GetReskilled

Pharmaceutical

Facility Design

Full Time | Part Time | Online

Contents

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?

Pharmaceutical Facility Design 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 modern pharmaceutical science and engineering concepts of 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.

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:

An injection bypasses all of your body's natural defenses. How do make sure that the cleanroom used in the manufacture of sterile medicines are absolutely safe? How do you make sure the water used in these injections is pure? In this course you will learn about the air and water systems used for pharmaceutical manufacturing that underpin aseptic/sterile processing and the quality systems used in this highly regulated environment to ensure the manufacture of safe and effective medicines for the public.

Why Take This Course:

- Calculate of the mass balance for a process
- Design the Cleanroom layout and the Environmental Controls pressure profiles necessary to meet the materials and personnel flows in a manufacturing facility
- Design the piping, instrumentation and process control for the generation and distribution of clean utility systems
- Learn about the Quality Systems approach to pharmaceutical manufacturing and aseptic/sterile processing for a vial filling operation
- Site Master Planning of the typical layout and function of individual units in a new or modified Manufacturing Facility.

Core Content:

Week 1 – Controlling Air Quality and Clean Utilities

- Manufacturing Logistics Calculations
- Process Flow Diagram (PFD)
- Controlling Air Quality
- Heating, Ventilation, and Air Conditioning (HVAC) Systems
- Biopharmaceutical Unit Operations - Drug Substance / Drug Product
- Pharmacopeia Grade Waters
- Process Support and Utilities
- ISO 9001:2008
- Typical GMP list for drug substance
- Operational Activities
- GMP for Personnel
- Quality Systems Approach to Pharmaceutical cGMP Regulations - The Quality Systems Model
- Maintenance: Good and Best Practices

Week 2 – Purified Water Generation and Distribution

- Project Lifecycle for New and Modified Facilities
- Plant Layout
- Layout For Bulk Process Building
- Site Layout
- Zoned Air Conditioning Systems
- Isolator technology & RABs
- Cell Breakage
- Purified Water Generation Storage and Distribution
- Clean Room and Clean Air Device Monitoring
- Good Engineering Practices Procedures
- GMPs for Buildings and Facilities
- Maintenance Program

Week 3 – Clean Steam and Sterilization

- Conceptual Design – Part-I
- HAVC Requirements for Non Sterile API Manufacturing
- Plant Automation
- Plant Steam
- Clean Steam Generators
- Steam Sterilization-In-Place
- GMPs for Process Equipment
- Quality Systems Approach to Pharmaceutical cGMP Regulations - Resources

Week 4 – Controlling Material and Personnel Flows

- Conceptual Design – Part-II
- Air Flow Patterns for Laminar Flow Systems
- Cleanroom Layout HVAC Containment (non-sterile API manufacturing)
- Filter Ratings - European Standards & MERV Rating
- Logic Gates Functions, and Programmable Logic Controller (PLC)
- Water for Injection (WFI) Storage and Distribution
- Principles of Good Engineering Practices (GEP)
- Quality Systems Approach to Pharmaceutical cGMP Regulations – Manufacturing
- Maintenance Work Execution

Week 5 – Aseptic Processing and Vial Filling

- Site Master Planning – Part-I

"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

- Classification of Clean Areas - Vial Filling
- Classification of Clean Areas - Cleanroom HVAC Configurations
- Area Classification Protection
- Compressed Air, and Pneumatics
- Aseptic Filling - Sterile Medicinal Containers
- Aseptic Filling - Vial Filling
- Cleanroom Gowning
- Aseptic Processing -– Manual & Automated Loading Systems
- Aseptic Processing - Automated Barrier Systems
- Cleanroom Monitoring - Physical Tests
- Quality System - Evaluation Activities
- Maintenance Management

Week 6 – Controlling Cleanrooms and Automation

- Site Master Planning – Part-II
- Open versus Closed Processing
- Facility Layout Concept
- Blow/fill/seal technology
- PLC Programming and Case Studies
- Cleanroom Monitoring - Microbiological Tests and Cleaning Procedure
- Terminally sterilised products
- EU Guidelines on Clean Room Aseptic preparation

Week 7 – Quality Systems for Cleanrooms

- HVAC Critical Parameters for Sterile and Non-Sterile Manufacturing
- Batch Process Control
- Nitrogen Supply and Distribution
- Environmental Monitoring Program
- ICH Q10 – Pharmaceutical Quality System
- FDA Guidance on Aseptic Processing

Week 8 – Construction Lifecycle for New and Modified Facilities

- Construction Lifecycle - New and Modified Facilities
- Construction Lifecycle - Test Packs
- Construction Lifecycle - Modular and Sustainability
- Software Functional Block Diagram (FBD)
- ASTM E 2500

Complete the Following Activities & Workshops:

You will produce a number of deliverables during the course including:

- Calculating Mass Balances and Equipment Sizing
- Designing a Clean Utility generation and distribution system
- Defining the cleanroom layout for safe material and personnel flows
- Describing the Quality System necessary for manufacturing safe medicines

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

Develop a site master plan for an aseptic manufacturing process and the design of its environmental control and clean utility systems

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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