Cleanrooms and Aseptic Practices Workshop
Beijing 3rd and 4th August 2015

3rd August 2015 - Day 1		
Presenter S. Williams 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	

4th August 2015 - Day 2		
Presenter S. Williams 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 wit ha 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	