13:30*	Process optimization opportunities (GE) Practical workshop exercises	
16:00	Coffee break	
16:30	Open discussion and summary	
18:00	Adjourn	
Day 5		
Fundamental Quality Systems (Continued) – S. Williams		
8 :00	Viral Inactivation – Industry Requirements Cleaning and Cleaning Validation in a Biologics Facility Microbiological Controls	
10:00	Coffee break	
10:30	Effective Internal Auditing	
12:30	Lunch break	
13:30	Practical workshop	
16:00	Coffee break	
16:30	Post-training evaluation test and feedback	
18.00	Adjourn	

*guest speakers