Qualitative and Quantitative analysis of vaccines' quality:
Validation, Risk Management and Quality Control of Vaccines Workshop
Dhaka Bangladesh January 2017 (Steve Williams)

Day 1 – Sunday 15th January 2017 - Welcome and Introduction		
Incepta, DCVMN and ICDDR		
14:00 Welcome address by Incepta 14:30 Introduction to DCVMN initiatives 15:00 Train-the-trainers and e-learning 15:30 Quality Policy 16:00 Coffee break 16:30 ICDDR introduction and collaborations 17:00 Q&A and test 1 17:30 adjourn 18:00 welcome reception		
Day 2 - Monday 16th January 2017 - Validation		
By Steve Williams - CBE Pty Ltd		
8 :00	**Validation Principles and Practices** • Set up of a Validation Master Plan (VMP) for sterile products • Application of risk management to Validation and Qualification • Preparation of a process validation protocol to meet international standards • process validation and how this fits into process control. • Aseptic process simulation of bulk manufacturing facility by media fill	**Presentation**
10:00	Refreshment break	
	Continued	**Presentation**
12 :30	Lunch break	
13 :30	**Validation Case Work and Practice**	**Case Study/Workshop**
15 :30	Refreshment break	
16 :00	**Validation Case Work and Practice (Continued)**	**Case Study/Workshop**
16 :30	Quality by Design (QbD) to Tangential Flow Filtration (TFF) operations	Subhasis Banerjee ,Merck
17 :30	Adjourn	

Day 3 – Tuesday 17th January 2017 - Quality Risk Management (QRM)		
By Steve Williams - CBE Pty Ltd		
8:00	• Quality Risk Management Application • Risk Management and Quality Systems • Applying QRM to Deviations and CAPA • Applying QRM to Computerized Systems • Application of risk management to process validation of bulk antigen.	**Presentation**
10:00	Refreshment break	
10 :30	Continued	**Presentation**
12 :30	Lunch break	
13 :30	Effective Monitoring of Vaccine Cold Chain by Product, Facility and Shipment Monitoring	Ajit Tamhane, LisaLine (Temptime)
14 :30	**Risk Management Case Work and Practice**	**Case Study/Workshop**
15 :30	Refreshment break	
16 :00	**Risk Management Case Work and Practice (Continued)**	**Case Study/Workshop**
17 :30	Adjourn	

Day 4 – Wednesday 18th January 2017 - Quality Control Practical training Or optional visit to ICDDR from 8 am to 5 pm		
Cleanrooms and Aseptic Practices Workshop by Steve Williams or Rai Karklins - CBE Pty Ltd		
8 :00 – 17:00	Visit ICCDR (Optional for non-Incepta staff)	
8 :00	**Incepta staff only: Practical Workshop Group 1** • Inspection of Aseptic Processes • Sterile gowning • Group Q&A on Aseptic Processing	**Incepta staff only: Practical Workshop Group 2** • Mock Audit of the Warehouse • Fumigation Methods for Cleanrooms • Q&A on deviation management
12:30	Lunch break	
13:30	**Incepta staff only: Practical Workshop Group 1** • Inspection of the Water System • Biological Testing • General Q&A	**Incepta staff only: Practical Workshop Group 2** • Animal House • Data Integrity • General Q&A

17 :00	Adjourn

Day 5 – Thursday 19th January 2017 - Quality Control (Continued) and Q&A Session		
By Steve Williams - CBE Pty Ltd		
8 :00 – 10:00	**Qualitative and Quantitative Analysis of Vaccines:** • Testing requirements and Test Method Validation • Qualitative Test Methods • Quantitative Test Methods • Validation of Animal/ Biological Test Methods. • Bioburden and Sterility Testing. • Requirements for ability Programs.	**Presentation**
10:00	Refreshment break	
10:30	**Good Laboratory Practices – Principles and Practices** • Laboratory Quality Systems • Validation strategies for Pharmacopeia test methods versus In-House developed Analytical Methods • Analytical Laboratories • Management and Investigation of OOS Events • Laboratory Data Integrity – what do auditors look for ?	
12 :00	**Test 2**	**Test**
12 :30	Lunch break	
13 :30	**Quality Control Case Studies and Workshop**	**Case Study/Workshop**
15 :30	Refreshment break	
16 :00	**Open Forum – Q&A on Pre-Qualification GMPs**	**Q&A**
17 :30	Adjourn	

Developing Countries Vaccine Manufacturers Network

Centre for Biopharmaceutical Excellence

DCVMN Training – Dhaka Bagladesh

Presenter Profiles and Agenda

Steve Williams BSc, Grad Dip Quality Management

Steve has over 40 years' experience in the Biotechnology, Pharmaceutical and Medical Device industries in quality and manufacturing, including 25+ years consulting in GxP Quality Management and Regulatory Compliance.

Steve conducts FDA and EU/TGA/PICs compliance audits and gap analyses, assists companies in remediation programs and prepares companies for regulatory inspection. He has developed multiple training courses in PQS, GMP, GLP, Process Validation, Risk Management, Sterile Manufacture and Medical Device Quality Systems. He specializes in sterile products, risk management and compliance training solutions for the Life Sciences Industry.

Over hsi career Steve has managed a number of Quality Control Laboratories (licensed to PICs and FDA) conducting biological and safety/toxicity testing of vaccines as well as managed microbiology testing laboratories. Steve regularly conducts inspections of laboratories for regional clients.

Steve is a registered auditor for the Australian Pesticides and Veterinary Manufacturing Authority (APVMA) and in this role, conducts GMP licensing audits on behalf of the Australian government. He is a past member of International Board of Directors for ISPE (voluntary position). He is also a director SWA Biopharm Pty Ltd.

Rai Karklins BSc – Chemistry and MBA

Rai has over 30 years experience in the Chemical, Pharmaceutical, and Biotechnology industries in senior Quality Assurance, Manufacturing, R & D, and Project Management roles. He has managed and lead the following functions within various companies; VP Quality, Operations Manager, QC Manager, Project Manager, Site Director. He has also conducted multiple compliance audits and gap analysis for the organisations I worked for including, vendor supply chain, due diligence and routine internal audits. He has performed business process re-engineering with both Operations and Quality units using Quality Best Practice methods such as LEAN.

Rai has direct experience hosting TGA and FDA audits, preparing for PAI's and working through significant observations, 483's avoiding warning letters in the process. He has gained practical 1st hand knowledge of creating, driving and managing Quality Management remediation projects.