DCVMN Advanced Workshop:
Biosafety compliance, Bioprocess optimization and Clinical studies design
5-8 February 2018, Singapore

DAY1, Monday 5 February- Welcome and Biosafety Compliance Introduction		
Time	Topic	Speaker
8:30-9:00	Welcome and introduction by host	Merck
9:00-9:30	DCVMN Activities Updates	DCVMN
9:30-10:30	DCVMN's E-learning platform	DCVMN
10:30-11:00	Coffee Break	
11:00-12:00	Cell-based manufacturing of vaccines (TBC)	TBC
12:00-12:30	Test 1	Participants
12:30-13:30	Lunch	
13:30-14:00	Background and introduction	Dr. Paul Huntly
14:00-15:30	Overview of biosafety, biosecurity and containment principles	Dr. Paul Huntly
15:30-16:00	Coffee Break	
16:00-17:30	Current and evolving standards, regulations and oversight mechanisms - WHO LBM, GAPIII and TRS 926	Dr. Paul Huntly
17:30	Adjourn	

DAY2, Tuesday 6 February- Biosafety		
Time	Topic	Speaker
9:00-10:30	Overview of facility-related containment principles and issues • *Primary, secondary and tertiary containment* • *HVAC* • *Kill tanks* • *Autoclaves, pass-throughs and dunk tanks* • *Room decontamination and shutdown strategies*	Dr. Paul Huntly
10:30-11:00	Coffee Break	
11:00-12:30	Overview of biorisk management system-related principles and issues • *Developing an effective programme* • *Identifying and incorporating requirements* • *Policy and leadership* • *Key roles, recruitment and competency* • *Integration with QMS, GMP, etc.* • *Managing emergencies and incidents* • *Biosecurity* • *Review, oversight and certification*	Dr. Paul Huntly
12:30-13:30	Lunch	
13:30-15:00	Small group discussion on practical issues and challenges	Participants
15:00-15:30	Coffee Break	
15:30-17:00	Presentation and problem solving with open discussion	Participants
17:00-17:30	Q&A and Conclusions	All
17:30	Adjourn	

DAY3, Wednesday 7 February				
Location	Room 1		Room 2	
Time	Topic	Speaker	Topic	Speaker
9:00-10:30	• Cell-base Vaccine- A Case Study on Influenza • Challenges and Solution for Pertussis Vaccines • Challenges and Solutions for Polysaccharide Conjugated Vaccine	Miles Shi, Associate Director Asia Vaccine and Viral Therapies Segment	• Clinical development plan: define target disease endpoints and study sites • Regulatory and IRB approval • Balance between in-house clinical team and outsource to CROs	Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute
10:30-11:00	Coffee break			
11:00-12:30	• New Virus-Like Particle (VLP) Vaccines – A Case Study on Hepatitis C • Viral vector vaccine – Innovation for The Future	Miles Shi, Associate Director Asia Vaccine and Viral Therapies Segment	• Defining the roles of sponsor and CROs in managing the studies • Select and engage site investigators (site feasibility assessment) • Data management and analysis	Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute
12:30-13:30	Lunch			
13:30-15:30	• Biosafety testing for human vaccines • Cell line and virus seed characterization for human vaccines	Edmund Ang, Principal Scientist, Field Development Services, BioReliance	Group discussion & Case studies	Participants
15:30-16:00	Coffee break			
16:00-17:30	• Regulatory aspects of vaccine	Priyabrata Pattnaik, Head of Biologics	Group discussion & Case studies	Participants

	processes in early stage trials and scaling up • Virus safety in vaccine production	Operations - Asia Pacific		
17:30	Adjourn			

DAY4, Thursday 8 February				
Location	Room 1		Room 2	
Time	Topic	Speaker	Topic	Speaker
8:30-9:30	Downstream Process Development and Optimization	Michael Payne, Senior Technical Consultant	Optional visit to CRO	CRO
9:30-10:30	Implement of Single-use Technology in Vaccine Production	Miles Shi, Associate Director Asia Vaccine and Viral Therapies Segment		
10:30-11:00	Coffee Break			
11:00-11:45	Natrix: Novel Chromatography Technology for Virus Purification	Chester Hu, Head of Sales Development Chromatography - Asia Pacific		
11:45-12:30	Best Practice of Nucleic Acid Impurity Reduction in Viral Vaccine Manufacturing	Priyabrata Pattnaik, Head of Biologics Operations - Asia Pacific		
12:30-13:30	Lunch			
13:30-15:30	Hands-on practice in M-lab on downstream technology (NFF, TFF, chromo)	All participants		
15:30-16:00	Coffee Break			
16:00-17:30	Hands-on practice in M-lab on single-	All participants		

	use technology			
17:30	Adjourn			

Speakers:

Dr Paul Huntly, Managing Director of Riskren, specialising in risk assessment and management associated with biorisk management (biosafety / biosecurity), infection control in healthcare, and in particular areas concerning GAPIII, addressing measures associated with poliovirus eradication and containment. Paul has provided consultancy advice on biorisk and conducted audits and assessments for a variety of organisations, including the WHO, DCVMN, China CDC, the American Society for Microbiology (ASM), A*STAR (Singapore), the Swedish National Institute for Infectious Disease Control, the Canadian Science Centre for Human and Animal Health and several vaccine manufacturers around the world. A microbiologist by training, Paul has specialised in a management systems approach to managing biological risk, and developed the concept that led to publication of CWA 15793:2008 - Laboratory Biorisk Management Standard, together with the DNV Managing Infection Risk Standard (2012). Paul is based in Singapore, but works extensively throughout Asia and the rest of the world.