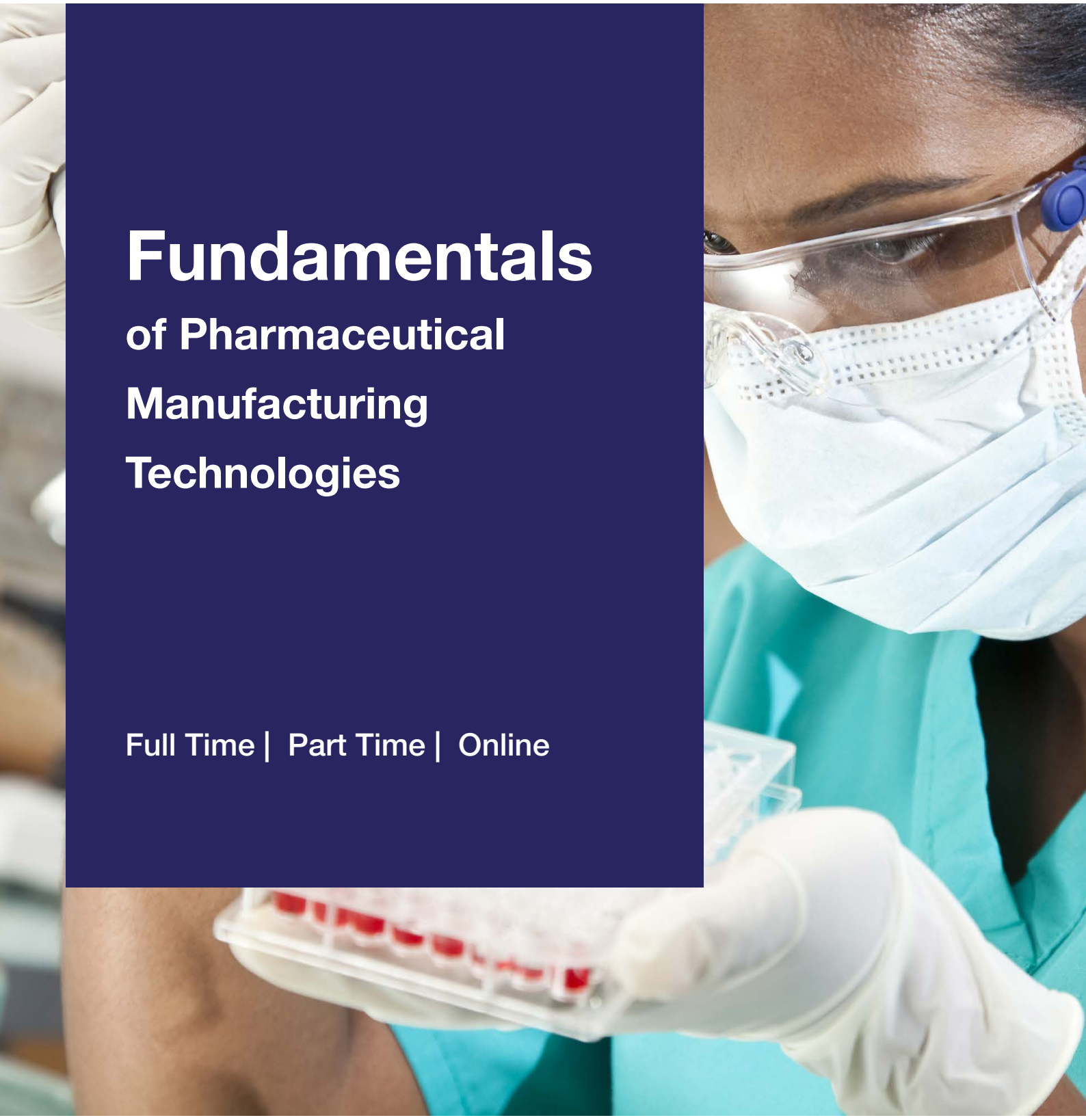
GetReskilled

Fundamentals

of Pharmaceutical Manufacturing Technologies

Full Time | Part Time | Online



www.getreskilled.com

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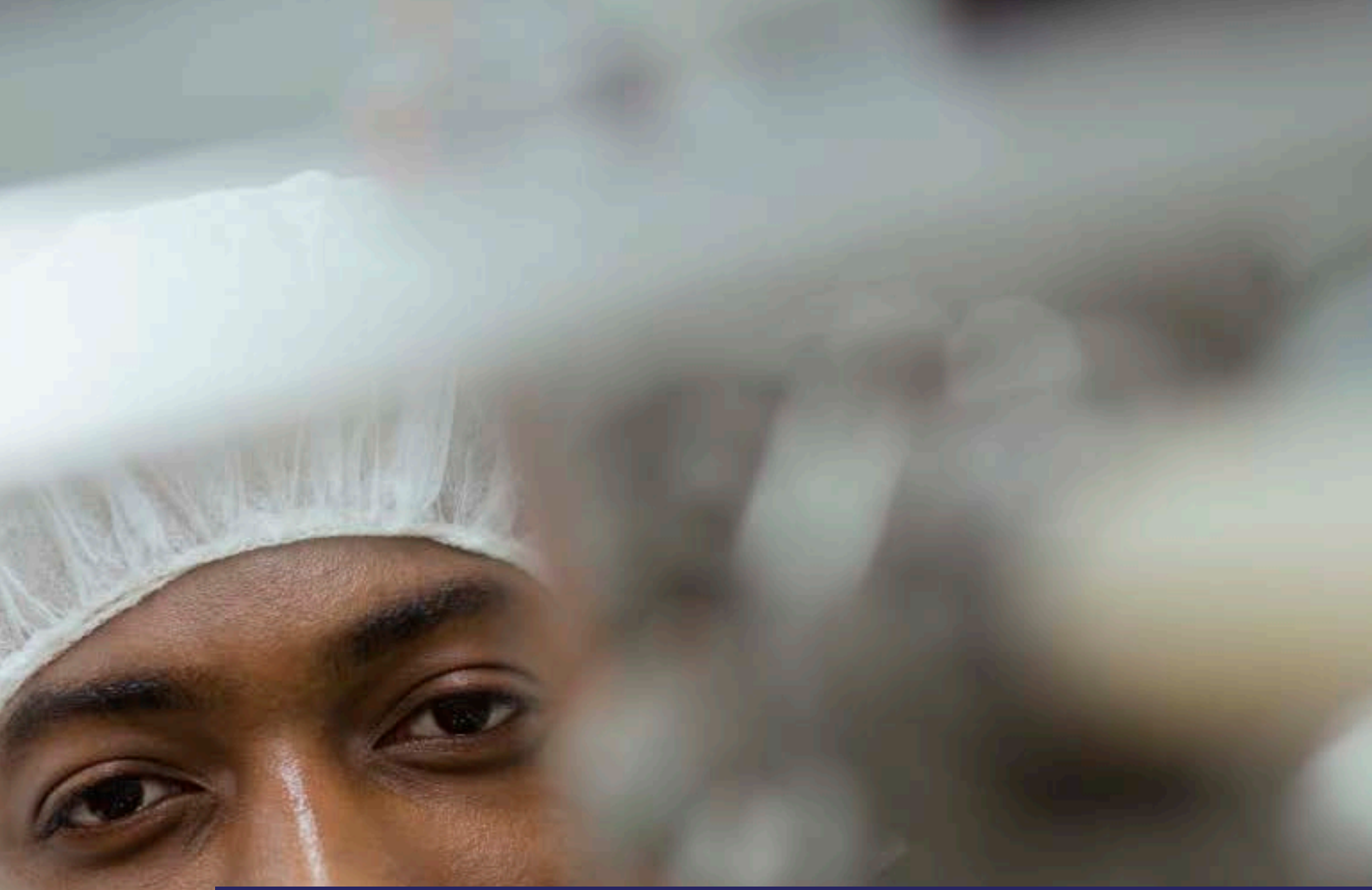


Welcome

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?

The Fundamentals of Pharmaceutical Manufacturing 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 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 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:

How do you make safe and effective medicines? What do NASA and the Pharmaceutical Industry have in common? Learn the answers and more in this module where you will get a broad understanding of Pharmaceutical Manufacturing Technologies, the rules that govern manufacturing and the guidelines on how these rules are applied. Also learn how to use Quality Risk Management tools to make decisions in a cGMP (current Good Manufacturing Practices) regulated environment, so as to meet the FDA requirements for manufacturing safe medicines and devices, at an affordable cost, for the public.

Why Take This Course:

- Learn how to apply the cGMP's (current Good Manufacturing Practices) to manufacture safe medicines and medical devices
- Use Quality Risk Management tools to make good decisions in real life manufacturing situations.
- Understand the manufacture technologies for active pharmaceutical ingredients (API), biopharmaceuticals, and medical devices

Core Content:

Week 1 – Manufacturing Safe Medicines

- Finished Medicinal Products
- Introduction to Quality Risk Management (QRM)
- Risk Management Tools - Fault Tree Analysis (FTA)
- Clinical Trials
- Focus on Patient Safety and Product Quality
- Process Validation

Week 2 – GMP's and Quality Management Systems

- ISPE Baseline Guide 5 - Commissioning & Qualification Practices
- Risk Management Tools - Cause and Effect Diagram
- ISO 9001:2008 'Quality Management Systems – Requirements'
- Good Engineering Practices (GEP)
- ASTM E 2500– 07 Standard Guide for Specification, Design, and Verification of Equipment

Week 3 – Good Automated Manufacturing Practices (GAMP)

- GAMP5 - Software Categories & Scalable Validation Deliverables
- GAMP5 - Operation Activities
- Risk Management Tools - Failure Mode, Effects (and Criticality) Analysis (FMEA / FMEAC)
- GAMP5 - Risk-Based Decision Making
- Product Quality and Current Good Manufacturing Practices (cGMP)

Week 4 – API Manufacturing Technologies

- Chemical Reactions
- Separation Technologies
- Batch Organic Chemical Synthesis
- Risk Management Tools - Preliminary Hazard Analysis (PHA)
- Multi-Stage Sequence API Synthesis
- Regulatory guidelines for synthetic API Manufacturing
- Relationship Between BPC and API

Week 5 – Biopharmaceutical Manufacturing Technologies

- Biopharmaceuticals Manufacturing, Upstream, Fermentation
- Cellular Protein Synthesis
- Risk Management Tools - Hazard Operability Analysis (HAZOP) –TC
- Biopharmaceuticals Manufacturing - Downstream Processing – Column Chromatography
- Biopharmaceuticals Manufacturing: Special Considerations

Week 6 – Cleaning Validation

- Engineering Aspects of Cleaning, and Cleaning Equipment
- Chemistry Aspects of Cleaning
- Risk Management Tools - Event Tree Analysis (ETA)
- Cleaning Validation
- ISO-9001 ‘Continual Improvement’ & ICH Q10 Pharmaceutical Quality System

Week 7 – Medical Devices and Sterile Manufacturing

- Tablet Manufacturing
- Vial Filling & Freeze Drying
- FDA Medical Device Rules
- Risk Management Tools - Hazard Analysis and Critical Control Points (HACCP)

"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

- Medical Devices – EU Classification
- Aseptic & Sterile Manufacturing
- Medical Device Regulations and Guidelines

Week 8 – PQ OQ IQ

- PQ, OQ IQ
- Documenting the Quality Risk Management Process
- Product Realization & Pharmaceutical Development

Complete the Following Activities & Workshops:

You will gain practical experience of how and where to apply a number of risk management techniques including.

- Fault Tree Analysis (FTA)
- Failure Mode Effect and Criticality Analysis (FMECA)
- Hazard Operability Analysis (HAZOP)
- Event Tree Analysis (ETA)

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.

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

Write a paper on “Why cGMP’s are required for the Manufacture of a Life Sciences Product”.

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

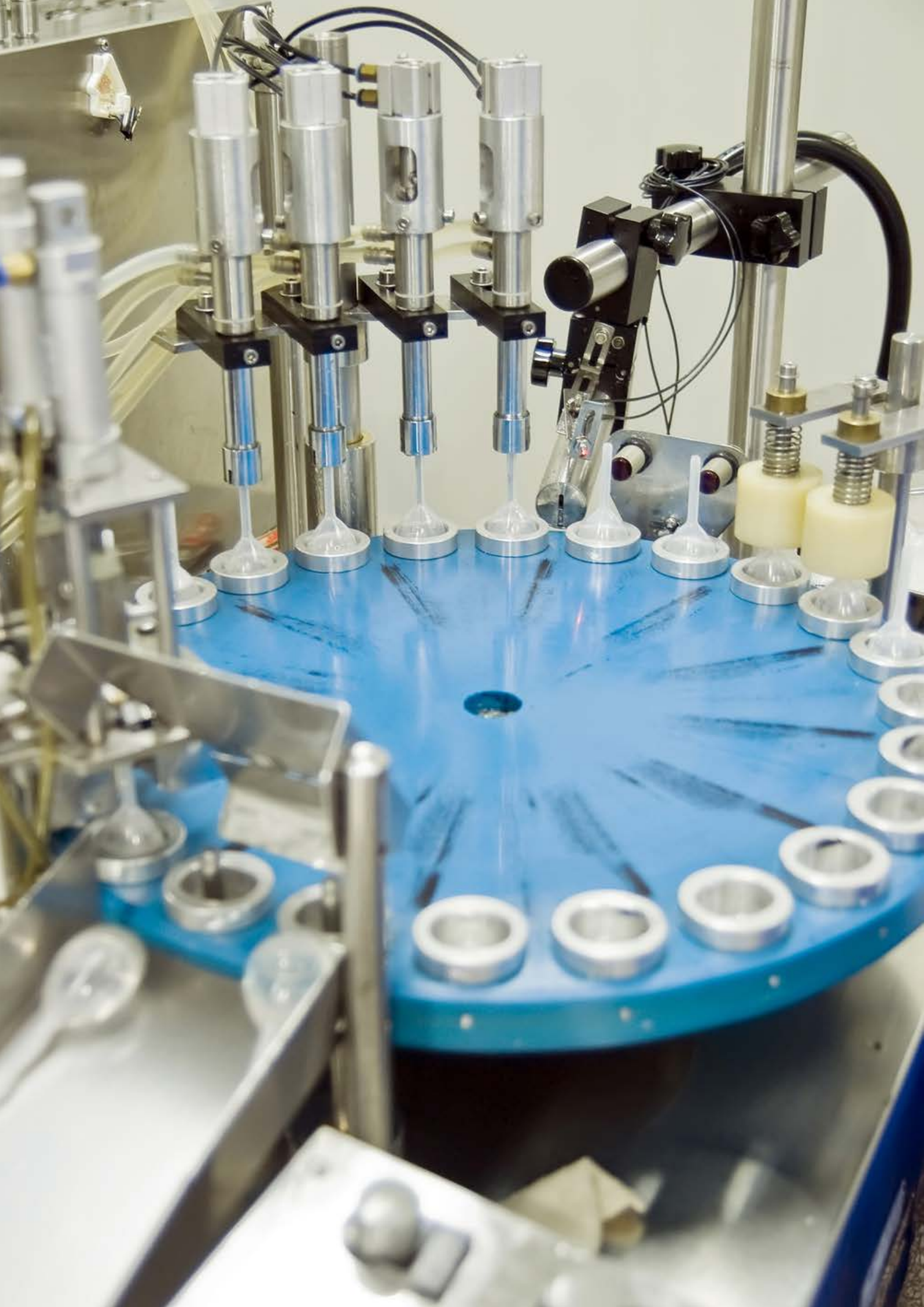
Admission Criteria

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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