Workshop: Quality Management, Biosafety and Facility Design:
20-24 March 2017, Hanoi, Vietnam

DAY 1, Monday 20th March 2017- Introduction and Quality Management		
	Topic	Speaker
8h00 – 8h30	Registration	Registration desk
8h30 – 9h00	Welcome and introduction by Vabiotech	Dr. Do Tuan Dat, Vabiotech
9h00 – 9h15	Keynote speech by the Drug Administration Department of Vietnam (DAV)	Mr. Nguyen Tan Dat, DAV
9h15 – 10h00	DCVMN introduction	DCVMN
10h00 – 10h30	Coffee break	
10h30 – 12h00	Quality Management: - Quality Policy - Quality Manual	Dr. Maureen Dennehy
12h00 – 12h30	Test 1	
12h30 – 13h30	Lunch	
13h30 – 15h00	Quality management (cont) - Requirements of ICH and other guidance documents. - Link to Management Review and Quality Objectives	Dr. Maureen Dennehy
15h00 – 15h30	Quality Management: - Excellence Through Education - Building a Strong Quality Culture - Training Programs for GMP	Dr. Maureen Dennehy
15h30 – 16h00	Coffee break	
16h00 – 17h00	Quality Management: - Survey - Requirements - Induction, On-the-Job, Competence, Senior Management - Warning Letters	Dr. Maureen Dennehy
17h00 – 17h30	Q&A	

17h30	Adjourn	
18h00	Welcome reception	

DAY 2, Tuesday 21st March 2017- Biosafety and Biorisk Management		
8h30 – 17h30	Optional private Consultation on Quality Policy and Quality Manual	Dr. Maureen Dennehy
	Topic	Speaker
8h30 – 9h00	Background and introduction	Dr. Paul Huntly
9h00 – 10h00	Biosafety and biosecurity Standards and regulations Principles of containment Containment levels and biorisk management	Dr. Paul Huntly
10h00 – 10h30	Coffee break	
10h30 – 12h00	Continued	Dr. Paul Huntly
12h00 – 12h30	Element 1: Biorisk Management System	Dr. Paul Huntly
12h30 – 13h30	Lunch	
13h30 – 14h00	Element 2: Risk Assessment	Dr. Paul Huntly
14h00 – 14h30	Element 3: Biological Agents and Toxin Inventory and Information	Dr. Paul Huntly
14h30 – 15h00	Element 4: General Safety	Dr. Paul Huntly
15h00 – 15h30	Element 5: Personnel and Competency	Dr. Paul Huntly
15h30 – 16h00	Element 6: Good Microbiological Techniques	Dr. Paul Huntly
16h00 – 16h30	Coffee break	
16h30 – 17h00	Element 7: Clothing and Personal Protective Equipment (PPE)	Dr. Paul Huntly
17h00 – 17h30	Element 8: Human Factors	Dr. Paul Huntly
17h30	Adjourn	

DAY 3, Wednesday 22nd March 2017- Biosafety and Biorisk Management		
8h30 – 17h30	Optional private Consultation on Quality Policy and Quality Manual	Dr. Maureen Dennehy
	Topic	Speaker
8h30 – 9h00	Element 9: Healthcare	Dr. Paul Huntly
9h00 – 9h30	Element 10: Emergency Response and Contingency Planning	Dr. Paul Huntly
9h30 – 10h00	Element 11: Accident/ Incident Investigation	Dr. Paul Huntly
10h00 – 10h30	Coffee break	
10h30 – 11h00	Element 12: Facility Physical Requirements	Dr. Paul Huntly
11h00 – 11h30	Element 13: Equipment and Maintenance	Dr. Paul Huntly
11h30 – 12h00	Element 14: Decontamination, Disinfection and Sterilisation	Dr. Paul Huntly
12h00 – 12h30	Element 16: Security	Dr. Paul Huntly
12h30 – 13h30	Lunch	
13h30 – 15h30	GAPIII – example of disease-specific standard for vaccine production	Dr. Paul Huntly
15h30 – 16h00	Q&A and open discussion	
16h00 – 16h30	Coffee break	
16h30 – 17h30	Using separation processes to Prevent and remove bioburden from critical BioPharmaceutical processes" - Risk based identification of critical and moderately critical biopharmaceutical operations - Evaluating removal mechanisms based on quality attributes - Monitoring bioburden as part of an overall Biosafety strategy	Mr. Michael Payne
17h30	Adjourn	

DAY 4, Thursday 23rd March 2017- Facility Design		
8h30 – 17h30	Optional private Consultation on Biosafety (contact DCVMN secretariat for appointment)	Dr. Paul Huntly
	Topic	Speaker
8h30 – 9h30	Regulatory basics for facility design (WHO GMP): Summary of current GMP requirements	Christian Bachofen
9h30 – 10h30	Regulatory basics for facility design (WHO biosafety): Summary of current biosafety requirements	Christian Bachofen
10h30 – 11h00	Coffee break	
11h00 – 12h30	Case study: Observations made by CB Consultancy during inspection of vaccine manufacturing facilities (discussion of interesting examples regarding violation of GMP / biosafety requirements; avoidance of inspection observations by using a thorough "quality by design" approach => related risk assessments will be performed as an interactive exercise together with the audience; solutions for remediation of the observations)	Group
12h30 – 13h30	Lunch	
13h30 – 15h00	Case study continued	Group
15h00 – 16h00	Case Study: Differences in the facility design philosophy / principles between Europe and Asia (presentation and discussion of examples for different design approaches)	Group
16h00 – 16h30	Coffee break	
16h30 – 17h30	Case study continued with group discussion	Group
17h30	Adjourn	

DAY 5, Friday 24th March 2017- Quality by Design		
	Topic	Speaker
8h30 – 9h00	Recap from yesterday	Christian Bachofen

9h00 – 10h30	Steps, structure and organization of a facility design, planning and construction project (structured approach: Project definition (URS), conceptual and basic design, detailed design, construction, commissioning)	Christian Bachofen
10h30 – 11h00	Coffee break	
11h00 – 12h00	Continued	Christian Bachofen
12h00 – 12h30	Test 2	
12h30 – 13h30	Lunch	
13h30 – 14h30	Quality management and "quality by design" activities which are performed during a facility design, planning and construction project (risk assessments, design review, design qualification, critical review and approval stops, controlled implementation of project changes, controlled remediation of errors and defects)	Christian Bachofen
16h00 – 16h30	Coffee break	
16h30 – 17h30	Test discussion and test result Q&A and wrap up	Christian Bachofen
17h30	Adjourn	

Course presenters

Dr. Maureen Dennehy owns an independent pharmaceutical consulting (Quality Assist) based in Cape Town, South Africa. It offers services primarily in Quality Assurance, Pharmaceutical Quality Systems setup and improvement, Quality Risk Assessment and Qualification/ Validation. She is also an associate at McGee Pharma International, based in Dublin, Ireland. Her primary interest is in manufacture of vaccines. Maureen has a PhD in vaccine development and assessment from the Institute of Infectious Disease and Molecular Medicine, University of Cape Town. She has 20 years of experience in industry, which started with QC of BCG and Rabies vaccines at the State Vaccine Institute, and later led to Quality Manager positions at Biovac.

Dr Paul Huntly is Managing Director of Riskren, specialising in risk assessment and management associated with laboratory biorisk management (biosafety / biosecurity), infection control in healthcare, and 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, 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 GSK Biologicals (Belgium). A microbiologist by training, Paul is based in Singapore, but works extensively throughout Asia and the rest of the world.

Mr. Christian Bachofen, is an independent engineering consultant with Project Management experience, as cGMP specialist for Clean Room and HVAC Design, Pharma Water Systems Design, Quality Management, Layout for Pharmaceutical Facilities, Vaccine Production Facilities, Fill Finish Facilities.