SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











# GMP for Manufacturers of Active Pharmaceutical Ingredients

LS014

# GMP for Manufacturers of Active Pharmaceutical Ingredients

**This programme is available In-House and currently delivered through virtual classroom training.**

Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any production process that cannot be eliminated through testing the final product. GMP covers all aspects of production from the starting materials, production process, production controls, packaging, labeling, storage, premises and equipment to the training and personal hygiene of staff.

This involves ensuring that systems are in place to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made. GMP compliance is widely-accepted as the best way to conduct business, putting product quality first. Implementation of GMP is an investment in good quality product. It is more expensive finding mistakes after they have been made than preventing them in the first place. GMP is designed to ensure that mistakes do not occur. Regulations governing the production of pharmaceutical products require that all staff involved in drug manufacture receive ongoing training in Good Manufacturing Practices.

**This programme is customised for each company in order accommodate specific in house challenges they are experiencing. This course material is put together based on the clients information, trends, pictures etc in order to illustrate the positives and weaknesses of practices & GMP within their facility.**

**Generally, an on-site visit is performed first in order for the tutor to gain an understanding and some experience in the specific areas the company would like covered. Exercises can be developed around these in order to enhance the learning experience.**

## Duration & Price

Duration: 1 day
Delivery mode: This programme is available In-Company

## Dates & Locations

*In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.*

## In-Company Training

Please contact us for more information on our In-Company training options

## What's covered?

These are topics that can be included, however these can be changed based on the company's own specific needs and requirements.

- Introduction to GMP
- GMP Licence
- 10 Principles of GMP
    i. Facility Design
    ii. Validated Processes
    iii. Good Procedures
    iv. Identify Responsibility
    v. Effective Record Keeping
    vi. Personnel Training & Competency
    vii. Good Hygiene
    viii. Maintain facilities & equipment
    ix. Build quality into the whole product lifecycle
    x. Perform regular audits
- Previous Audit Findings
- Specific requirements of EU GMP Part II or FDA CFR Part 211 for the above topics are referenced throughout the course material.

## Who should participate?

Any person within the organisation involved in API manufacture, implementation of quality systems or personnel responsible for GMP compliance

## What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the requirement for GMP and the importance of maintaining our licence
- Understand the key principles of GMP (specific to the company's requirements)
- Understand the benefits and the need for GMP in performing daily tasks within this industry
- Awareness of areas of GMP that may need improvement
- Understand the specific requirements of either EU GMP Part II or FDA CFR Part 211.

## How do we train and support you?

**In-House Courses**

For In-House courses, the Tutor will contact the Course Organiser in advance to discuss the programme in more detail in order to tailor it specifically to the organisation.

**Course Manual**

Delegates will receive a very comprehensive course manual.

## Tutors



**Kevina O’Donoghue**
View Profile

## What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.




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SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

## LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

## COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

## LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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