



**GetReskilled**

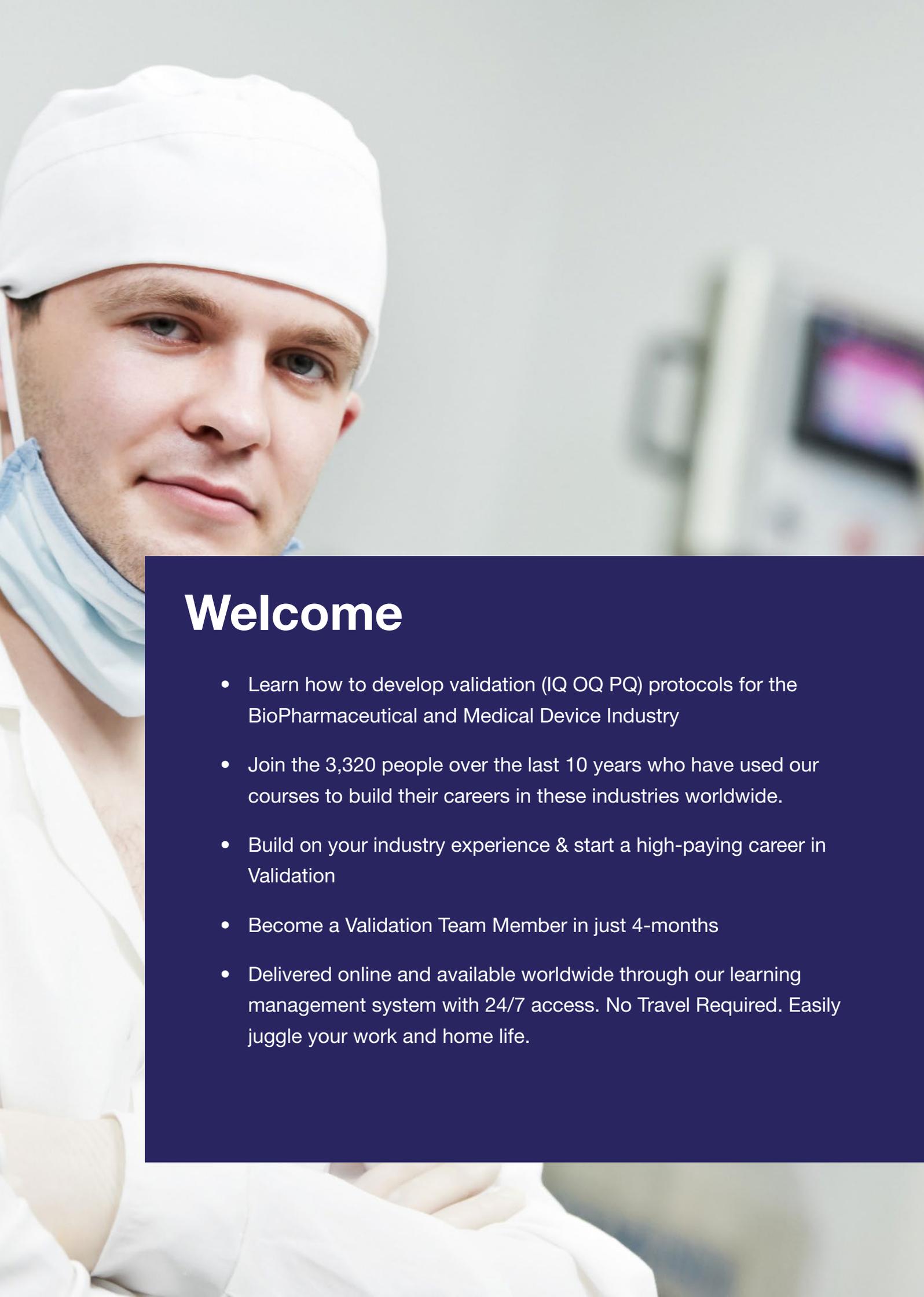
# **Commissioning & Qualification (IQ OQ PQ) of Equipment and Systems**

**Full Time | Part Time | Online**



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# Welcome

- Learn how to develop validation (IQ OQ PQ) protocols for the BioPharmaceutical and Medical Device Industry
- Join the 3,320 people over the last 10 years who have used our courses to build their careers in these industries worldwide.
- Build on your industry experience & start a high-paying career in Validation
- Become a Validation Team Member in just 4-months
- Delivered online and available worldwide through our learning management system with 24/7 access. No Travel Required. Easily juggle your work and home life.

# Program Overview

## Who is this module for?

Commissioning & Qualification (IQ OQ PQ) of Equipment and Systems is suitable for anyone with work experience in the BioPharma/MedTech manufacturing industry OR or with quality, maintenance, engineering, science or manufacturing experience in one of the following:

- Oil and Gas
- Semiconductor
- Contract Engineering Consultancies
- Food Manufacturing
- Mechanical or Electrical Construction
- Plastics Manufacturing
- Service Industries to the Above

And who wants to move into Validation and work as a Validation Team Member.

## 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 and your classmates on discussion boards.

## By the end of this program, you will be able to:

- Develop your own 100-page Validation Protocol to commission and qualify a clean-in-place system to ensure that it meets regulatory requirements.
- Learn how to read the engineering documentation used to develop Validation protocols including P&ID's, piping isometrics and electrical loop drawings.
- Qualify equipment, instruments and piping systems, along with automation controls and building facilities.
- You will have a working knowledge of the everyday activities of a Validation Team Member, allowing you to take the first steps in your high-paying Validation career.



*"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

# Lecturer

## **Dr. Joe Brady**

**Lecturer, Dublin Institute of Technology**

Dr. Joe Brady is full-time practicing Validation Lead and an assistant lecturer with the Dublin Institute of Technology (DIT), in the School of Chemical and Pharmaceutical Sciences. Joe is a certified trainer, and highly experienced in competency based training. He designs and prepares educational modules and full academic programs including MSc, MEngSc, BSc and Certificate level, for a range of academic institutions.

He is also a supervisor for MSc/MEngSc and PhD theses. Joe has over seventeen years project experience in the pharmaceutical, biopharmaceutical and medical device industries in Ireland, Singapore, China, The Netherlands, France and the USA.

# Program Content

## Course Overview:

Learn how to develop test protocols for equipment in a GMP environment in this practical hands-on workshop driven course. Understand how to read the engineering documentation used to specify and design equipment or systems in a manufacturing facility and how to develop the test protocols (IQ OQ PQ) to ensure that it operates as intended and meets the regulatory requirements.

## Core Content:

### Week 1 — Industry Regulations and Guidelines

- Finished Medicinal Products
- Focus on Patient Safety and Product Quality
- ISO-9001 ‘Quality Management Systems — Requirements’
- Product Quality and cGMP Practices

### Week 2 – Process Validation & Documentation and Risk Management Tools

- Process Validation
- ASTM E2500 ‘Specification, Design & Verification of Manufacturing Systems’
- PQ, OQ and IQ (Performance Qualification, Operational Qualification, Installation Qualification)
- Cleaning Validation

### Week 3 – Key Manufacturing Technologies

- Batch Organic Chemical Synthesis
- User specification for a Reactor
- Biopharmaceutical Manufacturing
- Tablet Manufacturing
- Aseptic & Sterile Manufacturing

### Week 4 – Supporting Technologies and Cleanrooms

- Purified Water Generation, Storage & Distribution
- Clean Steam
- Water for Injection, Storage and Distribution
- Engineering Aspects of Cleaning
- Chemistry Aspects of Cleaning
- Steam Sterilization
- HVAC for Non-Sterile Manufacturing
- Cleanroom Layout



*"I would rate the course 10 out of 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**

## **Week 5 – Assignment Part 1 focused on GMP Manufacturing from content in Week's 1-4**

- 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 6 – 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 7 – 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 8 – 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 Walkdown
- Installation Test and Equipment Verification
- Pumps



*"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**

## **Week 9 – 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 10 – Instrument Loops & Checksheets**

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

## **Week 11 – 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 12 – Assembling the Validation Protocol**

- Protocol Content – Part – 4: General Attachments
- Protocol General Attachments
- General Contents of a Validation Master Plan
- Protocol Deviation Procedure
- Change Control Procedure
- Protocol Testing Template
- Testing Traceability Matrix for Equipment System

## **Week 13 – Validation Protocol Final Review**

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

## **Weeks 14 -15 – Complete an End of Module Assignment**

- Write an IQ OQ PQ protocol for a Clean-in-Place system.

## **Complete the Following Activities & Workshops:**

You will become familiar with a range of documents commonly used in projects including piping and instrumentation diagrams (P&ID), equipment specifications, instrument specifications, line lists, piping isometrics, 3D layouts, electrical and hardware control – panel diagrams, and wiring and loop diagrams. These design documents are used to generate IQ OQ PQ commissioning and qualification protocols.

You will also become familiar with:

- User Requirement Specifications (URS)
- cGMP impact-assessments
- cGMP design reviews
- Design Qualification (DQ) reports
- Specification and testing traceability matrices
- Typical testing IQ OQ PQ protocol templates

## **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).

## **15 Weeks to Complete (Part-Time)**

Complete this module with 13 weeks of study and an extra 2 weeks to complete the end of module assignment.

## **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.



## Flexibility on the Schedule

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

## 91% 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

Write a 100+ page IQ OQ PQ protocol for a Clean-in-Place system.

## Certification

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

- 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 or scientific background looking to work in production, engineering and quality roles within the pharmaceutical, biopharmaceutical or medical device manufacturing sector.

- Strong Documentation Bias – as you will be managing and documenting the entire validation process
- Enthusiasm for working in a Team – validation of equipment systems is a team activity and you will need good verbal and listening skills to share information amongst the team members
- Good Computer Skills – there is a lot of documentation processed via computer systems.
- Structured approach to working – your work will impact others in the overall Validation team as there will be many documents that require sharing and signing with multiple team members

## Available Worldwide

Available worldwide. Contact us for details.



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