



BIOPHARMA TRAINING FACILITY

Profile of Life Sciences Manufacturing Operations Programme
Carrigaline Biopharma Training centre, Carrigaline Industrial Park, Crosshaven Road,
Carrigaline, Co. Cork, P43 D274
Tel: 0214376726

Duration

Bioprocessing option 37 Weeks in-house plus 16 weeks in-company work experience

Overview

The programme was developed in consultation with Life Sciences Manufacturing Industry; modules cover key skills required by industry at process operator/ technician level. Essentially the process operator is the person who actually manufactures and/ or packages & labels the product which may be a medicine or a medical device. The course is certified at QQI Level 5 (major award). The ideal candidate has good mechanical aptitude, problem solving skills, excellent written English, attention to detail, good computer skills, good hand eye coordination and the ability to work as part of a team.

Job opportunities

The course will give participants the skills to work in the, Biopharmaceutical/Pharmaceutical industry, Medical Devices Industry, Food and beverage industry etc.

Eligibility

You don't have to be in receipt of a social welfare payment for this programme but if you are you may be entitled to a weekly allowance for the programme duration

The training facility

The training facility is equipped with many of the items of equipment used in industry but at a smaller scale. For example, in industry a vessel of 1,000 or 10,000L may be used but here we have the equivalent in a 60L size. We typically use water instead of product when operating the equipment. You will learn to use equipment such as bioreactor, autoclave, glovebox, purified water skid and work in a mimic cleanroom. The practical area is run as a mimic GMP environment – this means we behave as if we were working in the industry. We gown up in labcoats, hairnets, shoe covers etc and accurately follow documentation when we are carrying out our work. If you think this course is all about using equipment you would be very wrong. This is a very sophisticated industry and the people who work within it must have a very extensive knowledge and understanding of a broad range of subjects. This means that there is a lot of time spent in the classroom as well.

Modules covered while on course (Any module can be independently certified as a minor award)

The programme is a major level 5 award comprising eight modules which are described below.

There are probably a lot of words you are not familiar with in the description. They are terms that are very important when working in the life science sector. Do not worry about terms you can't understand now, by the time the course is finished you will know what they mean.



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Mandatory modules

Health, Safety and Environmental awareness

Equips the learner with the skills to perform a range of tasks in compliance with current health, safety and environmental regulations. Topics include: risk assessment, incident reporting, hazardous spill clean ups, etc. Assessment: Skills Demonstrations (i.e. practical tests) and theory test.

Good Manufacturing Practices (GMP),

Provides learners with skills to perform a range of manufacturing tasks in compliance with quality standards and good manufacturing practice (i.e. legal requirements for the sector).. Topics covered include: the importance of quality, Documentation systems, Standard operating procedures (SOPs), Manufacturing Batch Records, quality management systems. Assessment: Portfolio (i.e. collection) of work and theory test.

Continuous improvement.

Introduces learners to Lean tools which will help banish waste in any organisation. It also introduces learners to six sigma which is today's most talked about and successful, business improvement initiative. Assessment: Portfolio of work and theory test.

Generic modules

Career planning and work experience

Enables the learner to identify transferable skills and career opportunities. To give the learners the skills to write their own curriculum vitae and cover letter in accordance with industry best practice. Also cover behavioural interviewing which is a style of interviewing that most life sciences company's use in their hiring process. In-company work experience is also assessed.

Team working

Provides the learner with the relevant knowledge, skill and competence to work as an effective member of a team including understanding the fundamentals of team working, team working essentials, building effective teams, setting team objectives and skills for team working. Assessment: Portfolio of work and skills demonstration (ie planning and execution of a team project).

Remaining modules for Bioprocessing

Utilities module

The Utilities module covers the operation and monitoring of various types of utilities including steam, water, Heating Ventilation and Air Conditioning (HVAC) systems and gases that are used in the Life Science Sector. It also includes design and operation of different types of pipes, pumps and valves. By the end of the module you will be able to interpret Piping and Instrumentation Diagrams (P&IDs). This is an extremely valuable skill to have in the bio/pharmaceutical industry. Assessment: Assignment (i.e. write report on topic), Skills demonstrations, Theory.

Bioprocessing module

The bioprocessing module covers the manufacture of biopharmaceuticals. These are the new generation of medicinal products believed to represent the future of the pharmaceutical industry. We look at the technology that is involved, starting with modifying cells so that they can make the product. These cells are then grown under controlled conditions to produce the product. This stage is called cell culture (upstream processing). The product is then purified (downstream processing). The module covers how all of this is done and the operation of the equipment used in these different stages. Assessment: Skills demonstrations and theory test.



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Clean room operations

Finished pharmaceuticals, biopharmaceuticals and most medical devices are produced in a cleanroom environment in order to protect the product from contamination. In this module we carry out practical tasks such as gowning, sanitising a cleanroom, environmental monitoring, operating an autoclave, use of microscope, gram staining, etc. **Microbiology** is also covered which includes areas like the growth and control of micro-organisms which is vital knowledge for working in a cleanroom. Assessment: Skills demonstration and theory.

Times of attendance at centre

8.30am to 3.45pm Monday to Thursday

8.30am to 12.45pm Friday

Note: times of attendance at work experience will be decided by the company and will differ from in-centre training times.

Description

Assignment

An assignment is an exercise carried out in response to a brief with specific guidelines as to what should be included. An assignment is usually of short duration and may be carried out over a specified period of time.

Skills Demonstration

A skills demonstration is used to assess a wide range of practical based learning outcomes including practical skills and knowledge. A skills demonstration will require the learner to complete a task or series of tasks that demonstrate a range of skills.

Examination - Theory

An examination provides a means of assessing a learner's ability to recall and apply knowledge, skills and understanding within a set period of time and under clearly specified conditions. A theory-based examination assesses the ability to recall, apply and understand specific theory and knowledge.

Portfolio / Collection of Work

A portfolio or collection of work is a collection and/or selection of pieces of work produced by the learner over a period of time that demonstrates achievement of a range of learning outcomes. The collection may be self-generated or may be generated in response to a particular brief or tasks/activities devised by the assessor.