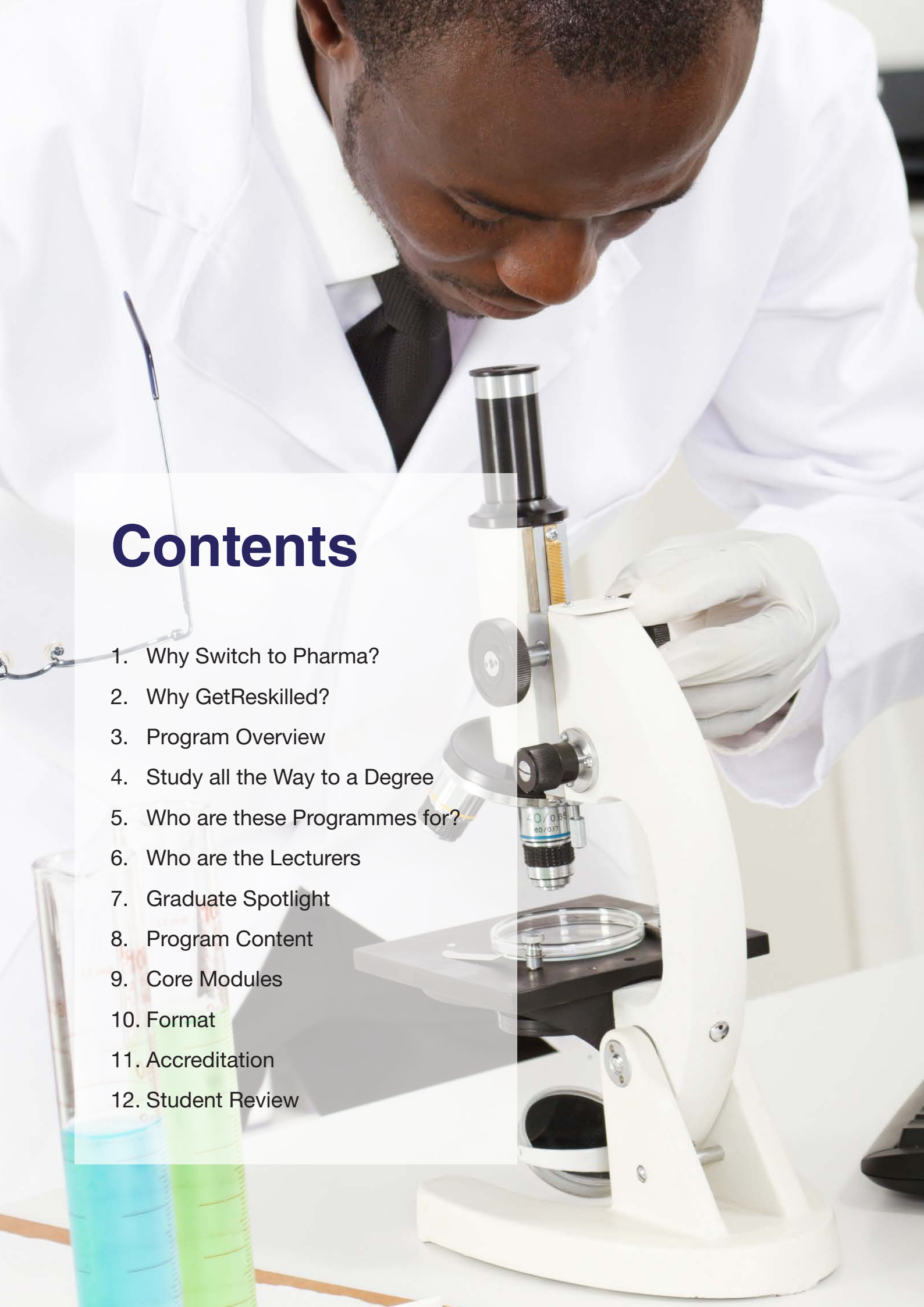
GetReskilled

CPD certificate

in eBioPharma Validation (DT 7202)

Full Time | Part Time | Online



Contents

Make a career change into the Pharmaceutical and Medical Device manufacturing industries in the shortest time possible with this blended online programme.

Why Switch to Pharma?

- Pharma manufacturing jobs are stable, safe and secure.
- The industry supplies well paying jobs with wages running 30% above average.
- It doesn't suffer from cyclical ups and downs and has performed well throughout many dips in other sectors.
- The industry has demonstrated consistent year on year growth, and with an ever expanding ageing population worldwide, it will continue to have excellent prospects for growth for many years to come.
- It offers rich opportunities for career growth with a variety of new and exciting career paths opening up.

Why GetReskilled?

We have retrained over 3,200 experienced workers in the last 7 years into new jobs and careers. These people have come from technical, quality and manufacturing backgrounds in other industries and sectors.

81% of our 2016 graduates found a new job in 6 months, with over 40% of them securing a new position even before they completed our programme.

Our newly qualified students are working for over 50 companies including Pfizer, Eli Lilly, MSD, and Abbott. To help our current students and new graduates, GetReskilled has a highly comprehensive job hunting resource centre and operates the largest Pharmaceutical Jobs Board, which is updated every two weeks and is FREE to use.

GetReskilled courses have been heavily over-subscribed for the last 6 years. We are delighted that 97% of students say that they would recommend this programme to a friend.

Our 2017 student survey identified that 95% agree that GetReskilled programmes are beneficial and that they can apply their learning to the skills they need in their jobs.

Program Overview

The Certificate in e-BioPharma Validation is a 12 month, part-time, online programme. You will develop the skills and knowledge necessary to validate equipment systems for the manufacture of safe medicines in an FDA regulated environment.

This course covers the modern BioPharmaceutical science and engineering concepts along with the equipment, processes, facilities and systems which you need to validate the equipment. It also discusses the processes used to manufacture these products in line with the various worldwide regulations and current Good Manufacturing Practices (cGMP) guidelines.

This will prepare you with the necessary skills and knowledge to take up Validation Professional roles in the biopharmaceutical manufacturing industry.

The Dublin Institute of Technology, Ireland academically accredits this programme. This certification along with the portfolio building assignments that you'll complete during the programme will confirm your capabilities to validate equipment systems for the manufacture safe medicines, to potential employers.

This course is delivered online so you can complete it from the comfort of your own home, at your own pace, and get the qualification you need to get a start a new career in this sector.

The programme is designed so that end of module assignments can be compiled into a portfolio for students to take to job interviews, as proof of their understanding of validating equipment systems.

In addition to the technical materials covered on this course, you'll also gain many transferable skills including working on your own initiative, report writing, communication skills and IT skills.

“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

Career Coaching Included

The programme includes a concurrent 25-week Advanced Job Hunting Skills course. Our HR specialists will guide you along the complex path of getting a job in this hi-tech, highly regulated manufacturing sector. Over the 25 weeks, you will complete a minimum of 100 job applications.

82% of our trainees agree that GetReskilled's career coaching support significantly benefitted them. Most importantly, 80% of our trainees secure new employment within 6 months - 40% actually secure employment before they even graduate.

Study all the Way to a Degree

This e-BioPharma Validation qualification accounts for the first 50% of a BSc degree in the Manufacture of Medicinal Products (DT-291). Once you've completed this programme, you might choose to apply to study our eManufacturing modules, which make up the final 50%.

We deliver these courses online so you do not have to travel for a class or be available at a fixed time to study. It can be fitted into your current time commitments and lets you study where and when it works best for you.

Who are these courses for?

This course is perfect for anyone who would like to pursue a career in the pharmaceutical or medical device manufacturing industry, who has experience in any of the following backgrounds:

- Manufacturing
- Science/Laboratory
- Food Processing
- Quality Engineering
- Quality Assurance
- Process Engineering
- Production Engineering
- Chemical Engineering
- Project Engineering
- Maintenance Technology
- HVAC/Cleanroom
- Project Management
- Automation/Instrumentation
- Design Engineering
- Construction
- Logistics/IT

Graduate Spotlight

Student: Regina McNamara

"I would absolutely recommend this course for anyone that wants to get a job in the Pharmaceutical and Med Device industry and is interested in building a successful career in this area. The companies I applied for were impressed. It demonstrates that I am a self starter and wished to improve my chances of getting a promotion in the future. I am currently working in Boston Scientific."

“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

Code	Title
VOMP3001	Fundamentals of Pharmaceutical Manufacturing Technologies
VOMP3002	Commissioning & Qualification of Equipment Systems
VOMP 3018* VOMP3019*	Practical BioPharmaceutical Processing / Aspects of Regulatory Science in Pharmaceutical Manufacturing
VOMP3006	Pharmaceutical Facility Design
VOMP3008	Planning a Validation Strategy
VOMP3011	From URS to PQ – A Practical Validation Strategy

VOMP 3001 Fundamentals of Pharmaceutical Manufacturing Technologies:

This module will give you a broad understanding of pharmaceutical manufacturing technologies, the rules that govern manufacturing and the guidelines on how these rules are applied along with the risk management tools to be used when making decisions that could impact the safety of the medicines being manufactured.

- Manufacturing Safe Medicines
- GMP's and Quality Management Systems
- Good Automated Manufacturing Practices (GAMP)
- API Manufacturing Technologies
- Biopharmaceutical Manufacturing Technologies
- Cleaning Validation
- Medical Devices and Sterile Manufacturing
- PQ OQ IQ

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading

VOMP 3002 Commissioning & Qualification of Equipment Systems:

This module explains the engineering documentation used to specify and design equipment or systems in a manufacturing facility – and how to develop the test protocols (IQ, OQ) to ensure that it operates as intended and meets the regulatory requirements.

- Interpreting P&ID's
- System Impact Assessment & Traceability Matrix
- Installation Tests & Equipment Verification

- Piping Isometrics & Checksheets
- Instrument Loops & Checksheets
- URS & Functional Testing
- Assembling the Validation Protocol
- Validation Protocol Final Review

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

Choose one of the following two modules:

VOMP 3018 Practical Pharmaceutical Bioprocessing*

For bulk-chemical and protein therapeutic drugs, the aim of the module is to describe the processing of (1) active pharmaceutical ingredient bulk formulations, (2) drug product finished formulations, (3) container enclosure systems and combination products, and (4) packaging and labeling considerations.

Note:
This bioprocessing pilot plant practical module is made up of two 1-day practicals which will provide you with the hands-on knowledge and skills associated with operations in a typical modern biopharmaceutical processing facility. We will release preparatory materials before the lab for you to study, review and print out.

Week 1 Release of the Materials ahead of attending Bioprocessing Pilot Plant Practical:
Week 2 to Week 8 – Reviewing of Materials and attending of practicals
Practical 1 - Facility Design Practical
Practical 2 - Contamination Practical
Practical 3 - Upstream Processing Practical
Practical 4 - Downstream Processing Practical

Following attendance at the 2 Day Practical in NIBRT you will be given a graded assignment to complete at home and submit for grading".

or

VOMP 3019 Aspects of Regulatory Science in Pharmaceutical Manufacturing*

This module will explore the emerging regulations and guidelines for manufacturing in an FDA regulated environment through the lens of newly emerging tools to manage product risk, so as to develop an understanding of the role played by OPEX and how leading Quality Metrics can be used in a predictive and proactive manner to enhance the quality and performance of the product over the manufacturing phase of the lifecycle.

- Emerging Regulations in Regulatory Science
- The Product Life Cycle
- Quality Risk Management Tools
- Risk Communication / Mitigation / Management
- Heuristics
- OPEX Tools and Implementation
- Lagging Quality Metrics
- Leading Quality Metrics

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

* Elective Module - You will only need to complete one of the two.

VOMP 3006 Pharmaceutical Facility Design

In this module you will receive a strong grounding in the modern pharmaceutical science and engineering concepts of the environmental controls (air) and clean utility systems design that underpin an aseptic manufacturing facility and the quality systems used in this highly regulated environment to ensure the manufacture of safe and effective medicines for the public.

- Controlling Air Quality and Clean Utilities Manufacturing Logistics Calculations
- Purified Water Generation and Distribution
- Clean Steam and Sterilization
- Controlling Material and Personnel flows
- Aseptic Processing and Vial Filling
- Controlling Cleanrooms and Automation
- Quality Systems for Cleanrooms
- Construction Lifecycle for New and Modified Facilities

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3008 Planning a Validation Strategy

This module will give you a broad understanding of how to develop a Validation Master Plan (VMP) for a typical product lifecycle and to prepare the Process Validation Protocol for presentation during a regulatory audit.

- What's new in Validation and in Quality
- ISPE Guidance Documents and ASTM E2500
- Preparing for Process Validation
- The Quality Plan, Change Control and the Validation Master Plan (VMP)
- Process Validation
- The Process Validation Report
- Cleaning Validation
- Health & Safety at the Operator/Product Interface

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3011 From URS to PQ – a Validation Project

This is a workshop-driven module where you will develop a P&ID and then back-engineer it into a URS (User Requirement Specification) which will be used to identify the key process measurements that will form the basis of the Performance Qualification (PQ) test script.

Supplementary Content: Generation of Piping and Instrumentation Diagrams, URS for Hot Detergent and Hot PUW Generation and Distribution Skid System, Equipment List, Instrument List (Incl. both an Attachment and Video Link), Inline Components List (Incl. both an Attachment and Video Link), Piping Line List (Incl. both an Attachment and Video Link), P&ID Instrument Identification (Incl. Video Link Only)

- P&IDs
- URS Matrix
- Workshop
- Workshop
- Workshop
- Workshop
- PQ Template
- PQ Template

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading

"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

Admission Criteria:

This is a technical training programme for people coming from a manufacturing, science, engineering, quality or logistical background looking to work 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.

Format:

Our online modules are delivered on our Learning Management System, allowing you to complete the course at your own pace. They contain a mixture of short (10 minute) content rich videos, downloadable notes, case studies, worked examples and interactive Q&A webinars.

Duration:

The programme will take approximately 12 months, dependent on class schedule

Acreditation

The completion of all six modules will lead to an academically accredited CPD certificate in eBioPharma Validation (DT7202) awarded by the Dublin Institute of Technology. This forms 50% of a Baccalaureate Degree (DT291) in the Manufacture of Medicinal Products.

Student Review

Student: Mehmet Hascan

"Having faced a career change in the middle of an economic downturn, I lost some of myself confidence and needed a major boost. The area of Biopharmaceutical operations and validation was of interest to me as it does play an important role in the pharmaceutical industry at present.. The administration staff and lecturers at Getreskilled/DIT are first class and the course material was delivered in an engaging, interesting and supportive way. I have now been working at Johnson and Johnson Vision Care as Validation Engineer in Limerick and I look forward to putting what I have learned into practice."

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