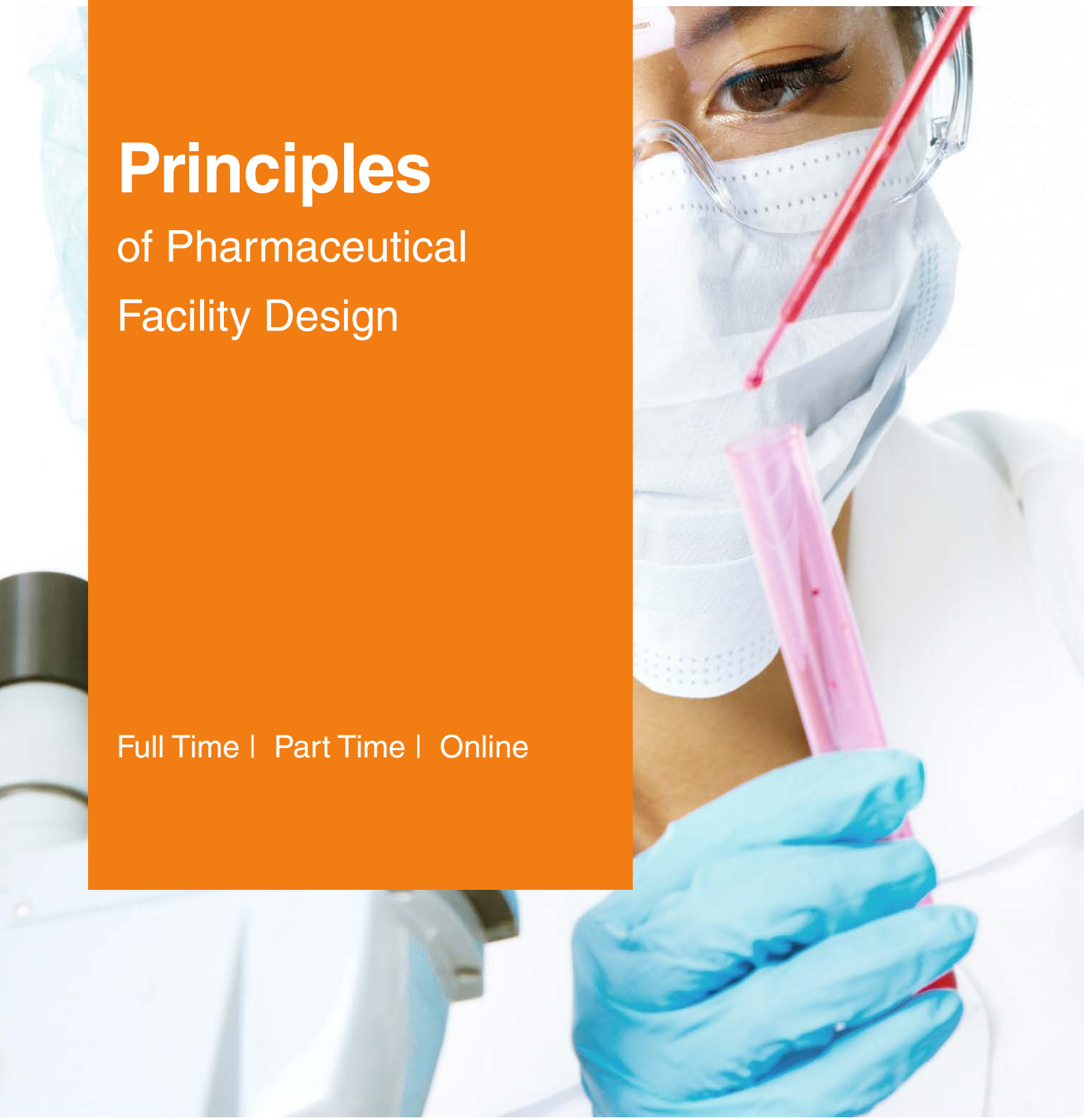
dpseducation

For the Pharma and Medical Device Industries

Principles

of Pharmaceutical Facility Design

Full Time | Part Time | Online



www.dpseng.com.sg

Contents

1. Welcome
2. Programme Overview
3. Programme Content

Welcome

Transition into a new career in the Pharmaceutical and Medical Device manufacturing industries, in the shortest time possible with our WSQ accredited courses.

- Join the 1,000 people over the last 6 years who have used our courses to build a new career in this sector in Singapore.
- These programmes combine the extreme flexibility of our online course delivery, industry recognition and our career coaching workshops to help you find a job in the biomedical sector.
- 80% success rate for people taking these courses and re-skilling into these industries in Singapore
- Meet and exceed your career goals through an industry recognised and valued professional qualification in Pharmaceutical and Medical Device Manufacturing.

Programme Overview

Who are these courses for?

DPS Education's modules are suitable for anyone with a technical, engineering, science, production, logistical or quality background and who would like to pursue a career in the pharmaceutical or medical device manufacturing industry. These modules are suitable for professionals of all levels and disciplines, and will prepare you to take up a specialist role within the BioMedical Sector.

What can you expect?

- This module is delivered online through a mixture of short content rich videos, downloadable notes, case studies, worked examples, and discussion forums allowing you to study whenever and wherever you wish. You will have access to our online learning environment where you can communicate with us, your classmates and lecturers as well as download all course materials.

- This module culminates in the completion of a competency based assessment which offers you the opportunity to solidify your knowledge and apply what you have learned in a real world situation.

What will you learn?

You will develop an understanding of the regulatory framework and learn the current trends and best practices in the Biomedical Sector. You will also learn a scientific based decision making process that will help you make better decisions on product quality and patient safety.

Who are the Lecturers?

All our lecturers still work in industry and have years of frontline industry and regulatory experience. They will deliver the most up-to-date course content while blending their insights and experience into a program that gets you results.

“Reading materials are provided to read through and a short video helps to emphasize the more important points in each chapter. It is flexible as I am able to read and learn during my free time and does not compromise on my working hours. I can also plan my time more efficiently.”

Ng Chieh Yin, Merck & Co.

"I would definitely recommend the program to my ex-colleagues knowing and experiencing the benefit upon attending the program myself"

Ms. Chong Yit Cheng, Rachel,
Baxter Healthcare SA

Programme Content

Module 3: Principles of Pharmaceutical Facility Design

Goal:

In this course you will cover the principles of pharmaceutical facility design including the lifecycle of a manufacturing facility from its original scoping, design, construction and commissioning and through to its operating life and onto its eventual retirement and decommissioning.

Core Content:

Week 1 – Controlling Air Quality and Clean Utilities

- Manufacturing Logistics Calculations
- Process Flow Diagram (PFD)
- Controlling Air Quality
- Heating, Ventilation, and Air Conditioning (HVAC) Systems
- Biopharmaceutical Unit Operations - Drug Substance / Drug Product
- Pharmacopeia Grade Waters
- Process Support and Utilities
- ISO 9001:2008
- Typical GMP list for drug substance
- Operational Activities
- GMP for Personnel
- Quality Systems Approach to Pharmaceutical cGMP Regulations
- Maintenance: Good and Best Practices

Week 2 – Purified Water Generation and Distribution

- Project Lifecycle for New and Modified Facilities
- Plant Layout
- Layout For Bulk Process Building
- Site Layout
- Zoned Air Conditioning Systems
- Isolator technology & RABs
- Cell Breakage
- Purified Water Generation Storage and Distribution
- Clean Room and Clean Air Device Monitoring
- Good Engineering Practices Procedures
- GMPs for Buildings and Facilities
- Maintenance Program

Week 3 – Clean Steam and Sterilization

- Conceptual Design – Part-I
- HAVC Requirements for Non Sterile API Manufacturing
- Plant Automation
- Plant Steam
- Clean Steam Generators
- Steam Sterilization-In-Place
- GMPs for Process Equipment
- Quality Systems Approach to Pharmaceutical cGMP Regulations - Resources

Week 4 – Controlling Material and Personnel Flows

- Conceptual Design – Part-II
- Air Flow Patterns for Laminar Flow Systems
- Cleanroom Layout HVAC Containment (non-sterile API manufacturing)
- Filter Ratings - European Standards & MERV Rating
- Logic Gates Functions, and Programmable Logic Controller (PLC)
- Water for Injection (WFI) Storage and Distribution
- Principles of Good Engineering Practices (GEP)
- Quality Systems Approach to Pharmaceutical cGMP Regulations – Manufacturing
- Maintenance Work Execution

Week 5 – Aseptic Processing and Vial Filling

- Site Master Planning – Part-I
- Classification of Clean Areas - Vial Filling
- Classification of Clean Areas - Cleanroom HVAC Configurations
- Area Classification Protection
- Compressed Air, and Pneumatics
- Aseptic Filling - Sterile Medicinal Containers
- Aseptic Filling - Vial Filling
- Cleanroom Gowning
- Aseptic Processing -– Manual & Automated Loading Systems
- Aseptic Processing - Automated Barrier Systems
- Cleanroom Monitoring - Physical Tests
- Quality System - Evaluation Activities
- Maintenance Management

Week 6 – Controlling Cleanrooms and Automation

- Site Master Planning – Part-II
- Open versus Closed Processing
- Facility Layout Concept
- Blow/fill/seal technology

"In my new role in GSK Biologicals working as a Quality Assurance Executive, I can apply what I have learned from this Training Programme as I assist in validation deliverables review to assure validated status of facility. I have gained extensive knowledge from this Program"

Ms. Liao Peiqi, GSK Biollogicals

"Along with the technical training in Pharmaceutical Manufacturing, the course provider also offers assistance with CV preparation and interview techniques specific to the Pharmaceutical Manufacturing Industry".

Mr. Lian Bee Kwang, Lonza Biologics

- PLC Programming and Case Studies
- Cleanroom Monitoring - Microbiological Tests and Cleaning Procedure
- Terminally sterilised products
- EU Guidelines on Clean Room Aseptic preparation

Week 7 – Quality Systems for Cleanrooms

- HVAC Critical Parameters for Sterile and Non-Sterile Manufacturing
- Batch Process Control
- Nitrogen Supply and Distribution
- Environmental Monitoring Program
- ICH Q10 – Pharmaceutical Quality System
- FDA Guidance on Aseptic Processing

Week 8 – Construction Lifecycle for New and Modified Facilities

- Construction Lifecycle - New and Modified Facilities
- Construction Lifecycle - Test Packs
- Construction Lifecycle - Modular and Sustainability
- Software Functional Block Diagram (FBD)
- ASTM E 2500

Outcome:

On completion of the module you will be able to:

- Describe the typical layout and function of individual units and components in a Pharmaceutical Manufacturing Facility.

Format

Delivered online using short videos, course materials which you can review online or download, tests, online collaborative activities.

Duration:

Online (100 Hours over 8 Weeks).

Accreditation

Accredited by the WDA under the WSQ system.

Assignment Based Assessment:

- One hour Open Book Online Exam
- Write a paper on "Why cGMP's are required for the Manufacture of a Pharmaceutical Product"

dpseducation

For the Pharma and Medical Device Industries

training@dpseng.com

(65) 6513 9500

www.dpseng.com.sg