dpseducation

For the Pharma and Medical Device Industries

Fundamentals

of Pharmaceutical Manufacturing Technologies

Full Time | Part Time | Online

www.DPSeng.com.sg

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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 1000 people who have used our courses to transition into new jobs and build new careers.
- Enjoy the flexibility of our online course delivery to match your work-lifestyle balance, combined with our career coaching workshops to help you find a job in the biomedical sector.
- Benefit from our 80% success rate in finding a new job after successfully completing these courses.
- Get industry recognition and a valued professional qualification in Pharmaceutical and Medical Device Manufacturing.

Programme Overview

Who are these courses for?

The Fundamentals of Pharmaceutical Manufacturing Technologies is suitable for anyone with a manufacturing, science, engineering, quality or logistical background and who would like to advance their career in the pharmaceutical or medical device manufacturing industry with a valued professional qualification. This module is suitable for technical people across all levels of a manufacturing site.

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 your classmates and lecturers while you complete the course at your own pace.

- 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 learn how to manufacture safe and effective medicines and medical devices for the public within the Good Manufacturing Practices (GMP) regulatory framework. The learning is based at an introductory level for an operator and technician audience.

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 1: Fundamentals of Pharmaceutical Manufacturing Technologies

Goal:

This module will give you an introductory level understanding of the rules which govern manufacturing in a GMP regulated environment and the guidelines as to how these rules are applied for the manufacture of safe and effective medicines and medical devices for the public. It also teaches you how to apply risk management tools so as to make scientifically based cost effective decisions in the operation of a GMP regulated manufacturing facility

Core Content:

Week 1 – Manufacturing Safe Medicines

- Finished Medicinal Products
- Introduction to Quality Risk Management (QRM)
- Risk Management Tools - Fault Tree Analysis (FTA)
- Clinical Trials
- Focus on Patient Safety and Product Quality
- Process Validation

Week 2 – GMP's and Quality Management Systems

- ISPE Baseline Guide 5 - Commissioning & Qualification Practices
- Risk Management Tools - Cause and Effect Diagram
- ISO 9001:2008 'Quality Management Systems – Requirements'
- Good Engineering Practices (GEP)
- ASTM E 2500– 07 Standard Guide for Specification, Design, and Verification of Equipment

Week 3 – Good Automated Manufacturing Practices (GAMP)

- GAMP5 - Software Categories & Scalable Validation Deliverables
- GAMP5 - Operation Activities
- Risk Management Tools - Failure Mode, Effects (and Criticality) Analysis (FMEA / FMEAC)
- GAMP5 - Risk-Based Decision Making
- Product Quality and Current Good Manufacturing Practices (cGMP)

Week 4 – API Manufacturing Technologies

- Chemical Reactions
- Separation Technologies
- Batch Organic Chemical Synthesis
- Risk Management Tools - Preliminary Hazard Analysis (PHA)
- Multi-Stage Sequence API Synthesis
- Regulatory guidelines for synthetic API Manufacturing
- Relationship Between BPC and API

Week 5 – Biopharmaceutical Manufacturing Technologies

- Biopharmaceuticals Manufacturing, Upstream, Fermentation
- Cellular Protein Synthesis
- Risk Management Tools - Hazard Operability Analysis (HAZOP)
- Biopharmaceuticals Manufacturing - Downstream Processing – Column Chromatography
- Biopharmaceuticals Manufacturing: Special Considerations

Week 6 – Cleaning Validation

- Engineering Aspects of Cleaning, and Cleaning Equipment
- Chemistry Aspects of Cleaning
- Risk Management Tools - Event Tree Analysis (ETA)
- Cleaning Validation
- ISO-9001 'Continual Improvement' & ICH Q10 Pharmaceutical Quality System

Week 7 – Medical Devices and Sterile Manufacturing

- Tablet Manufacturing
- Vial Filling & Freeze Drying
- FDA Medical Device Rules
- Risk Management Tools - Hazard Analysis and Critical Control Points (HACCP)
- Medical Devices – EU Classification
- Aseptic & Sterile Manufacturing
- Medical Device Regulations and Guidelines

Week 8 – PQ OQ IQ

- PQ, OQ IQ
- Documenting the Quality Risk Management Process
- Product Realization & Pharmaceutical Development

"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

Workshops:

You will participate in a series of worked examples where you gain practical experience of how and where to apply a number of risk management techniques including.

- Fault Tree Analysis (FTA)
- Failure Mode Effect and Criticality Analysis (FMECA)
- Hazard Operability Analysis (HAZOP)
- Event Tree Analysis (ETA)

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 Workforce Skills Qualification (WSQ) certificate awarded by the Singaporean Workforce Development Agency (WDA)

Admission Criteria

This is a technical training programme for people coming from a technical, manufacturing, scientific or logistics background looking to work as operators and technicians in production, engineering and quality roles within the pharmaceutical, biopharmaceutical or medical device manufacturing sector.

Recognised prior learning (RPL) will be taken into account in assessing applicants for this programme.

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training@dpseng.com

(65) 6513 9500

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