



Agenda

Quality Management Systems
 Training for professionals of the vaccine industry
 In cooperation with SIBP, CNBG - China
 Chair: prof. Ze Chen, Co-chair: Mr Andrew Wong

Day 1		
Monday 16 March 2015		
WHO Prequalification: Dr Andrew Meek / Mrs Carmen Amelia Rodriguez Hernandez		

08:00	08:30	Registration
08:30	09:00	Welcome and Introductions: New DCVMN Initiatives
09:00	10:00	WHO PQ information
		01 WHO PQ Process & restructuring
		02 WHO Vaccines assessment PQ overview
		Q&A
10:00	10:15	Coffee break
10:15	12:30	03 WHO Quality aspects
		04 WHO Clinical aspects
		Q&A
12:30	13:30	Lunch break
13:30	14:30	05 WHO Programmatic Suitability for PQ
14:30	15:00	VVM features Leo Wang
15:00	16:00	06 WHO Post PQ monitoring activities
		Q&A
16:00	16:15	Coffee break
16:15	18:00	07 WHO Collaborative procedure for licensing PQd vaccines
		Q&A
18:30	-	Welcome reception

Day 2		
Tuesday 17 March 2015		
Qualification and validation: Sonia Pagliusi / Roger-Paul Bezier		
08:00	10:00	Quality management Sonia Pagliusi
		Train the trainers approach Sonia Pagliusi
10:00	10:15	Coffee break
10:15	12:30	Challenges in Final Filling of Sterile Injectable Vaccine and their Mitigation: Michael Payne and Priyabrata Pattnaik
12:30	13:30	Lunch break
13:30	16:00	Qualification and validation concepts Roger-Paul Bezier
16:00	16:15	Coffee break
16:15	17:00	QMS
17:00	18:00	Questions and Answers
18:00	-	Free time
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Day 3		
Wednesday 18 March 2015		
Qualification and validation : Roger-Paul Bezier		
08:00	09:00	Documents structure
09:00	10:00	Quality by design
10:00	10:15	Coffee break
10:15	12:30	VMP
12:30	13:30	Lunch break
13:30	15:00	Cleaning validation: Priyabrata Pattnaik
15:00	16:00	Qualification of water system
16:00	16:15	Coffee break
16:15	17:15	Qualification of HVAC
17:15	18:00	Open discussion and summary
18:00	-	Free time

Day 4		
Thursday 19 March 2015		
Qualification and validation: Roger-Paul Bezier		
08:00	10:00	Good engineering practices
10:00	10:15	Coffee break
10:15	11:15	Key messages
11:15	12:30	Questions and Answers
12:30	13:30	Lunch break
13:30	16:00	Train the trainers approach - continuation Sonia Pagliusi
16:00	16:15	Coffee break
16:15	17:15	Course evaluation
17:15	18:00	Course feedback
18:00	-	Free time

Day 5		
Friday 20 March 2015		
08:00	15:00	Visit of the SIBP facility
15:00	-	End of the programme