dpseducation

For the Pharma and Medical Device Industries

Computer

Systems

Validation

Full Time | Part Time | Online

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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 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 4: Computer Systems Validation

Goal:

In this comprehensive course, you will learn how to manage all of the electronic data for computer system validation from across a manufacturing facility in line with the rules and guidelines for the specification, design and verification of computerised systems in a regulated environment.

Core Content:

Week 1 – Software Categories, Life Cycle Phases, and Operational Activities

- Drivers for GAMPS
- Life Cycle Phases of Computerized Systems
- Computerized Systems in Regulated GxP Environments
- GAMP 5 Software Categories
- Operational Activities
- Handover
- Product and Process Understanding
- End User Activities

Week 2 – Record Anatomy and Data Flow Analysis

- Electronic Record Content, Structure and Context, and Record Anatomy
- Records and Signatures required by 21 CFR Part 211
- PLC Controlled Packaging Equipment
- Supervisory Control and Data Acquisition (SCADA)
- Data Flow Analysis
- Example Records and Signatures Required by ICH Q7

Week 3 – Science Based Quality Risk Management, Validation Planning, and Categorization of Laboratory Computerized Systems

- Supplier Activities
- Validation Planning
- Science Based Quality Risk Management
- Risk Management Considerations Generic Hazards
- Requirements Traceability Matrix (RTM)
- Efficiency Improvements (Continuous Improvements)
- Categorization of Laboratory Computerized Systems

Week 4 – Specification and Verification, Scalable Validation Deliverables and Configuration Management

- Organizational Change
- Outsourced IS/IT Environment
- IT Compliance
- Development versus Implementation Life Cycle
- ASTM E 2500 – 07
- Testing Documentation Structure & Verification Terminology
- Scalable Validation Deliverables
- Patch and Update Management
- Operational Change and Configuration Management
- Repair Activity
- Periodic Review
- Backup and Restore

Week 5 – Identify Regulated Records and Signatures, and Impact Assessment of Electronic Records

- HPLC System
- Chromatography Data System (CDS)
- GxP Records and Signatures Required by 11 CFR Part 820
- Prerequisites for Good Electronic Records Management
- Laboratory Information Management System (LIMS)
- Identify Regulated Records and Signatures
- Electronic Production Records (EPR)
- Impact Assessment of Electronic Records
- Spreadsheets

Week 6 – Good Electronic Records Management Transactions, and Audit Trails

- Good Electronic Records Management Transactions
- Audit Trails
- AutoCAD Used For Managing Pack Drawings
- Building Management Systems (BMS)
- FDA Predicate Rule 21 CFR Part 211 – Subparts D and J
- FDA 21 CFR Part 11 – 'Electronic Records; Electronic Signatures' (ERES)

Week 7 – Electronic Data Archiving, Business Continuity Management, and System backup, Archival, and Disaster Recovery

- Electronic Data Archiving Part
- Typical Tasks Supporting Validation (B)
- Security Management

"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

- Business Continuity Management
- System Retirement Decommissioning and Disposal
- Copies of Records

Week 8 – Controls to Maintain Electronic Record Integrity, and Risk Controls for Electronic Signatures

- Complying with 21 CFR Part 11 ERES - Types of Controls Required
- Complying with 21 CFR Part 11 - Key Areas for Guidance
- Batch Record System
- Enterprise Resource Planning (ERP) Systems
- Controls to Maintain Electronic Record Integrity
- Risk Controls for Electronic Records
- Risk Controls for Electronic Signatures
- User ERES Responsibilities
- Supplier ERES Responsibilities

Outcome:

Upon completion of this module you will be able to:

- Understand the fundamentals of computer system hardware and software with respect to developing a system description and defining user requirement.
- Understand the principals and practices of computer system validation and demonstrate the ability to apply principles to various pharmaceutical computer system projects
- Have a comprehensive understanding of the regulatory requirements for computer system validation.

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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training@dpseng.com

(65) 6513 9500

www.dpseng.com.sg