GetReskilled

Planning a
Validation Strategy

Full Time | Part Time | Online

Contents

Welcome

Accelerate your career in the Pharmaceutical and Medical Device Manufacturing Industries, in the shortest time possible with our online delivered modules.

- Join the 3,150 people over the last 10 years who have used our courses to build their careers in these industries worldwide.
- Get an industry recognised qualification and confirm your knowledge to your employers.
- Delivered online worldwide on our learning management system with 24/7 access. No Travel Required. Easily juggle your work and home life.
- Ideal for people who want to make a career change into the Pharmaceutical or Medical Device Manufacturing Industries or those who are currently in this sector and want to upgrade their skills set.

Program Overview

Who is this module for?

Planning a Validation Strategy 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.

What can you expect?

- This module is delivered on our Learning Management System with a mixture of short (10 minute) content rich videos, downloadable notes, case studies, and worked examples allowing you to complete the course at your own pace. You will have access to our online learning environment where you can communicate with us, your classmates and lecturers with discussion boards.

- This module culminates in the completion of a full assignment which offers you the opportunity to solidify your knowledge and apply the content in a real world situation. In addition, you will also be requested to regularly post on our discussion board forum and invited to join our LinkedIn Groups of Alumni.

What will you learn?

You will learn the elements involved in planning a Validation Strategy from developing a Validation Master Plan (VMP) to preparing a process validation protocol for a validated process.

Who are the Lecturers?

All our lecturers continue to work with 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.

"I found the course was run very professionally, The course notes and videos supplied were excellent, the notes tied in very efficiently and accurately with the videos. Dr Joe Brady's presentation on the videos and his expertise and help at the webinars was outstanding. I found it very easy to continue studying even though I found employment 2 months into the course."

Denis Hegarty

"This course is excellent. It is very well delivered through weekly lectures and webinar tutorials which entail self-assessments at the end of each week and gave me invaluable experience required to advance in this new sector."

Louise Dineen

Program Content

Course Overview:

Learn about what's new in Quality and in Validation, developing a Validation Master Plan (VMP) for a typical product lifecycle, generating the Process Validation Protocol and executing the Process Validation Study and preparing the summary Validation Report for a regulatory audit.

Why Take this Course:

- Understand the current regulatory guidance with respect to Validation
- Develop a Validation Strategy for the entire lifecycle of a product
- Identify the Critical Process Parameters (CPP's) and Critical Quality Attributes (CQA's)
- Prepare the Process Validation protocol
- Prepare for the final Validation Report for a regulatory audit

Core Content:

Week 1 — What's new in Validation and in Quality

- What's new in Quality and in Validation
- International Conference on Harmonization (ICH) Overview
- ICH Q8, Q9, Q10 & Q11
- Regulatory & Industry Reaction to ICH Guidelines

Week 2 – ISPE Guidance Documents and ASTM E2500

- ASTM E 2500-07 "Standard Guide for Specification, Design, and Verification of Equipment"
- ISPE Baseline Guide 5 "Commissioning & Qualification" (2001)
- ISPE Good Practice Guide "Applied Risk Management for Commissioning & Qualification" (2011)
- ISPE Guide "Science Risk Based Approach for the Delivery of Systems & Equipment" (2011)

Week 3 – Preparing for Process Validation

- FDA Guidance for Process Validation (2011)

Week 4 – The Quality Plan, Change Control and the Validation Master Plan (VMP)

- The Concept of Quality
- Evolution of Regulations in the EU & US
- Quality Management Systems
- The Quality Manual
- Validation Master Plan
- Supplier & Vendor Qualification

Week 5 – Process Validation

- Process Validation – Critical Quality Attributes (CQA's)
- Process Validation – Critical Process Parameters (CPP's)
- Process Validation Protocol
- Executing the Process Validation Study

Week 6 – The Process Validation Report

- Process Validation Report
- Preparing for the Regulatory Audit
- Periodic Review & Continuous Validation

Week 7 – Cleaning Validation

- Cleaning Validation Strategy
- Cleaning Validation Report

Week 8 – Health & Safety at the Operator/Product Interface

- The Operator/Product Interface
- Health & Safety Regulations

Complete the Following Activities & Workshops:

Engage in a series of activities and produce a number of deliverables during the course including:

- Risk management during validation planning
- Auditing suppliers and vendors and their quality plans and documentation
- Preparing the product validation strategy and plan
- Preparing the summary validation report

Delivered Online – No Travel Required

All modules are delivered online on a Learning Management System with 24/7 access using a mixture of short videos with downloadable notes, Q&A activities, worked examples, and online discussion boards.

6-Weeks to Complete (Full Time)

Complete this module with 4-weeks study and an extra 2- weeks to complete the end of module assignment.

10-Weeks to Complete (Part Time)

Complete this module with 8-weeks study and an extra 2- weeks to complete the end of module assignment.

"I would rate the course 10 out 10 and would highly recommend to others, the tutor managed to get excellent group interaction right from the beginning, very interesting, informative and very well presented. Relevant totally to my needs and expectations. The most practical course I have ever attended"

Andy Wnuk, MSc Eng

"I found this course very beneficial and I am delighted that, even at early stages in the course, it has already provided me with the opportunity to secure a position within the pharmaceutical industry."

David O'Shea

15 Hours per Week (Part-Time)

You will need to study around 15-hours per week depending on your prior experience and familiarity with the materials with an additional 30 hours to complete the end of module assignment.

Easily Juggle Your Work and Home Life

Taking these courses online makes juggling your work and home life so much easier than a classroom delivered course. No long commutes, traffic jams or crowded trains to deal with on the way to class.

Extreme Flexibility on the Schedule

We offer extreme flexibility on the delivery of our courses and can easily accommodate breaks in your schedule.

92% Course Completion Rate

We are serious about helping you finish this program so your course administrator will personally check your progress every week and follow up by email or even a phone call to keep you on schedule.

Complete an End of Module Assignment

Based on a case study, generate a protocol for a validated process

Certification

You will receive an end of course certificate from GetReskilled which along with others modules can build into an academic accreditation from the Dublin Institute of Technology (Ireland) subject to the following criteria:

- Passing a written or oral Exam on the materials
- The submission of all assessments and the end of module assignment

Admission Criteria

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

Recognized Prior Learning (RPL) will be taken into account in assessing applicants for this programme.

Available Worldwide

Available worldwide and in certain US States. Contact us for details.

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