DCVMN training – Hanoi

Agenda

Who Certification Gap Analysis and Quality Management Presentation and Workshop
Hanoi 23rd and 24th November 2015 (Steve Williams and Paul Fletcher)

23rd November 2015 - Day 1		
Presenters Steve Williams and Paul Fletcher - CBE Pty Ltd		
8 :00	**Gap Analysis** Presentation on conducting a Gap Analysis in relation to readiness for a Pre-certification Inspection. • Elements/Scope of the Gap Analysis • Rating for gaps • How to identify weaknesses	**Presentation**
10:00	Refreshment break	
10 :30	**Preparing the site for External Inspection – Inspection Readiness** This session presents how to prepare for an external inspection – how to plan, set up and manage a regulatory inspection using a "packages approach.	**Presentation**
12 :30	Lunch break	
13 :30	**Quality Systems** Topics covered: • How does a QS fit together? • Risk Management • Internal Audit Programs	**Presentation**
15 :30	Refreshment break	
16 :00	**Quality Systems (continued)** Management of Deviations/Investigations and CAPA	**Presentation**
17 :30	Adjourn	

24th November 2015 - Day 2		
Presenters Steve Williams and Paul Fletcher - CBE Pty Ltd		
8 :00	**Workshop #1 – Developing a Gap Analysis checksheet** Designing a comprehensive Gap Analysis checksheet	**Workshop**
10:00	Refreshment break	
10 :30	**Workshop #2 - Deviations** Preparing and analysing examples of GMP Deviations	**Workshop**
12 :30	Lunch break	
13 :30	**Workshop #3 - Investigations and Corrective / Preventive Action** Devleoping Investigation and Corrective Action plans	**Workshop**
15 :30	Refreshment break	
16 :00	**Workshop #4 – Risk Management** Developing impact (equipment) and risk (product	**Workshop**

	process) assessments and mitigation plans	
17 :30	Adjourn	

Cleanrooms and Aseptic Practices Workshop
25rd and 26th November 2015 (Paul Fletcher and Steve Williams)

25th November 2015 - Day 3		
Presenters Steve Williams and Paul Fletcher - CBE Pty Ltd		
8 :00	**Cleanroom Management and Qualification:** Presentation on the current basic requirements for Cleanroom Layout, GMP Standards, Grades (ISO5, 7, 8 and 9) WHO expectations on HVAC system. Focus will be on: • Particulate and microbial standards • Entry of materials and personnel (flows) into ISO 7 (Grade B) and ISO5 (Grade A) space • Qualifying cleanrooms and Grade A space • Industry movement toward RABS and Isolators	**Presentation**
10:00	Refreshment break	
10 :30	Small group review of a cleanroom plan where participants will be asked to decide the product, materials and personnel flows for an aseptic cleanroom and appropriate locations of inlets and returns.	**Workshop**
12 :30	Lunch break	
13 :30	**Aseptic Processing Practices and Process Validation of Aseptic Operators:** This presentation will discuss cleanroom gowning and behaviours within Grade A and Grade B space, including a summary of good and poor aseptic practices in and around Grades A/ISO5/Class 100 and Grade B space.	**Presentation**
15 :30	Refreshment break	
16 :00	Small group review of aseptic practices, Grade A interventions, operator behaviours and gowning programs, including review of airflow studies in Grade A space.	Workshop
17 :30	Adjourn	

246h November 2015 - Day 4		
Presenter S. Williams and Paul Fletcher - CBE Pty Ltd		
8 :00	**Key Concepts for Sterilization and Validation:** This presentation will focus on the GMP requirements for steam, dry heat and filtration sterilization. The presentation will review the requirements for validation and what inspectors look for under cGMPs.	Presentation
10:00	Refreshment break	
10 :30	Small group review of steriisation validation protocols and data with a focus on steam sterilisation.	Workshop
12 :30	Lunch break	
13 :30	**Cleanroom Microbiology Controls and Environmental Monitoring Programs** This presentation will include a review of: • Fundamental EM Program – what to monitor: • frequency, location and methods for monitoring • setting appropriate limits • monitoring of water systems.	Presentation
15 :30	Refreshment break	
16 :00	Small group review of EM programs and evaluation of results from example monitoring data.	Workshop
17 :30	Adjourn	