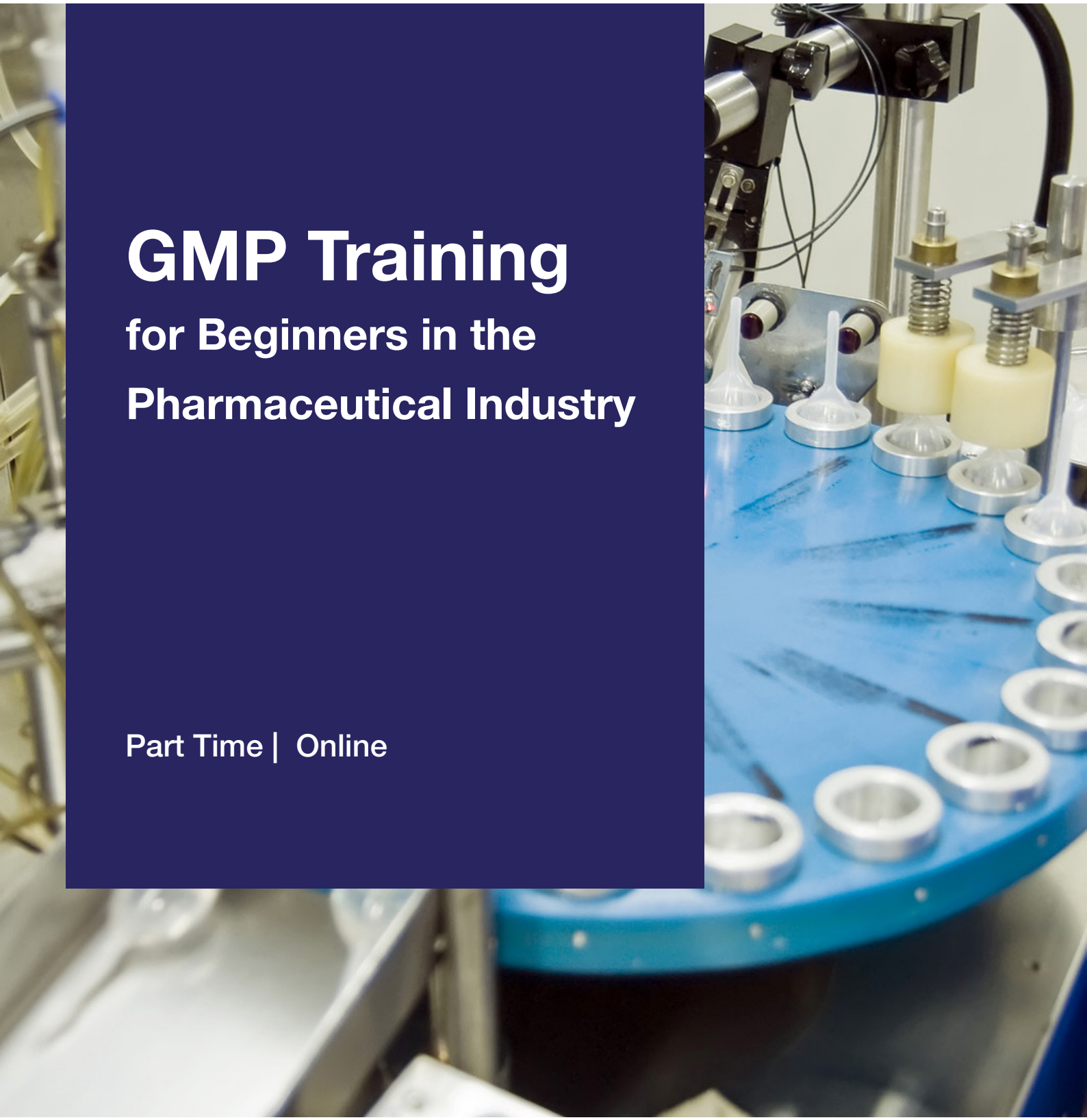
GetReskilled

GMP Training

for Beginners in the Pharmaceutical Industry

Part Time | Online



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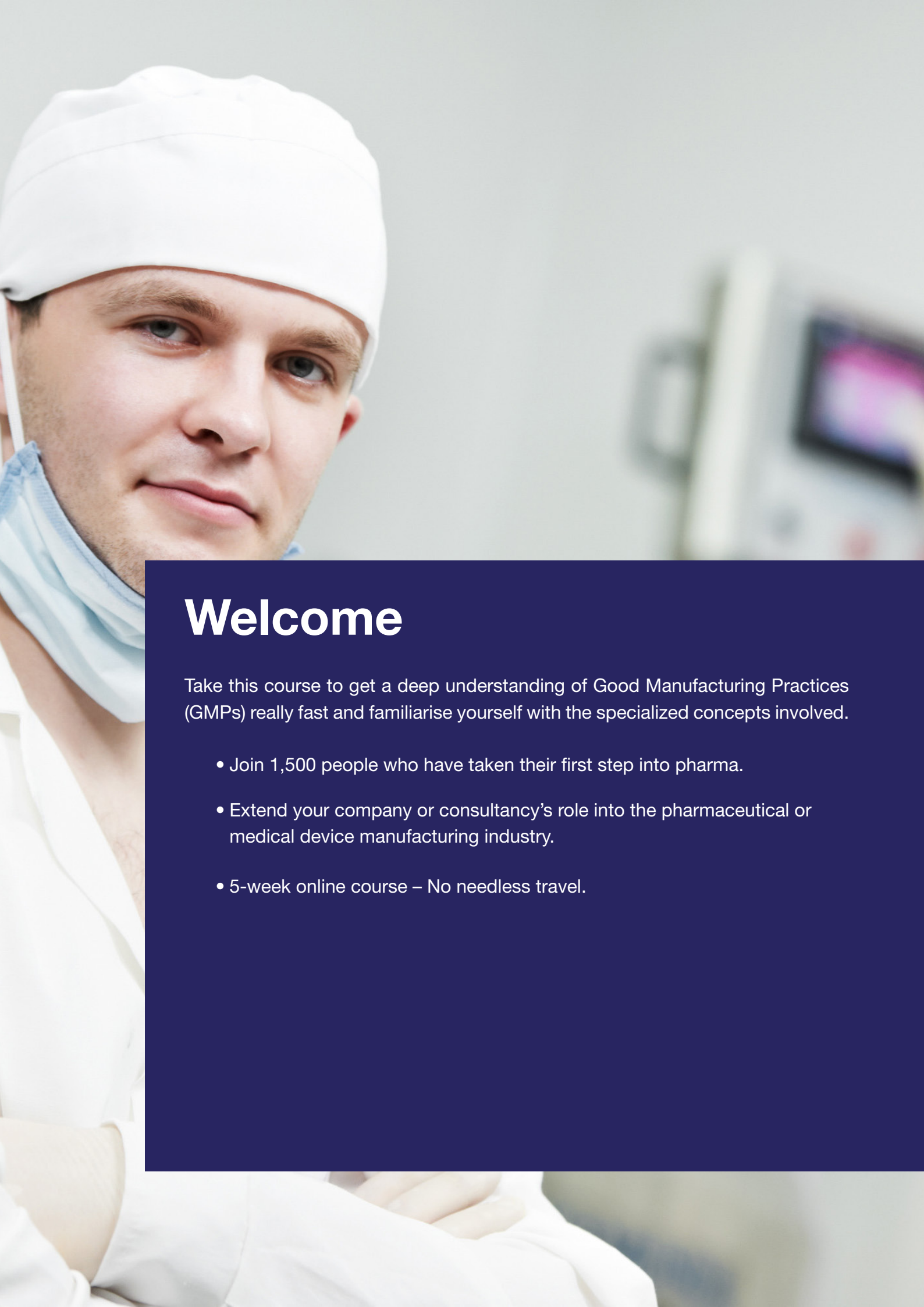

Welcome

Take this course to get a deep understanding of Good Manufacturing Practices (GMPs) really fast and familiarise yourself with the specialized concepts involved.

- Join 1,500 people who have taken their first step into pharma.
- Extend your company or consultancy's role into the pharmaceutical or medical device manufacturing industry.
- 5-week online course – No needless travel.

Program Overview

Who is this course for?

- You need to get a deep understanding of GMPs really fast and familiarise yourself or your team with the specialized concepts involved.
- You have to train your team on how safe medicines and medical devices are made in a regulated GMP manufacturing environment.
- You want end-of-week progress checks and follow-up by us make sure you or your team finish the course.
- You don't want to waste your time, money or training budget on hotel or travel junkets.

What can you expect?

- This course is delivered on our learning management system (Moodle) with a mixture of short (10 minute) content rich videos, downloadable notes and quizzes allowing you to complete the course at your own pace.
- This course 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.

What will you learn?

You will learn about manufacturing safe and effective medicines and medical devices in a GMP (Good Manufacturing Practices) regulated manufacturing environment.

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.

"The professionalism and passion of the lecturers comes across in the tutorials which gives the student confidence and encouragement to keep on top of the course. The course content material is concise and interesting. The timing of the release of the lessons is perfect, the student moves at a comfortable pace, one step at a time."

John Ryan

"Studying online gives you the time to do the course in your own time yet with assignment deadlines this made you disciplined to meet the deadlines set. I would have no hesitation in recommending these courses to anyone wishing to gain an education in the pharmaceutical sector."

Ronan Balfe

Program Content

Week 1 – Industry Regulations and Guidelines

- **Topic-1 Finished Medicinal Products**

  In this lesson, we learn about medical products and the various ways drug products are administered.

- **Topic-2 Focus on Patient Safety and Product Quality**

  In this lesson, we will develop a deeper understanding of the importance of patient safety and product quality for medicines and medical devices.

- **Topic-3 ISO9001:2008**

  This lesson is about the key requirements of a quality management system.

- **Topic -4 Product Quality and Current Good Manufacturing Practices [cGMP]**

  In this lesson, we learn how to scientifically define product quality. This lesson also gives an insight into the high-level principles of current good manufacturing practices (cGMP).

- **Topic -5 API Regulatory Guidelines**

  In this lesson, we describe the characteristics of a GMP that can be followed to manufacture an API.

- **Topic-6 ISO-9001 'Continual Improvement' & ICH Q10 Pharmaceutical Quality System**

  This lesson explains the concept of 'continual improvement' as part of a company's quality management system and describes an effective corrective action process and a preventive action process (CAPA). It also gives details on the product-lifecycle for a pharmaceutical product and describes the monitoring of process performance and product quality.

- **Topic-7 Quality Systems Approach to Pharmaceutical cGMP Regulations-The Quality Systems Mode**

  In this lesson, we describe a quality system model in accordance with management responsibilities, resources, manufacturing operations, and evaluation activities.

- **Topic-8 FDAMedicalDeviceRules-CFR820**

  In this lesson, we look at how the FDA classifies medical devices and explore the basis of that classification system.

- **Topic -9 Medical Device Regulations and Guidelines – ISO 13485 / CFR 820**

  In this lesson, we look at some GMP regulatory and ISO guidance documents that are associated with the manufacture of medical devices.

Week 2 – Process Validation & Documentation and Risk Management Tools

- **Topic-1 Process Validation**

  In this lesson, we will learn about the various definitions of ‘validation’, as well as for ‘commissioning’, ‘qualification’ and ‘verification.

- **Topic-2 ASTME2500 – Standard Guide for Specification, Design and Verification**

  In this lesson, we will describe a specification, design, and verification approach for equipment systems associated with the pharmaceutical, biopharmaceutical and medical device industries.

- **Topic-3 PQ,OQ and IQ**

  In this lesson, we are going to define the terms installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ), and we will also list what typical project design documents are required to prepare such testing protocols.

- **Topic-4 Cleaning Validation**

  This class takes a high-level look at a typical cleaning validation sequence. It looks at how to determine the basis for quantification limits and explains how to determine cleanliness levels on the basis of the analytical testing of representative samples. Sampling is described in terms of sampling-equipment, sampling -locations, and sampling –procedures.

- **Topic-5 Introduction to Quality Risk Management (QRM)**

  In this lesson, we will develop an understanding of the history and the crucial importance of risk management as well as the basic steps involved in its application.

- **Topic -6 Fault Tree Analysis (FTA) – step 4 ‘Workshop’ exercise**

  In this lesson, we learn about the risk management tool ‘Fault Tree Analysis’ and see an example of where and how we can use it.

- **Topic -7 Failure Mode, Effects (and Criticality) Analysis (FMEA / FMEAC) – Step 4 ‘Workshop’ exercise**

  This presentation shows an example of the main steps in performing a ‘Failure Mode, Effects Analysis’ (FMEA) and describes how this risk management technique summarizes the important modes of (a) failure, (b) factors causing these failures, and (c) the likely effects of these failures.

- **Topic-8 Documenting the Quality Risk Management Process**

  In this lesson, we take a practical look at managing a complete risk management process in terms of identifying risk, analyzing risk, evaluating risk, and controlling risk.

"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

Week 3 – Key Manufacturing Technologies

- **Topic-1 Batch Organic Chemical Synthesis**

  In this lesson, we describe the typical equipment and process stages of the manufacture of active pharmaceutical ingredients (API) using batch organic chemistry synthesis

- **Topic-2 Biopharmaceuticals Manufacturing, Upstream, Fermentation**

  This lesson describes a conventional biotechnological process and introduces the following process sequences:

  - o Stage-I – Upstream Processing
  - o Stage-II – Fermentation / Bio-reaction
  - o Stage-III – Downstream Processing

- **Topic -3 Tablet Manufacturing**

  In this lesson, we will explore the critical process parameters and quality attributes associated with the manufacture of medicinal tablets.

- **Topic -4 Aseptic & Sterile Manufacturing**

  In this lesson, we look at critical process parameters and quality attributes associated with aseptic processing and terminal sterilization products for parenteral products.

"I would highly recommend anyone in my situation who has been out of the industry for a period of time to do these courses. They have contributed to my new found confidence in my existing and new qualifications, my improved interview skills and my new job!"

Edel Harkins

Week 4 – Supporting Technologies and Cleanrooms

- **Topic-1 Purified Water (PUW) Generation, Storage and Distribution**

  2-6-1, 2-6-2, 2-6-3 In these presentations we look at methodologies to generate, store and distribute pharmacopeia grade purified water (PUW).

- **Topic -2 Clean Steam Generators – 2 videos**

  3-5-1, 3-5-2 the objective of this lesson is to demonstrate how we produce clean steam using 'Single-Effect Distillation' 'Multiple-Effect Distillation

- **Topic -3 WFI Storage and Distribution**

  In this lesson, we take a look at a process for the storage and distribution of pharmacopeia grade water for injection (WFI) and how to maintain its specification

- **Topic -4 Engineering Aspects of Cleaning, and Cleaning Equipment**

  This class discusses how to clean and decontaminate surfaces using CIP (clean-in-place), agitated Immersion, static Immersion (Soaking), and automated parts washers, ultrasonic cleaning, high-pressure spraying, and manual cleaning

- **Topic-5 Chemistry Aspects of Cleaning**

  This lesson explores chemistry aspects of cleaning in terms of solubility, solubilisation, emulsification, dispersion, wetting, hydrolysis, oxidation and physical removal.

- **Topic -6 Steam Sterilization in Place**

  In this lesson, we look at the mechanism behind sterilization of process equipment using saturated steam.

- **Topic-7 HVAC Requirements for Non-Sterile API Manufacturing**

  In this lesson, we look at how to use airflow direction as a means of a containment barrier between operational areas in a non-sterile multi-product active pharmaceutical ingredient (API) manufacturing facility.

- **Topic-8 Cleanroom Layout–2 videos**

  4-3-1, 4-3-2, In these presentations, we take a high-level look at a common cleanroom configuration and discuss items such as airflow direction, filter arrangements, cleanroom garments, and personnel and material flows. Another objective of this lesson is to also gain an understanding of personnel and material flows in a controlled airflow environment designed to contain high potency chemicals.

- **Topic -9 Area Classification Protection**

  In this lesson, we observe a range of airlock configurations typically used in combination with safety under operational conditions to maintain the specification of critical environmental zones, such as those used in open processing, that have a major impact on product quality and patient.

- **Topic -10 Cleanroom Gowning**

  In this lesson, we describe clothing that will minimize dispersion from skin and clothing for personnel working within a cleanroom environment

- **Topic -11 Cleanroom Monitoring – Physical Tests**

  In this lesson we discuss typical physical tests to monitor cleanroom environments: non-viable particle counts, pressure differentials, airflow velocity, air change rate, and filter integrity testing.

Week 5 – Assignment - based on GMP Manufacturing from content in Week's 1-4

Write a 4-5 page essay, which you could present at a job interview to clearly demonstrate your Technical Knowledge and Understanding of the Quality Culture necessary to work in a GMP regulated manufacturing environment. It will confirm your understanding of how to Manufacture Safe Medicines and Medical Devices in a GMP regulated environment and will include the following topics:

- The key requirements of a quality management system
- The manufacturing responsibilities for quality systems
- The cleaning validation sequence and how to determine cleanliness levels
- The documentation of a complete risk management process in terms of identify risk, analyzing risk, evaluating risk and controlling risk.
- The typical equipment and process stages used in the manufacture of active pharmaceutical ingredients
- The critical process parameters and quality attributes associated with the manufacture of tablets.
- The generation, storage and distribution of pharmacopeia grade Purified Water (PUW)
- The common cleanroom configuration and airflow direction that governs personnel and material flows in a biopharmaceutical manufacturing environment.

Program Details

Format:

Delivered online with 24/7 access through our Learning Management System (Moodle) using content rich short videos, downloadable course materials and review tests.

Duration:

This course takes 5 weeks to complete.

Assessment:

A written competency based assessment.

Certification

This course is individually accredited by GetReskilled subject to the following criteria;

- The submission of all assessments and the end of course assignment.

Admission Criteria

Suitable for all backgrounds such as;

- Management or Engineering Consultancies
- Engineers or Technicians
- Front/Backend Development or Enterprise Software
- Logistics – Supply Chain Managers, Procurement
- Business – MBA's, Finance, Accountants, etc
- Sales – Pharma Sales, Business Development, etc
- Marketing

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