



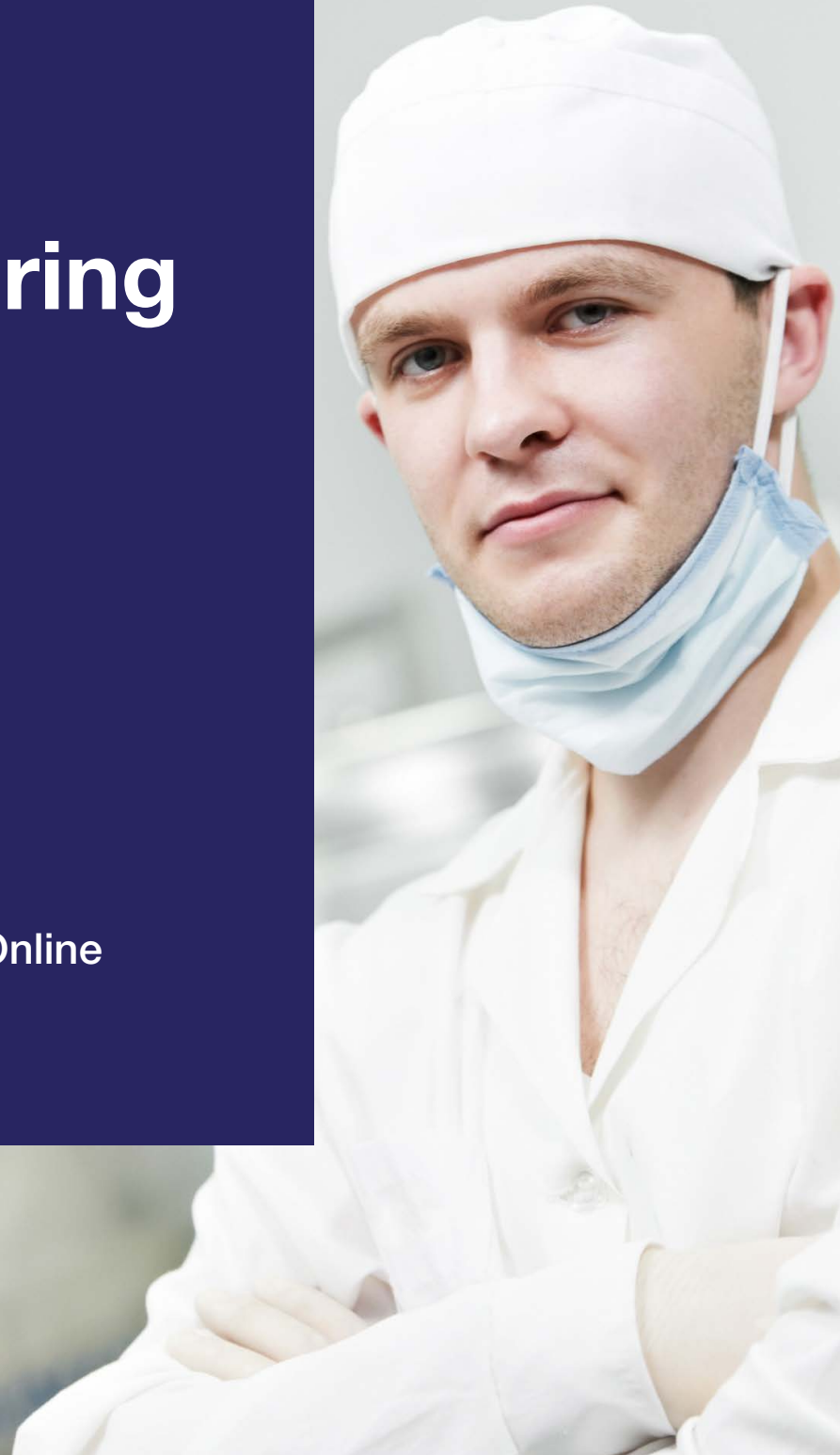
**GetReskilled**

# **Manufacturing**

## **Safe Medicines**

### **(Foundation)**

**Full Time | Part Time | Online**



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A person in a white lab coat is looking into a cleanroom. The cleanroom contains several rows of white cylindrical containers on a conveyor belt. The background is slightly blurred, showing more of the cleanroom environment.

# Welcome

Make a change into the Pharma industry with this short Foundation course to quickly find out if a career in Pharma is for you. Delivered online so as you can study at home and achieve a work/home life balance that's right for you.

- Join 1,300 people who have taken their first step into Pharma – and our alumni are now working with all of the top Pharma companies including Pfizer, Lonza, Amgen, GlaxoSmithKline, Abbott and Merck
- Get an industry recognised qualification to 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.
- If you are looking for a mid-career change then this is the course for you. The Pharmaceutical and Medical Device Manufacturing Industries are especially attractive now because of the huge skills shortage that exists.

# Program Overview

## Who is this module for?

Manufacturing Safe Medicines (Foundation) is suitable for anyone looking to decide if a mid-career change. It is an 10-week introductory course which will start you on your path, transitioning you into the pharmaceutical and medical device manufacturing industry.

## 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 through discussion boards.
- This module culminates in the completion of an 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?

This short Foundation course teaches you the building blocks for manufacturing safe medicines and medical devices. . Along with the technical course materials, there will be an online career coaching tutorial where our HR specialists will guide you through effectively presenting your CV and successfully navigating interviews when looking for jobs in the pharmaceutical and medical device manufacturing sector.

## 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

## Manufacturing Safe Medicines (Foundation)

### Course Overview:

This course will introduce you to the manufacturing of safe medicines and medical devices in a GMP (Good Manufacturing Practices) regulated environment. You will learn about the manufacturing technologies and the regulations which govern them as well as cGMP Enforcement (current Good Manufacturing Practices) - why it is so strict and so important.

### Why Take This Course:

- Learn about the Manufacturing technologies used to make medicines
- Understand the Regulations which govern manufacturing safe medicines and medical devices
- Understand and appreciate GMP Enforcement and Why it is so Strict and so Important
- Improve your Job readiness in:
  - **How to...** Write an Achievements Based CV
  - **How to...** Interview Effectively
  - **How to...** Research the Job Market
  - **How to...** Network Effectively

### Core Content:

**The course examines the 4 key areas of manufacturing safe medicines and medical devices.**

#### 1) Industry Regulations and Guidelines (2 Weeks)

- i) Finished Medicinal Products
- ii) Focus on Patient Safety and Product Quality
- iii) ISO- 9001 'Quality Manufacturing Systems - Requirements'
- iv) Product Quality and cGMP Practices
- v) Regulatory Guidelines for API Manufacturing
- vi) ICH Q10 Continual Improvements
- vii) Quality Systems Regulations - Manufacturing
- viii) FDA Medical Device Rules
- ix) Medical Device Regulations and Guidelines

## **2) Process Validation and Documentation (2 Weeks)**

- i) Process Validation
- ii) ASTM E2500 'Specification, Design & Verification of Manufacturing Systems'
- iii) PQ, OQ, and IQ
- iv) Cleaning Validation
- v) Introduction to Quality Risk Management
- vi) Fault Tree Analysis (FTA)
- vii) Failure Mode Effects Analysis (FMEA)
- viii) Documenting the Quality Risk Management Process

## **3) Key Manufacturing Technologies (2 Weeks)**

- i) Batch Organic Chemical Synthesis
- ii) Biopharmaceutical Manufacturing
- iii) Tablet Manufacturing
- iv) Aseptic & Sterile Manufacturing

## **4) Supporting Technologies (2 Weeks)**

- i) Purified Water Generation, Storage and Distribution
- ii) Clean Steam
- iii) Water for Injection, Storage and Distribution
- iv) Engineering Aspects of Cleaning
- v) Chemistry Aspects of Cleaning
- vi) Steam Sterilisation
- vii) HVAC for Non-Sterile Manufacturing
- viii) Cleanroom Layout
- ix) Area Classification Protection
- x) Cleanroom Gowning
- xi) Cleanroom Monitoring

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


You will gain practical experience through a series of activities during the course including:

- How and where to apply risk management techniques for making decisions
- Writing an Achievements Based CV
- Interviewing Effectively

## **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.





*“Along with the technical training in  
Pharmaceutical Manufacturing, the  
course providers also offers assistance  
with CV Preparation and Interview  
Technique specific to the Pharmaceutical  
Manufacturing Industry”*

**Mr. Lian Bee Kwang,  
Lonza Biologics**



## **10-Weeks to Complete**

Complete this module with 10-weeks of study and one additional 1- week to complete the end of module assignment.

## **Study 1-Hour per Day for 10-Weeks (Part-time)**

You will need to study between 7 to 10-hours per week depending on your prior experience and familiarity with the materials.

## **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.

## **90% Course Completion Rate**

We work with you to successfully complete this course 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**

Create a Portfolio of the knowledge you gain on the course which you can then bring to future interviews.

## **Certification**

This module is individually accredited by GetReSkilled 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 suitable for anyone looking to decide if a mid-career change into the pharmaceutical and medical device manufacturing industry is right for them. Recognised prior learning (RPL) will be taken into account in assessing applicants for this programme.



# GetReskilled

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