

Post-Diploma Certificate in Pharmaceutical Quality Systems

Modules	
1	cGMP Compliance (36 hours)
2	Validation (36 hours)
3	QA And Documentation (36 hours)
4	QC Analytics (36 hours)

This course will focus on GMP requirements for the manufacturing of pharmaceuticals, biopharmaceuticals and medical devices. Quality control methods for the biopharmaceutical industry will also be covered. The PDC in Pharmaceutical Quality Systems (PDC-PQS) will cover essential techniques and knowledge required by persons employed or seeking employment in the pharmaceutical, biopharmaceutical and medical technology industries.

At the end of this course, students will have a solid foundation in GXP regulatory standards and requirements, validation principles and practice, and good documentation practice for qualification and validation. Quality control regulatory requirements and methods used in determine the quality of Biopharmaceuticals will also be covered.

Topics covered under this PDC include:

- ISO Quality Management System
- ICH Guideline and ICH Q10 Pharmaceutical Quality System
- GMPs and the Quality Management Systems
- Root Cause Analysis
- Validation of critical utilities, cleaning & sterilization methods, computer systems and biopharmaceutical processes
- Techniques in biopharmaceutical quality analyses (total protein analysis, HPLC, ELISA, 2D gel electrophoresis, bioactivity assays and mass spectrophotometer)

The PDC-PQS is suitable for:

- Persons employed in biopharmaceuticals who wish to expand their job scope
- Persons seeking employment in the biopharmaceutical industry
- Technologists working in other fields who wish to upgrade their skills to gain employment in areas related to microbiology and chemical & biochemical analyses.

The curriculum will cover both basic and advanced topics and is suitable for persons with no prior knowledge of biological science. Engineers, chemists, production technologists, IT professionals will find this course useful should they wish to transit into new areas of employment.