dpseducation

For the Pharma and Medical Device Industries

Commissioning

& Qualification of Equipment and Systems

Full Time | Part Time | Online

www.dpseng.com.sg

Contents

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 2: Commissioning & Qualification of Equipment and Systems

Goal:

You will learn how to define the testing requirements for a range of typical mechanical, process, electrical and automation systems used in the manufacture of medicinal products. This will range from standard good engineering practices (GEP), standard commissioning approaches, and specific regulatory focused qualification testing.

Core Content:

Week 1 — Interpreting P&ID's

- Design Documents Required for the Generation of Installation and Functional Tests
- User specification for a Reactor
- Equipment Configuration and Process Sequence for a Reactor
- Generation of Piping and Instrumentation Diagrams (P&ID)
- URS for Hot Detergent and Hot PUW Generation and Distribution Skid System
- Equipment List
- Instrument List
- Inline Components List

Week 2 – System Impact Assessment & Traceability Matrix

- Protocol Content Part 1: Objective, System Description and Scope
- System Impact Assessment
- cGMP Testing Principles
- Valves
- Piping Line List
- Testing Traceability Matrix for Equipment Systems

Week 3 – Installation Tests & Equipment Verification

- Protocol Content – Part 2: Responsibilities and Installation Testing
- Minimum Elements of a Test Script
- Good Documentation and Records Management
- Component Level Impact Assessment – Part-1 Product Contact Components

- Installation Test P&ID Walk-Down
- Installation Test and Equipment Verification
- Pumps

Week 4 – Piping Isometrics & Checksheets

- Piping Components
- Piping Isometrics 2D P&ID and 3D CAD Images
- Piping Isometrics and 3D CAD
- Piping Material Traceability
- Piping Tests
- Heat Exchangers
- Instrumentation Identification
- Installation Test Piping Verification GMP-Checklist

Week 5 – Instrument Loops & Checksheets

- Process Control
- P&ID Instrument Identification
- Input Output (1/O) List
- Process Control Hardware Panels
- Loop Signal Verification
- Installation Test Instrument Verification
- Proportional-Integral-Derivative Controller (PID Controller)

Week 6 – URS & Functional Testing

- Protocol Content – Part-3 Operational/Functional Testing
- Component Level Impact Assessment – Part-2
- Operational Testing Primary Functions GMP Checksheet
- Testing Traceability Matrix for Equipment System Second Pass
- User Requirement Specifications (URS)

Week 7 – Assembling the Validation Protocol

- Protocol Content – Part - 4: General Attachments
- Protocol General Attachments
- General Contents of a Validation Master Plan

"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

- Protocol Deviation Procedure
- Change Control Procedure
- Protocol Testing Template
- Testing Traceability Matrix for Equipment System

Week 8 – Validation Protocol Final Review

- Conclude List of Installation Tests
- Conclude List of Functional Tests
- Final Protocol Template Review

Outcome:

On completion of the module you will be able to:

- Prepare and execute validation testing protocols
- Qualify equipment, instruments and piping systems, along with automated systems and building facilities.
- Have a clear understanding about what design specifications are required to generate testing scripts, and when and where they require generation and execution during the project lifecycle.

Format

Delivered online through our Learning Management System using content rich short videos, downloadable course materials, review tests, worked examples and discussion forums.

Duration:

Online (100 Hours over 8 Weeks)

Assessment:

- A written competency based assessment.
- A 20 minute oral interview with our Lecturers.

Certification

Upon successful completion of the written assessment and interview you will receive a Workers Skill Qualification (WSQ) certification awarded through the Singaporean Workforce Development Agency (WDA)

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