Bachelor’s Degree in Manufacture of Medicinal Products (DT291)

Full Time | Part Time | Online

www.getreskilled.com
Contents

1. Welcome
2. Program Overview
3. Program Content
4. Core Modules
5. Optional Modules
6. Format
7. Accreditation
Welcome

Make a career change into the Pharmaceutical and Medical Device manufacturing industries, in the shortest time possible with this blended online bachelor’s degree.

• Join the 2,600 people over the last 10 years who have used our courses to build a new career in these industries worldwide.

• Enjoy the extreme flexibility of our online course delivery to match your work-lifestyle balance, the worldwide recognition of our bachelor’s degree program and our career coaching workshops to help you find a job in this industry.

• Over 60% of our learners secure a new job even before they complete the program.

• Meet and exceed your career goals through an industry recognised and valued professional qualification in Pharmaceutical and Medical Device Manufacturing.
Program Overview

Who are these courses for?

GetReskilled’s blended online bachelor’s degree (DT291) is suitable for anyone with a manufacturing, science, engineering, quality or logistical background and who would like to pursue a career in the pharmaceutical or medical device manufacturing industry. This course is suitable for professionals of all levels and disciplines and will prepare you for a specialist role within the Life Science Sector.

What can you expect?

- A mixture of online delivered modules and face to face delivered laboratories.
- Our online courses are 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.
- The laboratories are delivered face to face at the Dublin Institute of Technology (Ireland). Flights are included in the course fees for overseas students.
- Each 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 about the fundamental science which underpins technical roles across Production, Engineering and Quality in a manufacturing organization and the Quality Culture required to make safe and effective medicines and medical devices for the public at an affordable cost and without requiring excessive regulatory oversight.

Who are the Lecturers?

All our lecturers continue to work within 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, May 2012
“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, Civil Engineer, August 2012
Program Content

The completion of the following 12 modules will lead to a Bachelor's Degree.

Complete the Following 12 Modules

**VOMP 3001 Fundamentals of Pharmaceutical Manufacturing Technologies**
This module will give you a broad understanding of Pharmaceutical Manufacturing Technologies, the rules which govern manufacturing and the guidelines on how these rules are applied.

**VOMP 3002 Commissioning & Qualification of Equipment and Systems**
This is a practical hands-on workshop driven course whose aim is to explain the engineering documentation used to specify and design equipment or systems in a manufacturing facility.

**VOMP 3003 Chemistry for API's**
The aim of this module is to provide a foundation in the general chemistry necessary to appreciate the fundamental concepts involved in the chemistry of API required for the manufacture of medicinal products.

**VOMP 3004 Mathematics & Statistics for Medicinal Products**
This module covers the fundamentals of mathematics and statistics required for method validation. The aim of this module is to provide students with a basis in the fundamentals of mathematics and statistics as applied to method validation.

**VOMP 3006 Pharmaceutical Facility Design**
In this module you will cover the principles of pharmaceutical facility design with a focus on clean air and water systems from its scoping, design, construction and commissioning and with a view to validating that technology in line with the various worldwide regulatory cGMPs (current good manufacturing practice guidelines).

**VOMP 3008 Planning a Validation Strategy**
The aim of this module is to teach students how to ensure all user requirements are tested and verified from the beginning and end of a typical project lifecycle, where in the project lifecycle that various testing should occur, and how to make systems functionally and regulatory fit for handover to operations and maintenance.
**VOMP 3009 Physical Chemistry for Industrial Process**

This module will provide students with the fundamentals of physical chemistry and enable them to apply them to industrial processing. The material covered will allow students to understand the principles of the topics covered and appreciate the application of these fundamentals to practical problems. In addition the student is introduced to the safety regulations applicable to the workplace and in particular to anywhere where chemicals are used.

**VOMP 3010 Process Development & Technology Transfer**

The aim of this module is to give students a broad understanding of clinical, regulatory, and statistical processes involved in the development of new pharmaceutical product applications for drugs, biologicals and medical devices. A further aim is to give students an overview of how to transfer the new drug, biological or device technologies to new and existing facilities.

**VOMP 3011 From URS to PQ - a Practical Validation Project**

The aim of this module is to teach students how to ensure all user requirements are tested and verified from the beginning and end of a typical project lifecycle. To teach students where in the project lifecycle that various testing should occur with a view to optimizing resources and minimizing reworks and repeat testing. Teach students how to make systems functionally and regulatory fit for handover to operations and maintenance.

**VOMP 3013 Design & Operation of Clean Rooms**

This module covers the fundamentals of Heating, Ventilation, and Air Conditioning (HVAC) design and how to determine the acceptance criteria for quality of the environment and the frequency of monitoring to minimize the risk of contamination in controlled environments.

**VOMP 3015 Pharmaceutical Manufacturing Unit Operations**

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.

**VOMP 3018 Practical BioPharmaceutical Processing**

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.
“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 Wnuck, MSc Engineer
“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, March 2012
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 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.

The laboratories are delivered face to face at the Dublin Institute of Technology (Ireland). Flights are included in the course fees for overseas students.

Duration:
Each module require approx.100 Hours of study and self-directed learning over 10-Weeks.

Accreditation
The completion of the twelve modules will lead to a Bachelor's Degree in Bachelor of Science BSc(Ord) Manufacture of Medicinal Products (DT291) awarded by the Dublin Institute of Technology (Ireland) subject to the submission of all assessments and end of module assignments.