Centre for **Biopharmaceutical** Excellence

Recent examples of training programs

Industry Education & Training in PICs Compliance and GMPs

CBE consultants have been the trainers of choice for the Hong Kong Pharmaceutical Manufacturers Association (HKPMA) for over 10 years. We provide 2 -3 day customized workshops in current PICs and GMP topics. Examples of recent programs include:

- Data Integrity, GDocP and Quality Metrics
- PICs cGMPs - General GMP Requirements
- Pharmaceutical Auditing and Supplier Assurance
- Cross - Contamination in Multi Facilities
- Design and Operation of Cleanrooms /Environmental Monitoring
- Supplier Qualification Program/Supplier Auditing/ Internal Auditing
- Process Validation / CPP CQA Programs
- Pharmaceutical Quality Systems (PQS) and ICH Q10
- PICs Risk Management – ICH Q9/PICs Annex 20
- Cleaning Validation

DCVMN – Vaccine Industry GMP and Quality Workshops

CBE consultants are qualified trainers for the vaccine industry via DCVMN. To date CBE have delivered the following programs in 2015/16.

India (2015): 3 day program on Practical QMS, Change Management, Validation, Biological Contamination Control, Sterility Assurance.

China: 3 day program on Cleanroom Management, Aseptic Processing Sterilisation and Environmental Monitoring,

Vietnam: 4 day program on WHO/PICs Gap Analysis, Quality Systems, Risk Management, Cleanroom Management, Aseptic Processing

Sterilisation and Environmental Monitoring.

Indonesia (2016) 2 day program**:** Pharamcovigilance of Vaccines

India (2016): 3 day program - Deviation, CAPA, Risk Management and Change Control, Aseptic Processing.

Bangladesh (2017): Designed workshop based program for vaccine manufacturers in Validation, Risk Management and Quality Control.

ISPE Education and Industry Workshops

Engagement with ISPE regionally and internationally for CBE Partners

- Chair of ISPE Professional Certification Initiative (CPIP)
- ISPE Accredited Regional Instructor Process Validation, QbD and QRM
- Chair ISPE Asia Pac. GMP Expert Compliance Group
- ISPE PQLI Process Validation Committee

Regulator Training

ISPE Trainer for China CFDA Inspectors workshop on QbD and Process Validation. HSA, HK DoH, and Iran regulator training

Client Training – Japan

CBE consultation workshop on:

- PICS Inspection / International GMPs – FDA vs PICS/EMA
- Aseptic processing and sterilisation
- Risk Management
- Data Integrity
- PICs Validation Requirements

Client Training – Hong Kong

CBE consultation workshop on:

- Internal and Regulatory Auditing - effective auditing workshop
- Sterilisation and Aseptic Processing
- Biological Testing Programs
- Filter Validation
- Biologics processing: Chromatography and Ultrafiltration
- Risk Management
- Internal Auditing
- Managing Regulatory Audits

Client Training – Australia/NZ

Multiple programs including Process Validation, Risk Management, FDA Compliance, Regulatory Inspection Preparedness, Quality Systems, aseptic processing, validation and GMP Compliance programs.

One-on-one training utilizing HACCP systems to promote process understanding and compliance.

A CBE partner has developed an in-depth training and competency program for analytical and physical testing of pharmaceutical products A CBE Partner was on the steering group for and was a course developer for a site-wide GMP and competency staff education and training program which saw over 150 staff participate over a 5 year period.

Post Graduate Masters in Pharmaceutical Quality and GMP - Australia

In 2004, a CBE Partner initiated the Australian **Masters in Pharmaceutical Quality and GMP currently** offered by Swinburne University. This vocationally orientated program has trained over 500 industry post graduates from around the Asian Region. The Partner was a significant contributor to the curriculum content of over 25 modules and delivered many of the content around GMP, GLP, Good Aseptic Practice, Validation, GCP, Auditing and QC Laboratory Practices.

Industry GMP Qualifications - New Zealand

In 2005-06, a CBE Partner was instrumental in formation of new national qualifications on the NZ Qualifications framework specifically for staff working in pharmaceutical and allied products manufacturing sectors.

The Partner worked on the industry group which completed the development of industry-specific unit standards and assessment guides for 2 new qualifications for the Pharmaceutical and Allied Products sector.

• National Certificate in Pharmaceutical and Allied Products Manufacture (Level 2 and 3)
• National Certificate in Engineering and Technology (Pharmaceutical and Allied Products) (Level 3)

Over 200 industry trainees have completed these unit standards within their workplace since that time.

Pharmaceutical Quality and GMP Certificate Course – Malaysia

Established the first industry training course in GMPs and Quality in 1999. This course is still running and has trained over 500 managers. The course was supported by the National Regulator.