

Essential GMP Skills GMP Overview and an Introduction to the world of GxP

Skills and Training Laboratories Training Course
Sycamore House
Cell and Gene Therapy Catapult

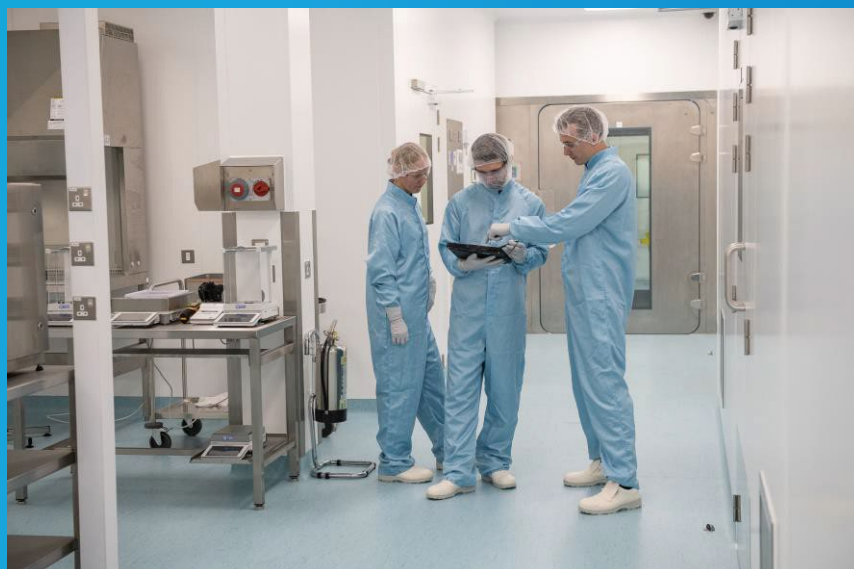
Essential GMP Skills

GMP Overview and an Introduction to the world of GxP

This one-day classroom course introduces key regulatory requirements and quality standards for employees in biotechnology, pharmaceuticals, and medical devices. It covers essential topics including documentation practices, quality control, validation, risk management, cleanliness, traceability, and the role of quality management systems (QMS) in advanced therapy medicinal product (ATMP) production.

Learning objectives:

- Understand the definitions, concepts, and significance of Good x Practice (GxP) and Good Manufacturing Practice (GMP) in maintaining product quality, safety, and compliance in regulated industries.
- Gain awareness of the regulatory agencies (such as the FDA and EMA) responsible for enforcing GMP guidelines and the global regulatory framework.
- Learn the core principles of GMP, including adherence to quality standards, traceability, documentation, and risk management.
- Understand how GMP principles apply across the product lifecycle, from research and development to manufacturing, distribution, and post-market surveillance.
- Learn the importance of accurate and comprehensive documentation, including batch records and standard operating procedures (SOPs).
- Understand the significance of personnel training, qualification, the design, qualification, and maintenance of GMP-compliant facilities and equipment.
- Understand the importance of identifying, investigating, and addressing deviations, non-conformities, and implementing corrective and preventative action (CAPA) measures, change management and the significance of data integrity in GMP.



Essential GMP Skills

GMP Overview and an Introduction to the world of GxP

Course title	Essential GMP Skills: GMP Overview and an Introduction to the world of GxP
Course level	Introductory
Course fee (per delegate)	£500 plus VAT
Course dates	Available upon request
Venue	Catapult, Sycamore House - Skills and Training Laboratories

Who should attend

Individuals new to biotherapeutics, ATMPs, or pharmaceuticals, as well as current professionals seeking a stronger grasp of regulatory production requirements and quality systems that safeguard patient safety.

Pre-course expectations and recommendations

- It is beneficial if delegates have a basic understanding of biotherapeutics, ATMPs or related industries, as well as concepts of manufacturing and quality control.
- If you are unsure if this course is suitable for you, please contact our Skills team via skillstraininglabs@ct.catapult.org.uk and we will be happy to advise.

Assessment

Various assessment modalities will be applied including:

- Pre- and Post-Tests to gauge participants' prior and end knowledge
- Case-based Assessments/Studies
- GxP-GMP principles will be applied in simulated scenarios
- Participants will be presented with hypothetical scenario-based questions and asked how they would respond, considering the principles they've learned
- Practical demonstration of specific skills, such as proper gowning procedures, gloving or hand washing to assess their practical knowledge.

Agenda

Time	Session Details
09.00 - 09.30	Welcome, Introduction & Ice breaker
09.30 - 10.30	GxP-GMP: How it all started. The Role Players: FDA, MHRA, EMA etc. Modern Day GMP incidents The GxP “family” Key Documents: Eudralex Vol 4, Orange Guide, ICH, PICS, BP
10.30 - 11.0.	Break
11.00 - 12.30	GMP-cGMP <ul style="list-style-type: none"> - (Bio-)Pharmaceutical QMS - Importance of documentation, SOPs, Batch records, change control - Risk assessment and management integrated into GMP to minimise hazard and deviations - Role of QC and QA – in-process controls, testing , CAPA, change management, internal and external audit -regulatory agencies
12.30 - 13.15	Lunch
13.15 - 15.15	ATMPs - 10 core principles of GMP Applied Are there loopholes in GMP Regulations to be aware of? GMP – 5Ps <ul style="list-style-type: none"> - People/Personnel - training, ongoing competency - Premises - design - Plant/Equipment - validation and qualification - Processes - Product
15.15 - 15.30	Break
15.30 - 17.00	Data Integrity in GMP; electronic recording, GAMP5, ALCOA PLUS Case Study: Risk Mitigation in your production SOP

Final agenda subject to change.



Address:

Sycamore
House
Leyden Road
Stevenage
SG1 2BP

How to find us

Driving - to park in our carpark use the vehicle security gate on Leyden Road

What3words ///slip.cakes.owners

By taxi or on foot - use the pedestrian security gate on Gunnells Wood Road

What3words ///parent.risk.lines

Once on site proceed to the main reception located on the south-west side of the building

No smoking

Please be aware that Stevenage Science Park is a no smoking site.

Contact us

We want you to enjoy this training course, but if you have any concerns, please do not hesitate to contact us at skillstraininglabs@ct.catapult.org.uk.

Sycamore House is located just outside Stevenage town centre.

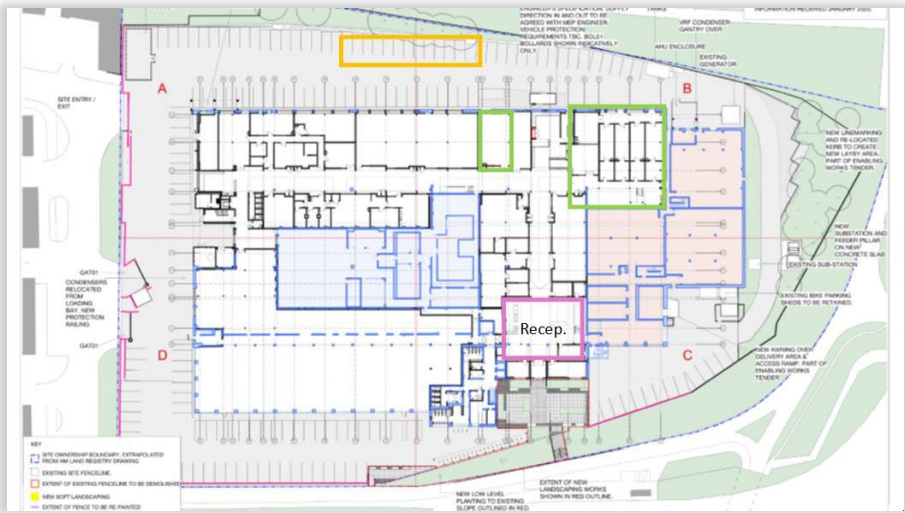
Sycamore House is close to the A1(M) via junction 7, the connectivity of the campus by car is considered good. Stevenage is well connected to major hubs. Cambridge is only 40 kilometres away and reachable within 40 minutes by train, and it takes only a 21 - minute train journey to reach King's Cross in London. In addition, Luton and Stansted international airports are reachable within 40 minutes and Heathrow within 1 hour.

Parking

There are designated car parking spaces available to CGT Catapult staff and visitors to Sycamore House including one electric charging parking space. Car parking is available on a first-come, first-served basis. Our parking spots are marked with the Catapult logo/sign. There are additional parking spots for visitors that is shared among the other tenants in the building. These spots can be booked via building reception in advance.

Additional parking at Stevenage Football Club is available for nine cars for Catapult employees and visitors - see map below.

Directions



Area marked in orange is car parking allocated to CGT Catapult employees on a first-come, first-served basis.

The building entrance / reception is marked with purple, and the CGTC ground floor areas, including our Skills and Training Laboratories are marked in Green.

Walking and cycling

Although the walk from the town centre and station takes approximately 25 minutes, there are continuous footpaths and cycleways, and safe crossings all the way to our entrance.

There are 33 cycle spaces for general use. There is a bike store located at the front of the building entrance accessed via Gunnells Wood Road. The spaces for the bikes are available on a first-come, first-served basis.



Car Parking at Stevenage Football Ground

Map showing the additional parking available at the East and West areas of Stevenage football ground.

