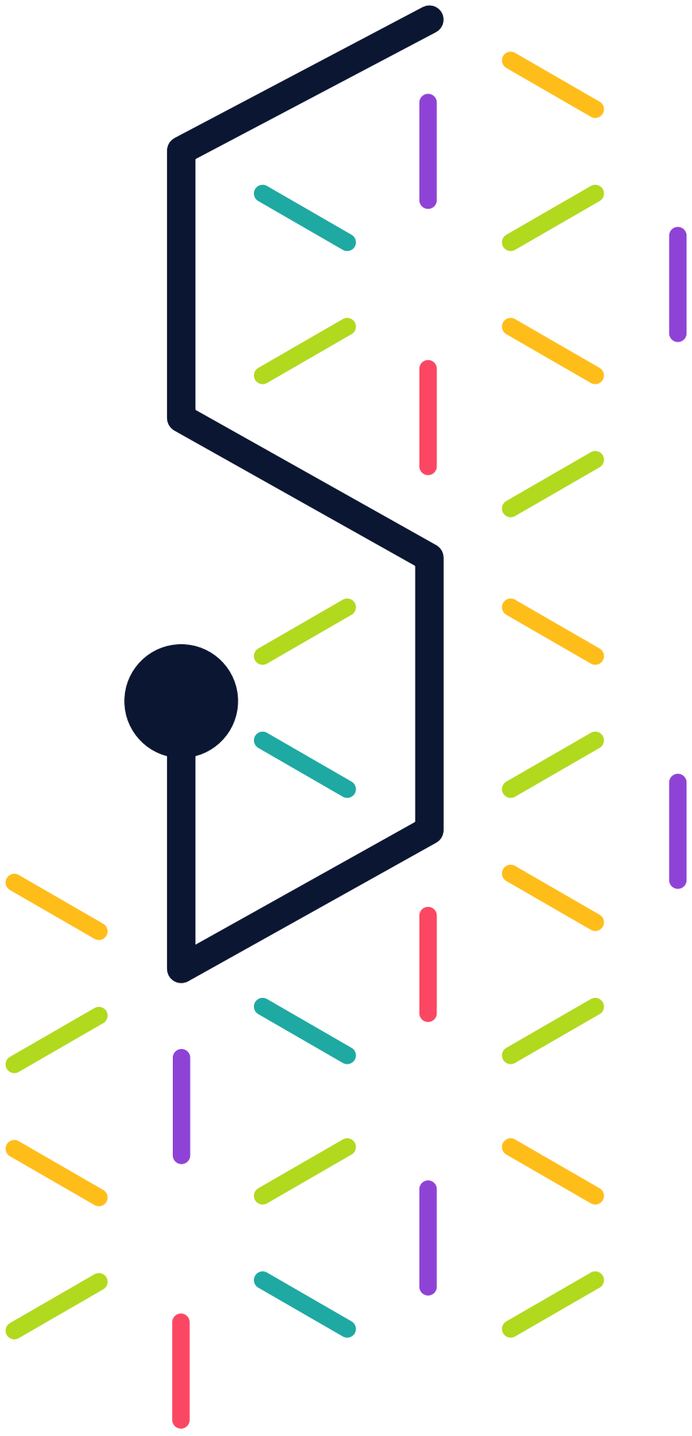
CONSTRUCTING SCIENCE

SETTING GUIDANCE FOR LIFE SCIENCES LABORATORIES

GOOD MANUFACTURING PRACTICE (GMP)

SUPPLEMENTARY REPORT
APRIL 2025



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INTRODUCTION

The UK's Life Sciences ecosystem is evolving rapidly. As a result, the Regulatory Innovation Office is accelerating the approval of new products and services to meet market demand within some of the UK's fastest-growing sectors. There will likely be an increased need for science real estate to respond by enabling test and scale-up facilities. These will vary in requirements across the sectors, many of them involving "clean facilities" that comply with GMP for the testing and manufacturing of new innovative products.

This guidance offers an introduction, practical resources, and preliminary guidance on key contributing factors around funding, briefing, design, and the construction of Life Sciences GMP facilities. A non-exhaustive resource due to the size, varied, and specialised nature of the GMP sector, relevant to all parties engaging with GMP facilities. It provides a basic level of knowledge to identify key questions required for design teams, and construction partners to achieve robust buildings, fit for the intended purpose.

DOCUMENT FOCUS AND SCOPE

GMP is an essential component of the life-sciences ecosystem, ensuring that products created in Research & Development facilities, used in clinical trials and produced for the market are consistent and safe.

As medicine evolves and the market increasingly relies on SMEs for product and device development, there is a growing need for Good Manufacturing Practice (GMP) and clean room facilities in the creation of therapeutics, products, and medical devices. This report focuses on GMP facilities within the life sciences and healthcare sectors, covering the entire process from the discovery stage through clinical trials to scale-up and small-scale manufacturing.

However, the term Good Manufacturing Practice (GMP/cGMP) is often overused or misunderstood, as it encompasses a wide range of facilities with varying regulatory requirements. This report is intended to serve as guidance to support the understanding of GMP facility considerations and provide insight into general parameters and constraints. It is not a design or building manual; our goal is to make this report more informational and less technical.

SCOPE

The publication is aimed at developers, design and construction professionals, stakeholders, users and operators, and local government exploring GMP development:

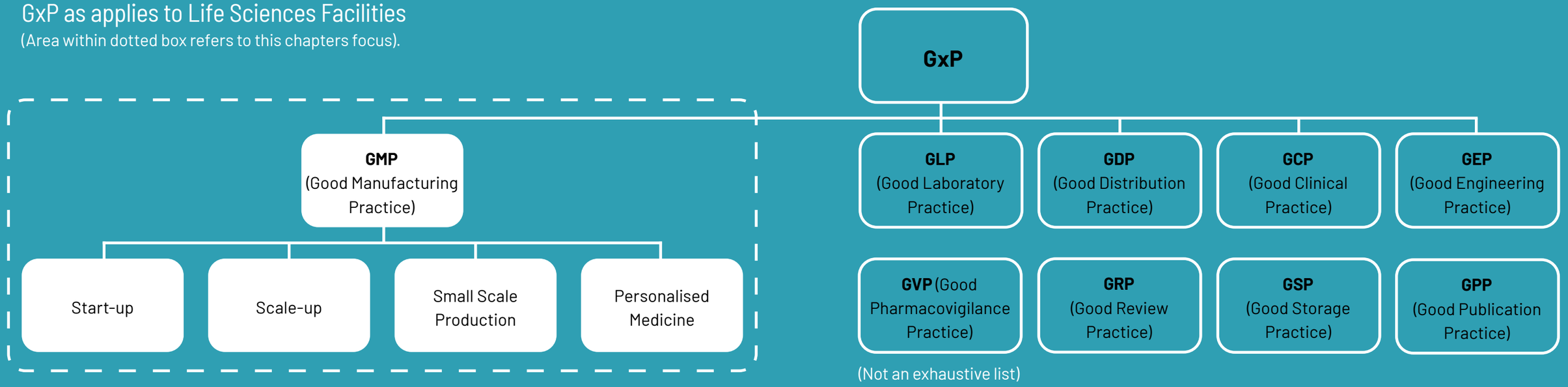
- Developers and Investors: It provides a reference point for assessing properties and spaces, whether for new developments or conversions and for identifying target market sectors.
- Design Teams: It outlines a pathway to define market baselines, demonstrate current standards to clients, and offer an accessible view of the industry.
- Local Government: By clarifying building typologies, locations, and safety concerns, the report aids in positioning different GMP typologies within the scientific ecosystem and provides valuable context for urban planning.
- Occupiers/End-Users: This report helps align GMP typologies with user maturity levels and short-term needs, translating these requirements into design and construction components while navigating regulatory constraints.

Additionally, the publication distinguishes between various facility types, from small hospital units to larger manufacturing sites. It does not cover industrial manufacturing clean rooms for sectors such as semiconductors, space exploration instrumentation, or food processing.

Large pharmaceutical manufacturing is also excluded, as these companies follow well established processes developed over time, with dedicated departments for regulatory compliance.

GxP as applies to Life Sciences Facilities

(Area within dotted box refers to this chapters focus).



(Not an exhaustive list)

DEFINING GMP

GMP is a set of processes and procedures that govern the design, construction and operation of a facility to allow for the safe production of products.

There is no single global consensus on GMP definitions. Different countries have different standards, and while a global effort is underway to create mutual recognition and alignment of these standards, there are still several main classifications.

In addition, different types of GMP processes require additional regulatory compliance which also differs from country to country. It is important to define the requirements of the process as early as is possible to ensure that the product will be manufactured in a way that allows it to be safely used.

GMP Cleanrooms are used in various industries, including pharmaceuticals, biotechnology, and electronics, to ensure that products are manufactured in a contaminant-free environment.

GMP Cleanrooms are classified based on the cleanliness level of the air inside the controlled environment. GMP Cleanrooms do not necessarily remove contamination albeit they regulate the cleanliness to a defined level, especially where operations are likely to cause defects to the final output or product.

ISO CLASSIFICATIONS

Many ISO Classifications apply to GMP facilities.

The key standard for Cleanrooms is ISO 14644.

Overview of the ISO Cleanrooms classifications:

- **ISO 1:** The cleanest, allowing the least number of particulates per cubic metre.
- **ISO 2 to ISO 4:** Increasingly less stringent, but still extremely clean environments.
- **ISO 5:** Equivalent to the Federal Standard 209E Class 100.
- **ISO 6:** Equivalent to Class 1,000.
- **ISO 7:** Equivalent to Class 10,000.
- **ISO 8:** Equivalent to Class 100,000.
- **ISO 9:** The least stringent however still maintains cleaner than a typical room.

GOOD MANUFACTURING PRACTICE

Good Manufacturing Practices were created to ensure that ingredients contained within an output such as a food, beverages, cosmetics or drugs are safe to be utilised by a living organism. The principle of the standard is to reduce the risk of microbiological, particle, and pyrogen contamination.

"Grade" GMP facility refers to a Cleanrooms environment used in the pharmaceutical, biotechnology, cosmetic, or food & beverage industries to ensure the regulated production of products, particularly medicinal products. These facilities are classified into four grades:

- **Grade A:** This is the highest level of cleanliness, typically used for high-risk operations such as filling zones, stopper bowls, and open ampoule's. It corresponds to an ISO 5 or higher cleanliness cleanrooms environment.
- **Grade B:** This grade is used as a background environment, secondary support area for Grade A operations or primary area for process. It corresponds to ISO 5 at rest and ISO 7 in operation.
- **Grade C:** This grade is used for less critical operations, such as sample preparation of solutions to be filtered. It corresponds to ISO 7 at rest and ISO 8 in operation.
- **Grade D:** This is the lowest level of cleanliness, used for less critical production such as medical devices, and stages of medicinal production such as goods in and out, anterooms or change-down facilities.

COMPARATIVE AIRBORNE CLEANLINESS							
Document Reference	Classification Designation	Maximum permitted number of particles per m^3 equal to or greater than the tabulated size				Air changes per hour	
		At Rest		In Operation			
		≥0.5µm	≥5µm	≥0.5µm	≥5µm	Min [(a)]	Max [(a)]
EU GGMP, Annex 1	Grade A	3,250	20	3,250	20	-	-
ISO 14644-1	ISO 5	3,250	a	3,250	a	n/a	n/a
EU GGMP, Annex 1	Grade B	3,250	29	325,000	2,900	-	-
ISO 14644-1	ISO 5	3.250	a	-	-	n/a	n/a
	ISO 7	-	-	352,000	2,900	70	160
EU GGMP, Annex 1	Grade C	352,000	2,900	3,520,000	29,000	-	-
ISO 14644-1	ISO 7	352,000	2,900	-	-	30	70
	ISO 8	3,520,000	29,000	3,520,000	29,000	10	20
EU GGMP, Annex 1	Grade D	3,520,000	29,000	Not defined	Not defined	-	-
ISO 14644-1	ISO 8	3,520,000	29,000	-	-	10	20

FACILITY TOPOLOGIES

Different types of processes, users, and stages of development require different types of facilities based on operational, regulatory, and capacity requirements. These factors are important to understand before designing a facility, or selecting a facility for occupation, as decisions made will affect the functionality and desirability of the facility.

LIFE SCIENCES GMP FACILITY REQUIREMENTS

Within the current market in the UK, there is a lack of easily accessible GMP spaces that are suitable for the various stages of user and product development.

At the time of writing this document there has been no government strategy to facilitate the growing need for this sector to enable the UK to keep IP within its borders. While stakeholders are invested in driving this forward there appears to be a potential gap in the R&D strategy in the UK.

We have identified three main facility categories. These are shared areas in managed multi-tenant GMP suites, single-tenant GMP suites, and GMP production facilities.

The facility requirements should be based on the type of production output. These criteria are based on the development phase and associated cleanliness and containment requirements.

The complexity of the regulatory, operational, and capacity requirements of the facility increases based on the maturity of the product development.

SCALE UP

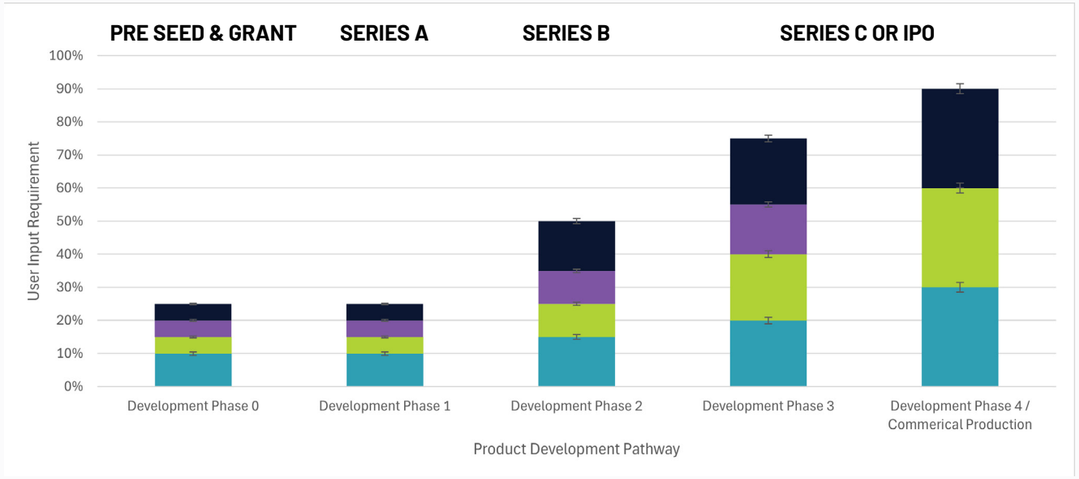
When working on facility transition, users should work with scale-up experts to understand what is required from the following points of view:

- Funding requirements
- Operational requirements
- Regulatory and Safety requirements
- Spatial requirements
- Process Requirements

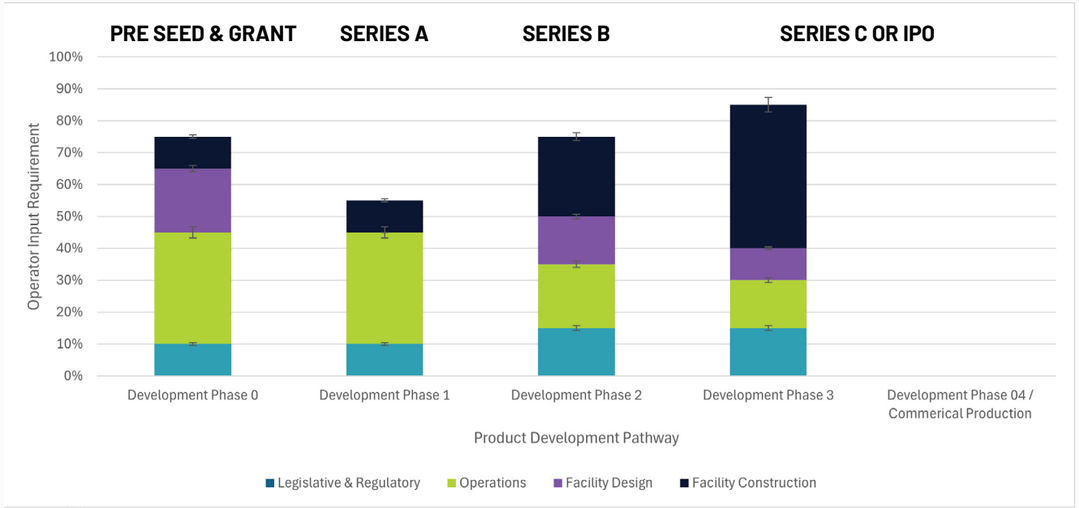
It is important to consider if bringing the next design stage of a process forward in parallel with the current manufacturing process is beneficial, and if there is sufficient funding and resources to do this.

INPUT REQUIREMENT

USERS



OPERATORS



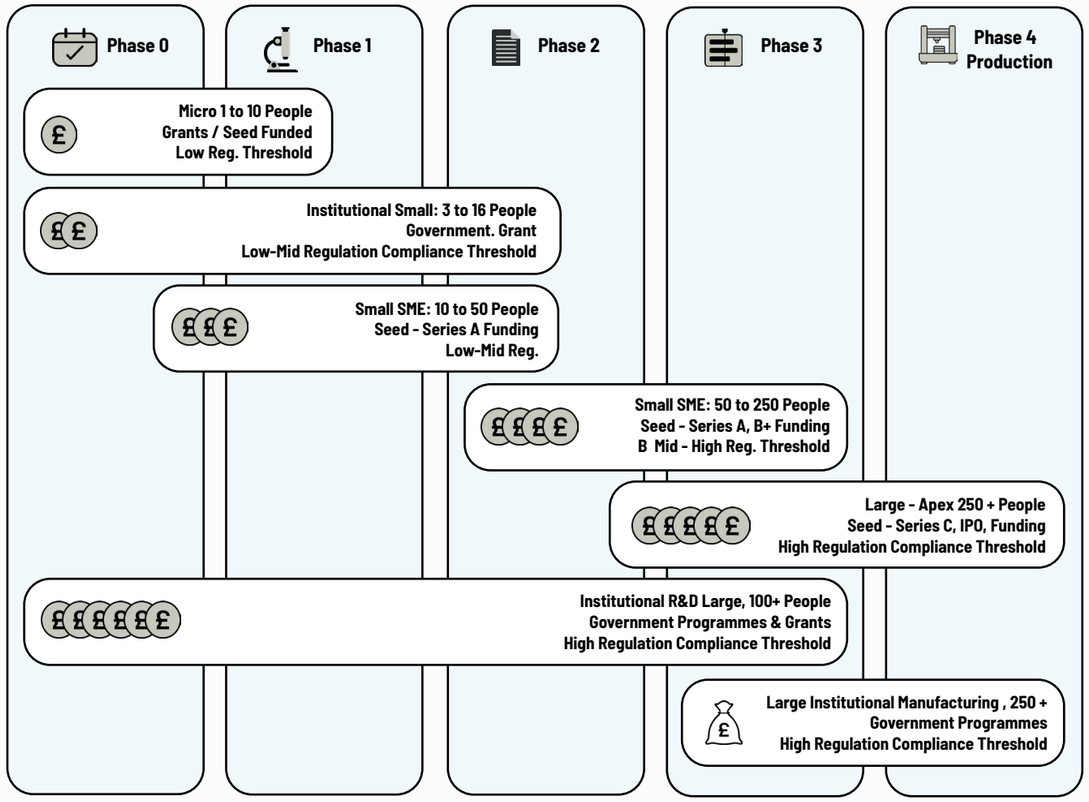
ORGANISATION TYPOLOGY & USER MATURITY

The complex and varying nature of life sciences and healthcare GMP facilities means they are unique and often in singularity.

As a result, even mature organisations may frequently have limited in-house experience in designing and delivering different typologies. It is recommended to validate the User Requirement Specification and end-user profiling.

APPLICABILITY

1. Institutional Bodies (NHS, Academic and Government)
2. Occupiers & End Users
3. Developers
4. Investors & Funding Partners
5. Biotech / Smaller Pharmaceutical Organisations



FACILITY TYPOLOGIES

While many parameters affect facility suitability for GMP use, there are four main typologies of facilities.

The parameters that govern suite selection and single vs multi-tenant suites fall under risk and regulatory exigencies, obligations, and capacity requirements. Principally, the benefits of shared operational requirements, shared specialist areas, and shared logistics reduce as the maturity of the client increases.

Provided that Standard Operating Procedures (SOP's) and appropriate risk mitigation are in place, some development pathways can be carried out in a multi-tenant suite. There are regulatory step changes in the development process that will require users to move between a multi-tenant suite and a single-user suite. In addition, there can be capacity requirements for these transfers. These transitions are costly and time-consuming, and it is in the interests of the users and developers to minimise these by following a thorough scale-

MULTI-TENANT SUITES

- Used for initial stages of product development.
- Working in the same area as other users, careful consideration must be given to cross-contamination and process compatibility.
- Shared facilities available.
- Significantly more FM and logistical support provided by managed services/developers.
- Ability to increase tenancy area with minimal facility reconfiguration.

SINGLE-USER SUITES

- Significantly less risk than multi-tenant suites when considering cross-contamination and process compatibility.
- May be required for early stage development if product has additional regulatory requirements.
- Greater user control of the operation of the facility and logistics.
- An increase in tenancy areas would be more likely to be on a suite-by-suite basis, which could require facility and flow reconfigurations.

SINGLE-USER SINGLE PRODUCT FACILITIES

- All facility operations under the control of a single entity.
- Provided the correct SOP's are in place and utilised, there is a reduced risk of cross-contamination.
- A single set of regulatory requirements.
- These facilities tend to be more bespoke than those for a single product and tend to be for larger organisations.

SINGLE-USER MULTI-PRODUCT FACILITIES

- All facility operations are under the control of a single entity.
- While there is single entity control, the multi-product requirement means that even though the correct SOP's would be in place and utilised, there is still some risk from cross-contamination.
- Potential need to implement varying regulatory requirements.
- Facilities tend to be more bespoke than those for a single product and tend to be for larger organisations.

WHAT BUILDINGS CAN FACILITATE GMP?

Different types of buildings lend themselves to different types and grades of GMP requirements.

NEW BUILD FACILITIES

New build facilities are ideal for GMP production. A key requirement of the higher grades of GMP is the ability to maintain the facility without breaking the containment envelope. Maintenance of MEPH occurs outside the cleanrooms boundary. This results in higher slab-to-slab heights than in conventional life sciences facilities.

RE PURPOSING EXISTING OFFICE BUILDINGS

It is possible to retrofit existing office buildings to low-grade GMP production, especially if adjacent areas are suitable for plant equipment. The key parameters will be slab-to-slab height, the size, and accessibility of the building risers, vertical transport systems, and the ability to clean existing facade structures impacted by the retrofit solution.

RE PURPOSING EXISTING INDUSTRIAL FACILITIES

Existing industrial and manufacturing facilities are often more easily re-purposed. The robustness of the building fabric will govern if the existing building envelope is fit to be used as a GMP envelope, or if a "box in a box" construction will be required. Like office buildings, the restricting factor is typically the heights of slab-to-slab and soffits.

IMPORTANT CONSIDERATIONS IN GMP FACILITY DESIGN

The importance of these parameters varies across the product development pathway. As these are dependent on the product, the process, the regulatory requirements, and the funding stage, it is not possible to give a blanket solution. However, it is important to understand and clarify the following before design, construction, or operation.

- Grade of facility required.
- Additional regulatory requirements.
- People, material and product flow.
- In process QA / QC Requirements including storage requirements.
- Goods in & out and distribution logistics.
- Waste pathways including regulated and controlled waste.
- Access and maintenance including Plant and preventative maintenance.
- Vertical and horizontal services distribution.
- Infrastructure including water, drainage, power, and data.

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OTHER FACILITY PARAMETERS

OTHER FACILITY PARAMETERS

GMP facilities needs extensive support from many different systems. It is important to understand the different factors that influence facility design and selection.

VENTILATION AND UTILITY PROVISION

When considering the ventilation and utility provision for clean environments, it is imperative that the space can be cleaned, decontaminated, and potentially fumigated. This impacts the setting out and specification of fixtures and fittings as well as the interface with the containment envelope.

For a full fresh air facility, the ventilation serving the clean environment is typically provided from an interstitial space above, housing the room (tertiary) distribution and ventilation control devices/filters, that connect to the secondary distribution ducts above. These, in turn, connect to the primary distribution system and the main AHU equipment. Given the large quantities of air air being moved, the primary distribution and plant may be located nearby the clean environment.

In facilities with recirculating ventilation systems, different strategies can be implemented with local fan filter units or recirculating air handling units. These are used to feed the room and include the local control and filtration systems. The primary and secondary distribution can be similar to the full fresh air systems above.

Clean environments often require unidirectional or laminar flow across the space which will require supply diffusers to be situated opposite (e.g. supply at the ceiling and extract from the floor) from the exhaust. The cleaner the space the greater the coverage of the supply diffuser and exhaust, leading to full ceiling, floor, or wall plenums.

The clean environment typically requires zones adjacent to the clean environment for ducts and services to drop down from high to low level, called a chase. It is important to consider these in space planning.

PRESSURE REGIMES

Clean environments are protected with air pressure regimes that positively pressurise the cleanest spaces and cascade the air to lower pressures to the dirtier spaces. Designers should consider the direction of the airflow and the pressure steps of the cascade to check for unintentional conflicts in the design, including large pressure differentials or unintentionally small pressure differentials.

Pressure barriers should be considered in conjunction with other building performance criteria to check all requirements are achievable. It is possible that a single product or solution (e.g. a door) may not be able to achieve all the associated requirements. Further conflicting elements may be fire, security, acoustic, and fumigation. It is often better to separate these requirements to treat them independently than try to achieve them all on the same building component.

MAINTENANCE OF UTILITY SYSTEMS

Maintenance and servicing of the building systems and equipment should generally be from outside of the clean environment and minimise disruption to operations as far as possible. Consideration should be taken to the business impact of shutdowns which may lead to a strategy where live or hot plant maintenance could be considered with changeover systems or equipment to prevent interruption as much as is practical.

SUPPORT SPACES

Shared Operational Support Areas

- Tissue Culture.
- Cell Banking.
- Viral Banking.
- Materials In, Waste out.
- Consumables.
- Product Out / Dispatch.
- Temperature Controlled Storage / Freezer Farms
- Equipment maintenance rooms.
- Wash-up / Autoclaves.
- Day stores (Just in Time Store).
- Write Up Space/ Office and amenities.
- Warehousing.

Shared Facilities Management

- Plant & control systems.
- Distribution Logistics, Loading Bays and service yard.
- Warehousing.
- General Facilities Maintenance.

HANDOVER : MOVING INTO AN AREA

Confirmation of satisfactory equipment installation, completion of commissioning, testing and validation activities

These activities are essential for a science start up; for complex equipment, timelines may be lengthy, making accurate programming important. For Group 3 items, activities will additionally cover specification, procurement, delivery, and installation of equipment. Items may have long 'lead-in' periods, so identification of this and early engagement with suppliers is key.

Procurement of appropriate service agreements

Contracts for ongoing maintenance and re-validation are essential, given the dependence of many science activities on reliable equipment. Rationalising agreements and/or establishing preferred suppliers can dictate specifications. These preferences must be imparted early to ensure implications for space and services are incorporated within the design and selection within the budget.

Development and implementation of occupant training

Staff need to be familiar with new equipment and systems. Appropriate SOP's for new and existing workflows must be put in place for scientific activity to start. Using mock-ups of spaces and equipment can be an effective way to develop and rehearse workflows/SOP's and thus accelerate occupational readiness.

Understanding and communicating the energy cost of equipment and systems

Establishing a mechanism for sharing this with occupants/staff is recommended as part of an occupational readiness stage. This will encourage sustainable behaviours from the outset and embed these into the working culture.

Ongoing Operational Readiness

Equipment such as autoclaves and ducted fume hoods become 'fixed' items within the laboratory, due to their size/footprint, number of 'hard' services connections, and validation protocols. Both installation and removal cause significant disruption to operations and surroundings, so once installed, they tend to remain in place for long periods until a wholesale renovation of the laboratory is due. However, regular servicing and re-validation will continue, meaning their Operational Readiness forms a regular and ongoing activity. Planning and managing this is a responsibility of the operational team.

DUAL FOCUS OF CQV

While the Commissioning, Qualification and Validation process focuses on both facilities and equipment, it's important to recognise the different challenges each presents:

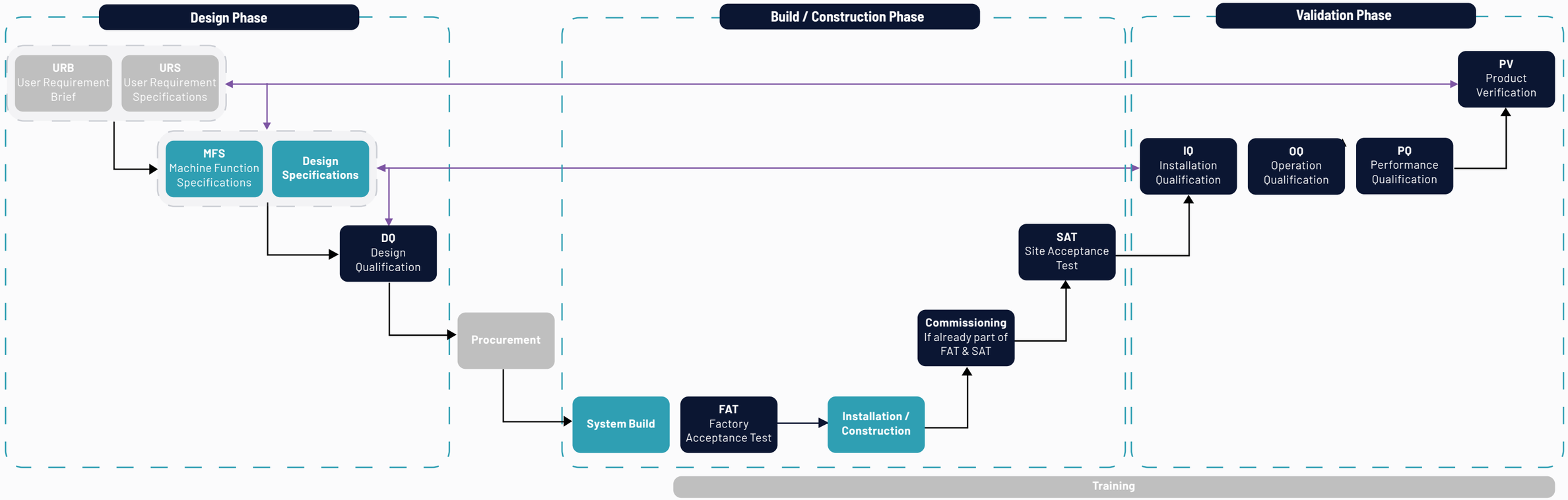
The CQV process underpins both Quality Assurance (QA) and Quality Control (QC) efforts. By ensuring that both facilities and equipment meet the necessary standards, the CQV process reduces the risk of failures or deviations, leading to fewer non-conformities in the product and higher compliance with regulatory requirements. A well-executed CQV process enables GMP facilities to deliver consistent, safe, and effective products, while also meeting the expectations of regulators, auditors, and customers.

FACILITY FOCUS

In GMP facilities, the facility itself plays a crucial role in maintaining product safety and quality. Controlled environments, such as cleanrooms, must adhere to stringent air pressure, particle count, and environmental controls. The commissioning and qualification of these systems are essential for preventing contamination, while ongoing validation ensures they continue to meet these standards over time.

EQUIPMENT FOCUS

For the equipment used in GMP environments, precision and reliability are essential. Equipment like bioreactors, filtration systems, and autoclaves must consistently perform to exact specifications to ensure that the manufacturing process produces compliant products. The CQV process verifies that these items are installed correctly, operate as intended, and maintain performance across different batches and time frames.



AUTOMATION, FMS, BMS, AND EMS

AUTOMATION

Automation in a GMP facility involves using advanced technologies to streamline and control manufacturing processes, ensuring compliance with regulatory standards. This includes integrating automated systems for monitoring, controlling, and documenting production activities. Automation enhances precision, reduces human error, and ensures consistent product quality. Key components include automated machinery, robotics, data management, and process control software systems. These systems help maintain stringent hygiene and safety standards, facilitate real-time monitoring, and ensure traceability of materials and processes.

EMS

An Environmental Monitoring System (EMS) in a GMP facility is designed to continuously monitor and record critical environmental parameters such as temperature, humidity, and particulate levels. This system ensures that the manufacturing environment remains within specified limits, essential for maintaining product quality and compliance with regulatory standards. The EMS provides real-time data and alerts for deviations, enabling prompt corrective actions. It also supports data integrity and traceability by maintaining comprehensive records crucial for audits and regulatory inspections. By automating the monitoring process, the EMS reduces the risk of human error and enhances overall operational efficiency.

BMS

A Building Management System (BMS) in a GMP facility is a sophisticated hardware network and, by minimising manual interventions, software designed to monitor and control various building functions. These systems ensure optimal performance, safety, and efficiency by managing heating, ventilation, air conditioning (HVAC), lighting, power supplies, fire alarms, and security installations. In a GMP context, BMS is crucial in maintaining controlled environments essential for pharmaceutical production, ensuring compliance with regulatory standards. By automating these processes, BMS helps reduce human error, enhance operational efficiency, and provide real-time data for better decision-making. This integration supports the stringent requirements of GMP by ensuring consistent environmental conditions, which are critical for product quality and safety.

FMS

A Facility Monitoring System (FMS) in a GMP facility is a specialised system designed to continuously monitor and record critical environmental parameters. These parameters include inert and viable particle counts, temperature, humidity, and pressure levels. The FMS ensures that these conditions remain within predefined limits, which are essential for maintaining the integrity and quality of pharmaceutical products. This system is crucial for compliance with GMP regulations, as it supports them by providing real-time data and alerts documentation and traceability of environmental conditions, thereby reducing the risk of contamination and ensuring product safety.

GROWING INFLUENCE OF AI

Artificial intelligence (AI) transforms life sciences, enhancing research, diagnostics, and treatment. AI algorithms can analyse massive datasets to uncover patterns, accelerating drug discovery and development. Machine learning models can predict disease outbreaks and patient outcomes, allowing for proactive healthcare measures.

In diagnostics, AI-powered tools can improve the accuracy of imaging and pathology, detecting anomalies that human eyes might miss.

Personalised medicine benefits greatly from AI, as it helps tailor treatments to individual genetic profiles, improving efficacy and reducing side effects. AI can also streamline repetitive administrative tasks, freeing up healthcare professionals to focus on patient care. AI's integration into life science can lead to more efficient, effective, and personalised healthcare solutions.

SCADA

Supervisory control and data acquisition systems are indispensable in life sciences, especially for managing process control in Pharmaceutical and Biotech manufacturing. They provide real-time monitoring, control, and visualisation of critical parameters such as temperature, humidity, and pressure, ensuring consistent product quality and stringent compliance with regulatory standards.

SCADA enhances the precision and reliability of automated processes, minimising human error and enhancing productivity. It also offers robust data logging and reporting capabilities, essential for traceability and audit compliance. These systems ensure the integrity of production environments and contribute to energy efficiency and cost reduction, making them a cornerstone of modern life sciences manufacturing.

GROWING INFLUENCE OF ROBOTICS

Robotic systems have revolutionised life sciences, enhancing precision, efficiency, and repeatability in various processes.

In pharmaceutical manufacturing, robots handle drug dispensing, packaging, and quality control tasks, minimising human error and contamination risks. In laboratories, robotic systems automate repetitive tasks like sample preparation, analysis, and data recording, freeing up scientists to focus on more complex research. These systems can operate in sterile environments, which is crucial for sensitive operations.

Robotic systems can significantly boost productivity, ensure consistency, and improve safety in life sciences. They are integral in advancing research, development, and production, pushing the boundaries of what's possible in the industry.

LOGISTICS AND SUPPORT

Logistics and support areas incorporate processes associated with transportation, storage, safe handling, and management of crucial materials in the GMP facility.

LOGISTICS

Efficient logistic provisions can help streamline production, reduce unnecessary costs, and ensure regulatory compliance. Logistics areas must adhere to health and safety guidelines and are paramount in GMP facilities to allow smooth deliveries, appropriate management of materials, and flows of operational processes. A production plan, inventory, and integrated digital material management system may ensure the quality and availability of the materials when necessary and highlight stock errors earlier.

Raw materials, active ingredients, and products must be stored appropriately:

- Dedicated Areas to enable separation from other ingredients or products that can alter their quality.
- Regulatory conditions and compliances must be adhered.
- Appropriate storage must promote good practices to avoid breaks, spillage, contamination, or mixing.

SUPPORT

GMP Support areas are an essential component in the functioning of the facility and maintaining the quality and safety of operational workflows attributed to the product. Support areas may consist of the following:

- Quality Control Laboratories.
- Dedicated Storage Areas.
- Maintenance Workshops.
- Dedicated Personnel Areas including gowning, transfer facilities, or amenity spaces.
- Cleaning and sanitation areas.
- Packaging and Labeling.
- Dedicated Infrastructure areas for cleanrooms operation.

OPERATIONS AND FACILITIES

ALL GMP FACILITIES BROADLY INCLUDE FIVE COMPONENTS:

- **Clinical Space:** This includes process suites, typology-specific preparation spaces, and auxiliary support spaces such as dispatch, equipment storage and maintenance, day stores, freezers, and constant temperature rooms. The net space requirement for auxiliary spaces increases with activity scale-up and operational requirements, reaching its peak in dedicated manufacturing facilities. Additional support labs may be located outside the controlled area. QA/QC labs are integral to the clinical process and require sufficient space and attention.

- **Distribution and Support:** This encompasses short-term storage, warehousing, inward and outward goods, labeling, packaging and service yards. Space requirements depend on the typology and number of users, and logistic space requirements should not be underestimated.

- **Administrative:** Office and amenities are often overlooked and under-provided, especially in clinical trial facilities.

- **Service Access Areas:** This includes walk-on ceiling space and dedicated spaces within the clinical space. Consideration should be given to dedicated equipment maintenance areas within the cleanrooms environment, and unimpeded access to secondary and tertiary plant control devices.

- **Plant Rooms:** The spatial driver for these spaces is often driven by the air change regime; the higher the facility grade, the larger the requirements. The primary plant spaces should be designed with a clear plant replacement strategy and a strong focus on maintenance and operational readiness.

Service, logistic, and administrative space provisions may already be sufficient for a small research GMP space if part of a larger R&D facility. Multi-tenanted facilities have the additional complexity of defining controls and separation boundaries. These facilities present greater maintenance and logistics management constraints that are only partially controlled by procedures. The facility management's responsibility for the smooth operation of systems, including a service regime that does not disrupt individual companies at varying maturity levels, is critical. Larger loading bays and segregated stores are recommended to support multi-point supplies and more complex material, product, and waste separation.

For all facilities, a dedicated engineering-focused management team is advised. The operational and logistics management of these facilities are as critical to their smooth running as the scientific activity within the suites.

FACILITY PERSONNEL

PERSONNEL & STAFFING STRATEGY

The maintenance and management of GMP facilities are crucial for operational efficiency and facility longevity. A risk-assessed planning approach is essential for all life sciences facilities, ensuring compliance with GCLP, GMP, and GDP standards, depending on sector and usage. This approach must balance user and public areas without compromising operational needs and involves both physical and procedural planning, along with periodic effectiveness assessments.

Attracting and retaining skilled personnel is vital for effective facility operations. Working in GMP environments is challenging due to complex procedures, restrictive gowning protocols, limited natural light, and demanding outputs. Therefore, all personnel require extensive training aligned with their roles and responsibilities.

Personnel can be categorized as follows:

Users: This includes those involved in product development or manufacturing, both academic and technical staff. With a shortage of technical staff and high training costs, retention is critical.

Maintenance Staff: Includes engineering personnel responsible for system upkeep and even cleaning staff, who require significant training and familiarity with SOP's.

Management Staff: Facility operations managers must understand both the scientific processes and engineering aspects. This is crucial due to regulatory compliance risks and the financial impact of downtime.

The long-term viability of the facility depends on the seamless maintenance of building systems and daily services, often a point of contention between users and management. While user areas are largely the responsibility of the tenant, public spaces, including major plant systems, pose risks to user activities and increase the potential for crossovers and errors. A highly functioning, professional management team is essential to maintain these facilities efficiently.

COMMERCIAL

COMMERCIAL CONSIDERATIONS AND DEVELOPMENT

The development cost advice included within this report represents an overall consideration from early-stage design activities through to completion of any required Operational Qualification (OQ) requirements to validate the facility, clean utilities, and process equipment installed. The advice and assessments do not cover any client direct costs, land or building acquisition, validation costs from the end of OQ including any consumables required for process validation and product registration.

The cost parameters and differentials between the escalating facility requirements follow the four development types that have been identified earlier in this publication. To identify the escalation in cost to complete each facility type we have used coin symbols. Simply, the system works on the basis that the base case, R&D Laboratory has no coins applied. Therefore, each development uplift will be multiples of cost. i,e one coin represents a cost differential of X1 on the base case. Included costs are also expressed as current day, meaning that future price inflation to start on-site is not included in any guidance. At this stage we have not provided a base rate, this can be found within the main report dynamic modeling calculator.

COMPLEXITY

For the purposes of this paper, the focus will be against the types of facilities outlined within this report and do not extend to assessing large scale manufacturing facilities that are typically the domain of Contract Development and Manufacturing Organisation (CDMO) and Pharmaceutical/ Biotechnology companies who manufacture at scale.

COST ASSESSMENT AND DEVELOPMENT TYPES

Development phase 0 & 1 – GMP small scale shared facilities

Typically, from micro-scale through to small SME companies to circa 50 people who are seeking or are functioning on grants and/or seed or series A investments. These facilities tend to be shared with other similar companies and have a low-level regulatory compliance threshold.

Development Phase 3 – GMP large with stand-alone facilities

Typically associated with large Apex companies 250+ people who are seeking or are functioning on series C or IPO funding. These facilities tend to be standalone single-tenanted facilities and have a high-level regulatory compliance threshold.

Development Phase 2 – GMP small/medium scale single tenant

Typically associated with SME companies between 20 to 250 people who are seeking or are functioning on series A, B+ funding. These facilities tend to be single-tenanted but could reside in shared buildings and have a medium to high-level regulatory compliance threshold.

Development Phase 4 – Full GMP Production Facilities

Typically associated with large institutional manufacturing companies with 250+ people who are self-financing or IPO funding. These facilities tend to be standalone single-tenanted facilities and have a high-level regulatory compliance threshold.

SPECIALIST FACILITY CONSIDERATIONS

- Modular Solutions
- Biocontainment & Biologicals
- Aseptic Manufacture
- Genetic Modification
- Advanced Therapies
- Clinical Trials
- Personalised Medicine
- Small Scale Batch Manufacture

The following section provides high-level guidance for each typology of facility. These facilities are extremely bespoke and often require more than a single type of regulatory compliance scheme, often with contradictory regulatory requirements. As a result, these pages should be taken as primers, not as design guidance to be relied upon.

MODULAR SOLUTIONS

DIFFERENCE FROM STANDARD GMP

Modular GMP facilities differ from other GMP facilities in their flexibility, scalability, and construction methods. Modular facilities are built using prefabricated units or modules that can be quickly assembled, modified, or expanded, making them highly adaptable for changing production needs.

They allow for faster construction and deployment compared to standard facilities, which are typically built from the ground up and require longer lead times. Modular facilities are ideal for accommodating new technologies or varying production scales, such as in biopharmaceuticals or personalized medicine. Additionally, modular designs offer cost savings and reduced downtime during upgrades or expansions, while still adhering to GMP standards.

REGULATORY REQUIREMENTS

Modular GMP facilities must meet the same regulatory requirements as standard GMP facilities but with additional considerations for their unique design and construction. Regulatory bodies like The Food and Drug Administration (FDA) and The European Medicines Agency (EMA) require thorough validation of each module to ensure compliance with GMP standards, including equipment qualification, environmental controls, and proper material flow. Modular facilities must demonstrate that their prefabricated units maintain the same level of sterility, safety, and containment as traditional facilities. The integration of modules into a cohesive system requires detailed risk assessments and verification that all interfaces (e.g., HVAC, plumbing, and electrical systems) function seamlessly. Regulatory approvals may also be needed for facility modifications or expansions, emphasising the importance of continuous compliance in modular setups.

FACILITY IMPLICATIONS

Modular GMP facilities offer flexibility and faster deployment, but require strict validation of each module to ensure compliance with GMP standards. Seamless integration of systems like HVAC and utilities is crucial, and modifications or expansions must be carefully assessed to maintain regulatory compliance and ensure product quality and safety.

KEY CONSIDERATIONS

Construction

Key risks in constructing modular GMP facilities include ensuring seamless integration of modules, maintaining airtight connections between systems such as HVAC and plumbing, and achieving consistent environmental controls across all units. Delays in regulatory validation, potential contamination during assembly, and challenges with customising modules to meet specific GMP requirements also pose significant risks.

Cleanrooms Retrofit

Retrofitting cleanrooms GMP facilities in existing buildings poses risks such as structural limitations affecting airflow and contamination control; difficulty in meeting stringent environmental requirements such as air filtration and temperature, and challenges with space constraints for equipment layout. Ensuring a process of integration and coordination during design should minimise associated risks.

Plant / HVAC

Key risks in using modular plants in GMP facilities include maintaining consistent environmental conditions across all modules, potential challenges in ensuring sterility between modular connections, and managing system integration. Regular validation of equipment and processes is crucial, as poorly integrated or customised modules may lead to compliance or contamination issues.

BIOCONTAINMENT AND BIOLOGICALS

DIFFERENCE FROM STANDARD GMP

GMP with biocontainment is distinct from other GMP due to its emphasis on preventing the escape of potentially hazardous biological materials into the environment. While both follow strict protocols to ensure product quality and safety, biocontainment GMP specifically deals with products involving genetically modified organisms (GMOs), pathogens, or toxins. Facilities must have specialised containment measures, such as air filtration, waste decontamination, and controlled access zones. Standard GMP focuses primarily on preventing contamination of the product, but biocontainment GMP adds an extra layer of environmental protection, ensuring that the organisms or materials do not pose external health risks.

REGULATORY REQUIREMENTS

Biocontainment in GMP facilities involves additional regulatory requirements beyond standard GMP to address the risks posed by biological agents. These include adherence to biosafety levels (BSL) appropriate for the organisms handled, with higher levels (BSL-3 or BSL-4) requiring more stringent controls. Facilities must implement advanced air filtration systems (HEPA), restricted access areas, and validated decontamination processes for waste and equipment. Regulatory agencies like the FDA or EMA may mandate specific risk assessments, environmental monitoring, and emergency protocols to contain biological hazards. Regular inspections and certifications are necessary to ensure compliance with these biocontainment regulations, which prioritise both human and environmental safety.

FACILITY IMPLICATIONS

Biocontainment significantly impacts facility design by requiring specialised infrastructure such as sealed environments, HEPA filtration systems, airlocks, and controlled access areas. Waste decontamination systems and secure ventilation are critical to prevent pathogen release. The layout prioritises containment, safety, and compliance with biosafety regulations to protect both workers and the environment.

KEY CONSIDERATIONS

Containment Boundary

The areas inside and outside of the containment boundary need to be clearly defined based on the Hazard Group, the Risk Analysis and SOP's. A sterile boundary should be set and understood by all personnel operating in the environment.

Airflow

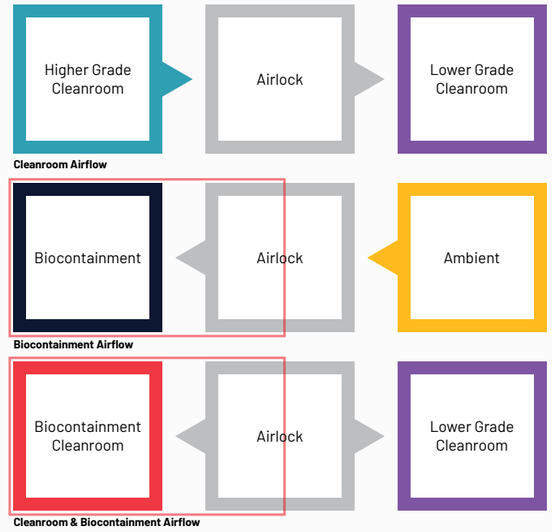
The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Waste

Waste generated in GMP areas must be removed as per local regulations and applicable to the suite operations. It must be segregated into the appropriate 'waste categories' and labeled appropriately. Coordinate with waste disposal contractors and ensure documentation of waste management log is adhered.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



ASEPTIC MANUFACTURING

DIFFERENCE FROM STANDARD GMP

GMP with aseptic processing differs from other GMP due to its focus on maintaining sterility throughout production. Whilst GMP ensures product quality and safety, aseptic GMP requires strict environmental controls to prevent microbial contamination, particularly for sterile products like injectables. Facilities must maintain cleanrooms conditions, with precise air filtration (HEPA), temperature, and humidity controls. Personnel must follow enhanced gowning procedures, and equipment must undergo rigorous sterilisation processes. Aseptic GMP also mandates extensive environmental monitoring and validation of sterilization methods. These additional controls are critical for products that must remain sterile to ensure patient safety and regulatory compliance.

REGULATORY REQUIREMENTS

Aseptic processing in GMP facilities may require additional regulatory compliances to ensure sterility and prevent contamination. Regulatory bodies like the FDA and EMA mandate the use of cleanrooms with strict classifications (e.g. ISO Class 5), validated sterilisation methods (e.g., autoclaving, filtration), and environmental monitoring for viable and non-viable particles. Personnel must adhere to stringent gowning and hygiene protocols, while critical operations occur in controlled environments with regular air quality testing. The facility design includes HEPA filters and unidirectional airflow to minimise contamination risk. Validation of aseptic processes and continuous training of staff are essential to meet these stringent regulatory standards.

FACILITY IMPLICATIONS

Aseptic processing in GMP facilities includes cleanrooms with specific air classifications, HEPA filtration systems, and unidirectional airflow to minimize contamination. Specialised layouts, airlocks, and controlled access zones limit personnel and material entry. Stringent sterilization protocols and environmental monitoring systems are critical to maintaining sterility and regulatory compliance.

KEY CONSIDERATIONS

Aseptic Boundary

The areas inside and outside of the aseptic boundary need to be clearly defined based on the Hazard Group, the Risk Analysis and SOP's. A sterile boundary should be set and understood by all personnel operating in the environment.

Gowning

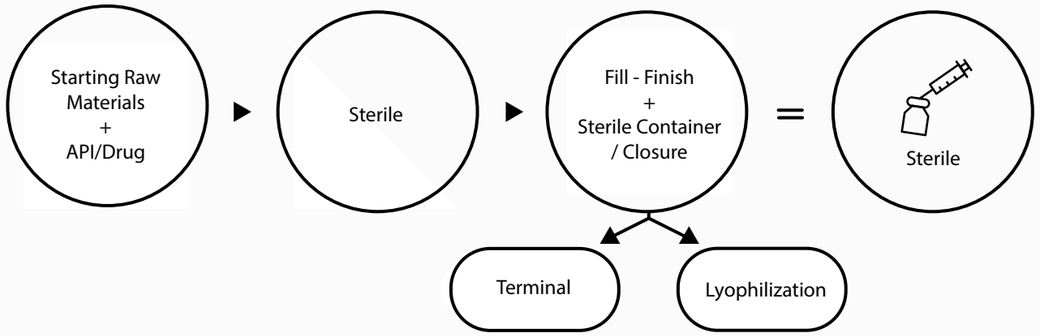
Designated gowning area equipped with benches, mirrors, and hand sanitisers to facilitate the process. Ensure all garments meet GMP or ISO 14644 standards for material quality and cleanliness. An aseptic gowning qualification program may be adopted incorporating training, education, hygiene and authorisations.

Airflow

The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



GENETIC MODIFICATION

DIFFERENCE FROM STANDARD GMP

GMP involving genetically modified organisms (GMOs) differs from other GMP due to the additional biosafety and regulatory concerns related to handling and containing these organisms. While GMP focuses on product quality and contamination prevention, GMP with GMOs also requires strict biocontainment measures to prevent the accidental release of GMOs into the environment. Facilities must implement specialised containment systems, such as air filtration, restricted access, and decontamination processes, to protect both the product and external ecosystems. Regulatory bodies often require risk assessments, traceability of GMO materials, and specific labeling protocols to ensure safe handling and regulatory compliance throughout the production process.

REGULATORY REQUIREMENTS

GMP facilities handling genetically modified organisms (GMOs) are subject to additional regulatory requirements to ensure environmental and human safety. Regulatory agencies like the FDA, EMA, and national biosafety authorities mandate comprehensive risk assessments and strict biocontainment measures to prevent accidental GMO release. Facilities must adhere to specific containment levels (e.g., BSL-2, BSL-3) based on the organism's risk profile, with controlled access zones, HEPA filtration, and decontamination protocols. GMO material must be traceable throughout the production process, with detailed documentation and labeling. Regular audits, environmental monitoring, and emergency response plans are also required to ensure compliance and prevent cross-contamination.

FACILITY IMPLICATIONS

GMO handling in GMP facility design requires enhanced biocontainment features, such as specialised air filtration, controlled access, and waste decontamination systems to prevent environmental release. Facilities must include secure containment areas, strict monitoring systems, and designated zones for GMO materials, ensuring compliance with biosafety regulations and protecting external ecosystems.

KEY CONSIDERATIONS

Genetic Boundary

The areas inside and outside of the genetic boundary need to be clearly defined based on the Hazard Group, the Risk Analysis and SOP's. A sterile boundary should be set and understood by all personnel operating in the environment.

Airflow

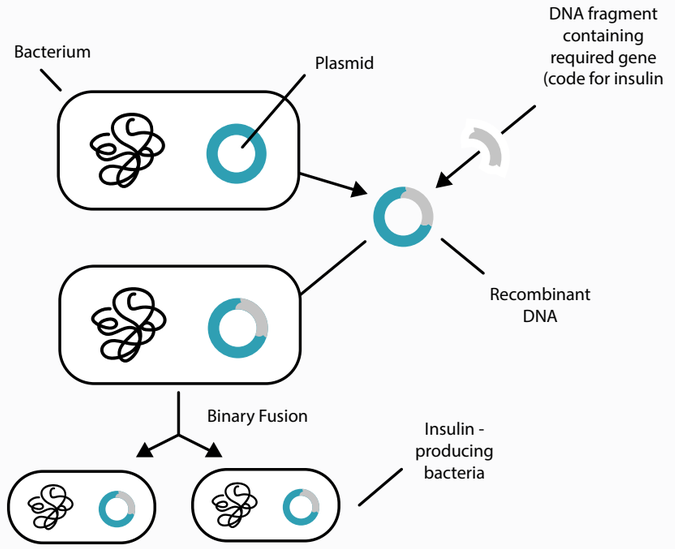
The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Waste

Waste generated in GMP areas must be removed as per local regulations and applicable to the suite operations. It must be segregated into the appropriate 'waste categories' and labeled appropriately. Coordinate with waste disposal contractors and ensure documentation of waste management log is adhered.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



ADVANCED THERAPIES

DIFFERENCE FROM STANDARD GMP

GMP for Advanced Medicinal Therapies (ATMPs), such as gene therapies, cell therapies, and tissue-engineered products, differs from other GMP due to the complexity, personalisation, and heightened safety risks of these treatments. While GMP focuses on large-scale production with consistent processes, ATMP GMP requires handling highly sensitive biological materials, often personalised for individual patients. Stringent controls are necessary to maintain the viability and functionality of cells or genetic material, with specialised equipment, containment measures, and advanced testing protocols. Regulatory oversight is more intensive, demanding traceability, sterility, and validation of novel technologies to ensure safety, efficacy, and compliance with evolving regulatory guidelines.

REGULATORY REQUIREMENTS

GMP facilities handling Advanced Therapy Medicinal Products (ATMPs) are subject to additional regulatory requirements due to the unique nature of these therapies. Regulatory agencies like the FDA and EMA mandate strict traceability from source material to final product, as many ATMPs are patient specific. Facilities must implement enhanced sterility controls, maintain cell or tissue viability, and prevent cross-contamination. Validation of cryo-preservation, storage, and transport processes is critical. Stringent environmental monitoring, along with dedicated cleanrooms and containment areas, is required for gene-modified cells or viral vectors. Additionally, regulatory authorities often require real-time patient-specific data, risk assessments, and post-market surveillance to ensure ongoing safety and compliance.

FACILITY IMPLICATIONS

ATMPs impact GMP facilities and contain specialised cleanrooms, cryo-preservation systems, and dedicated zones for handling sensitive biological materials like cells and gene therapies. Facilities need advanced containment measures, traceability systems, and secure transport protocols. Design must ensure sterility, prevent cross-contamination, and support the unique needs of patient-specific therapies.

KEY CONSIDERATIONS

Traceability

Traceability of a stringent process to identify and track all relevant data inputs and materials as part of the application and assembly related to advanced therapies. This covers correct dosages to the correct patients.

Gowning

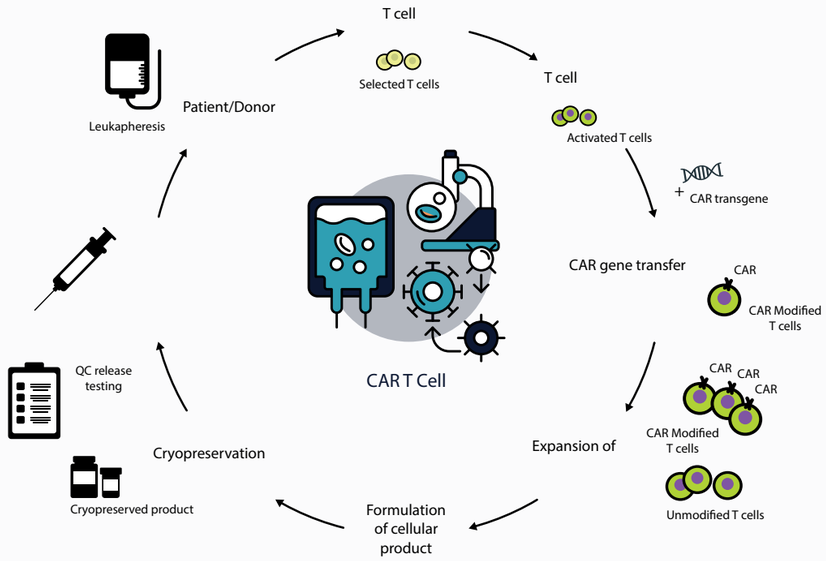
Designated gowning area equipped with benches, mirrors, and hand sanitizers to facilitate the process. Ensure all garments meet GMP or ISO 14644 standards for material quality and cleanliness. An aseptic gowning qualification program may be adopted incorporating training, education, hygiene and authorisations.

Airflow

The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



CLINICAL TRIALS

DIFFERENCE FROM STANDARD GMP

GMP for clinical trials differs from other GMP due to the experimental nature and smaller scale of production. Unlike commercial manufacturing, clinical trial GMP must accommodate flexibility for producing investigation products with evolving formulations or dosages. Strict documentation and traceability are required to track batches and variations, ensuring patient safety and regulatory compliance. Clinical trial materials often involve smaller, non-commercial batches, and their production may require rapid adjustments based on trial outcomes or regulatory feedback. Additionally, clinical trial GMP must emphasize blinding, randomisation, and secure labeling of trial materials while adhering to strict regulatory guidelines like Good Clinical Practice (GCP).

REGULATORY REQUIREMENTS

GMP facilities producing materials for clinical trials must meet additional regulatory requirements beyond other GMP. These include adherence to Good Clinical Practice (GCP) and Good Documentation Practice (GDocP) to ensure the safety and efficiency of investigation products. Strict batch traceability, documentation, and labeling are required to manage trial variations and ensure patient safety. Regulatory agencies, like the FDA and EMA, mandate rigorous quality control, randomisation, and blinding procedures to maintain trial integrity. Facilities must also implement secure storage and distribution systems, ensuring proper handling of trial materials. Importantly, regulatory oversight requires periodic audits and submission of manufacturing data to support trial approval and progression.

FACILITY IMPLICATIONS

Clinical trials impact GMP facility design by requiring flexibility to handle small-scale, variable production runs and rapid adjustments. Facilities need secure storage, strict labeling, and traceability systems to manage investigation products. Dedicated areas for blinding, randomisation, and documentation ensure trial integrity while maintaining compliance with regulatory requirements.

KEY CONSIDERATIONS

Traceability

Traceability of a stringent process to identify and track all relevant data inputs and materials as part of the application and assembly related to advanced therapies. This covers correct dosages to the correct patients.

Gowning

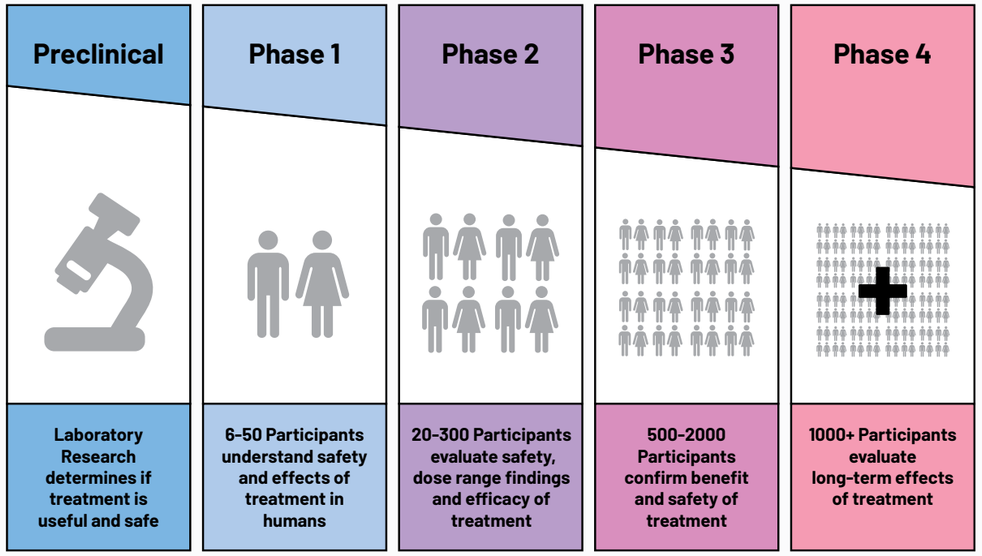
Designated gowning area equipped with benches, mirrors, and hand sanitisers to facilitate the process. Ensure all garments meet GMP or ISO 14644 standards for material quality and cleanliness. An aseptic gowning qualification program may be adopted incorporating training, education, hygiene and authorisations.

Airflow

The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



PERSONALISED MEDICINE

DIFFERENCE FROM STANDARD GMP

GMP for personalised medicine differs from other GMP due to the individualist nature of these therapies, tailored to specific patients' genetic or biological profiles. Unlike mass-produced pharmaceuticals, personalised medicine requires facilities to manage small, patient-specific batches with precise controls and traceability. The production processes are more complex, involving unique formulations, genetic modifications, or cell-based therapies, and must maintain sterility and functionality. Regulatory oversight is more stringent, with rigorous documentation, labeling, and quality checks for each patient. Personalised medicine also demands flexible manufacturing systems to accommodate rapid production adjustments, with real-time tracking and compliance with stricter safety, efficiency, and regulatory requirements.

REGULATORY REQUIREMENTS

GMP facilities for personalised medicine face additional regulatory requirements to ensure the safe, effective, and traceable production of patient-specific therapies. Regulatory agencies like the FDA and EMA mandate stringent traceability and documentation for each individual batch, as personalised treatments often involve genetic or cellular components tailored to a single patient. Facilities must implement robust identification, labeling, and record-keeping systems to prevent mix-ups. Specialised cleanrooms, enhanced sterility protocols, and containment measures are required, particularly for gene and cell therapies. Moreover, validated processes for cryopreservation, transport, and storage are critical, with real-time monitoring and compliance with personalised medicine-specific regulations, ensuring patient safety and therapeutic integrity.

FACILITY IMPLICATIONS

Personalised medicine impacts GMP facility design by requiring flexible manufacturing spaces for small, patient-specific batches. Facilities need specialised cleanrooms, advanced traceability systems, and precise labeling to manage individualist therapies. Cryopreservation, secure storage, and transport systems are essential to maintain the integrity of biological materials, ensuring compliance with stringent regulatory requirements.

KEY CONSIDERATIONS

Traceability

Traceability of a stringent process to identify and track all relevant data inputs and materials as part of the application and assembly related to precision medicines. This covers correct dosages to the correct patients.

Airflow

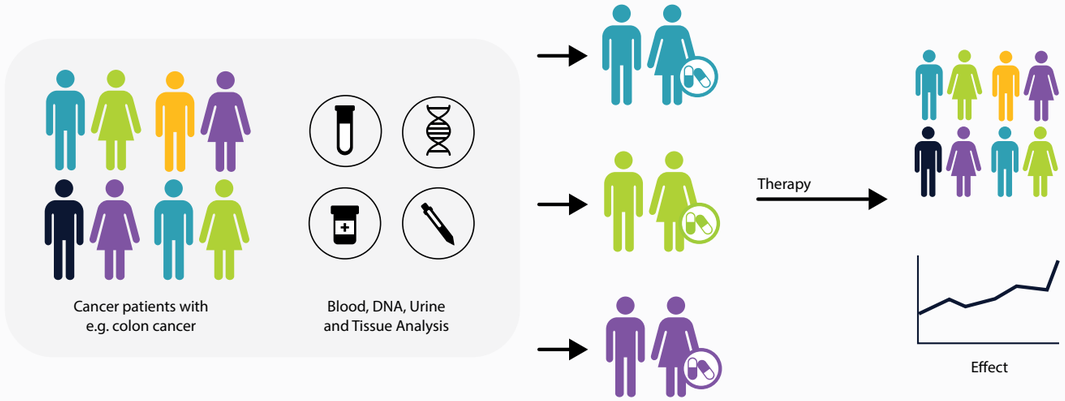
The airflow needs to be designed to comply with the requirements of processing. This tends to involve the use of bubbles and sinks.

Gowning

Designated gowning area equipped with benches, mirrors, and hand sanitisers to facilitate the process. Ensure all garments meet GMP or ISO 14644 standards for material quality and cleanliness. An aseptic gowning qualification program may be adopted incorporating training, education, hygiene and authorisations.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.



SMALL SCALE BATCH MANUFACTURE

DIFFERENCE FROM STANDARD GMP

GMP for small-scale batch manufacturing differs from other GMP due to the flexibility and precision required for producing limited quantities of products, often for clinical trials or niche markets. Unlike large-scale production, small batches may involve more frequent adjustments to formulations, equipment setups, and processes. This demands rigorous documentation and traceability to ensure consistency and quality. Facilities must be adaptable, capable of managing diverse products or variations within a smaller production footprint. Additionally, cleaning validation and cross-contamination prevention are critical due to frequent changeovers. Regulatory oversight remains strict, with the same quality standards as large-scale GMP, despite the smaller production volumes.

REGULATORY REQUIREMENTS

Small-scale batch manufacturing in GMP facilities involves additional regulatory requirements to ensure product quality and safety, despite lower production volumes. Regulatory agencies like the FDA and EMA mandate rigorous documentation for each batch, including detailed records of changes in formulation, equipment setup, and processes. Cleaning validation is crucial to prevent cross-contamination between frequent changeovers. Facilities must ensure robust traceability for materials and products, with precise labeling and batch control. Flexibility in manufacturing also demands strict validation protocols for equipment used in smaller runs. Additionally, regulatory bodies may require specific stability testing and quality assurance processes, ensuring compliance with the same high standards as large-scale production.

FACILITY IMPLICATIONS

Small-scale batch manufacturing requires GMP facility designs to prioritise flexibility, with adaptable spaces for frequent product changeovers and diverse processes. Facilities need advanced cleaning systems to prevent cross-contamination, efficient traceability systems, and modular equipment setups. Smaller production volumes necessitate precision in layout to maintain regulatory compliance and product quality.

KEY CONSIDERATIONS

Traceability

Traceability of a stringent process to identify and track all relevant data inputs and materials as part of the application and assembly related to small batches. This covers correct dosages to the correct patients.

Supporting Spaces

Small scale batch manufacturing may have an increased need for support spaces due to nuances of the associated processes and relationship with the development / CMC suites. Consider an appropriate dedicated gowning area.

QA/QC

Requirement for QA/QC for both material intake and product distribution. Ability to quarantine batches and keep reference samples to comply with GMP.

Decontamination / Sterilisation

Ability to decontaminate and sterlise the facility as per the facility SOP's. This may involve the use of vapourised hydrogen peroxide, and a review of material compatibility.

ADDITIONAL INFORMATION

ADDITIONAL INFORMATION

SUPPORTING INFORMATION

Our guidance publications are always free and will remain this way.

Website: https://constructingscience.com/our-publications

REGULATIONS AND STANDARDS

Non exhaustive list of ISO applicable regulations.

Website: www.iso.org/obp/ui/#iso:std:iso:14644:-1:ed-2:v1:en

GLOSSARY OF TERMS

Glossary of Terms

Website: https://constructingscience.com/glossary

CONCLUSIONS

GMP facilities in the UK will form a foundation for the next phase of expansion in the Science and Technology sector. There are currently limited existing assets where companies can carry out the production of Phase 2 and Phase 3 clinical drug trials, as well as limited facilities where personalised medicine can be created, assembled, dispensed, and administered.

A comprehensive, system-wide strategic policy must be developed in collaboration with the government, funding bodies, operators, and institutions to foster the retention of innovation, entrepreneurship, and the momentum generated by research and development in the UK. Ongoing support is critical to facilitate the establishment, spin-out, and growth of companies, thereby contributing to both local and national communities and economies.

Although GMP facilities are inherently complex, a clear understanding of both the challenges and advantages they present within communities—along with the demystification of GMP requirements and associated risks—can significantly enhance the UK Science and Technology sector. This will support its continued growth, particularly in the emerging market for rentable R&D real estate.

Unlike traditional research and development laboratories, GMP facilities are tailored to specific product types, require adherence to more stringent regulatory standards, and focus on large-scale repeatability, all of which are essential for advancing world-class scientific research.

It is our hope that this publication serves as an introductory overview of GMP, offers valuable insights into the key considerations surrounding this topic, and provides a pertinent resource for the design, construction, funding, leasing, and operation of GMP facilities.

APPENDIX

PUBLICATION AUTHORS

ARYIUM

Aryium specialise in comprehensive complex project services providing expertise in laboratories, clean manufacturing, biocontainment, pharmaceutical research, pharmaceutical production, and data centres.

Their knowledge spans a wide range of services, enabling them to deliver exceptional results across diverse industries and tailor solutions for clients. Aryium focuses on operations, regulatory requirements and sustainability in laboratories ensures seamless equipment and systems integration, promoting efficiency and productivity.

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Cundall is a global, independent, multi-disciplinary consultancy delivering sustainable engineering and design solutions across the built environment.

Cundall have 26 offices with over 1200 consulting engineers and designers who are empowered to act with flexibility and agility in response to the local market conditions and practices. The quality of their people is one of their biggest strengths.

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EEDN

EEDN is a dynamic and innovative construction project, programme and design management consultancy with focus on technically advanced projects.

We have delivered a multitude of projects in the SciTech sphere, from academic research to commercial science and cGMP manufacturing. Our team provides focused advice to the build environment from pre-feasibility to completion and operational readiness.

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OBERLANDERS

Oberlanders are a multi-award winning AJ100 architectural practice with studios across the UK. Growing from their roots in science & technology, they provide bespoke strategic design services to a multitude of sectors from occupier refurbishment projects to master planning entire communities for living and working. With a rich mix of experience and skills nuanced to each and every project, they design to a client's needs rather than a signature style.

They are committed to creating sustainable, energy-efficient architecture that provides healthy and comfortable spaces where people can thrive. By committing time upfront to listen, pushing the art of thoughtful design, and keeping to their word through honest and transparent communication, they add tangible value to projects. Their passion for what they do leads to the creation of more than just buildings, it creates relationships, trust, and exceptional outcomes.

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Gleeds is an international property and instruction consultancy with more than 135 years' experience in the property and construction industry. With 3,000 dedicated staff across six continents and 85+ offices, Gleeds prides itself on being a global business that is structured to act and think locally. Working with clients in almost every sector, Gleeds services the entire project lifecycle and categorises its offering into the following core areas: programme and project management, commercial and contract management, property and asset management and advisory.

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CROSSED 8 LTD

Crossed 8 is a consultancy organisation focused in supporting evolving biotech and pharmaceutical companies to shape their operational needs throughout their product portfolio and drug development life cycle. It offers executive-level advisory and hands-on interim management services for implementable drug development solutions and strategies; drug registration and dossier preparation; new business formation; change management, and strategic vendor partnerships.

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BURO HAPPOLD

Buro Happold is an international, integrated consultancy of engineers, designers and advisers. For over 45 years Buro Happold has built an unrivaled reputation by delivering creative, value-led solutions for the benefit of people, places and planet.

Described by clients as 'passionate', 'innovative' and 'collaborative', Buro Happold is synonymous with the delivery of exceptionally complex projects on every continent, working with the world's leading architectural practices and organisations, such as the United Nations, UNESCO and C40 Cities. Through a global community of driven, world-leading engineering, advisory and design professionals, Buro Happold is acting to address major challenges in an ever-evolving world.

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Cushman & Wakefield (NYSE: CWK) is a leading global real estate services firm that delivers exceptional value for real estate occupiers and owners. Cushman & Wakefield is among the largest real estate services firms with approximately 52,000 employees in over 400 offices and approximately 60 countries.

In 2022, the firm had revenue of $10.1 billion across core services of property, facilities and project management, leasing, capital markets, and valuation and other services. Cushman & Wakefield's Life Sciences team provides real estate advice to the sector, including site selection and design, lease and portfolio management, operational advice, financing and capital markets.

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CPC

CPC Project Services (CPC) is an independent Cost and Project Management Consultancy, operating across the UK. CPC is delivering some of the science sector's most well-known and award-winning Life Science projects with commercial developers, universities, Government agencies and end-users.

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EEDN

EEDN is a dynamic and innovative construction project, programme and design management consultancy with focus on technically advanced projects.

We have delivered a multitude of projects in the SciTech sphere, from academic research to commercial science and cGMP manufacturing. Our team provides focused advice to the build environment from pre-feasibility to completion and operational readiness.

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GLEEDS

Gleeds is an international property and instruction consultancy with more than 40 years' experience in the property and construction industry. With 3,000 dedicated staff across six continents and 85+ offices, Gleeds prides itself on being a global business that is structured to act and think locally. Working with clients in almost every sector, Gleeds services the entire project lifecycle and categorises its offering into the following core areas: programme and project management, commercial and contract management, property and asset management and advisory.

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CONSTRUCTING SCIENCE MEMBERS

GENSLER

Gensler is a global architecture, design, and planning firm with 53 locations and more than 7,000 professionals networked across the Americas, Europe, Greater China, Asia Pacific, and the Middle East. Founded in 1965, the firm works globally with more than 4,000 clients across more than 29 practice areas spanning the work, lifestyle, community, and health sectors. We are guided by our mission to create a better world through the power of design, and the source of our strength is our people.

By leveraging our diversity of ideas, our research and innovation, our shared values, and our One-Firm Firm culture, we are working seamlessly as a borderless firm in 140 countries and making the greatest impact on our communities as we continue to tackle the world's challenges.

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HOARE LEA

Hoare Lea is an award-winning engineering consultancy with a creative team of engineers, designers, and technical specialists. We provide innovative solutions to complex engineering and design challenges for buildings.

We're engineers of human experiences, problem solvers who care how a pace makes you feel when you step inside – who bring buildings to life. We overcome every challenge with ingenuity, determination, and pride.

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MEDCITY

MedCity is the Life Sciences cluster organisation for London. MedCity fosters collaborations between biotech, medtech and pharmaceutical companies and the capital's Life Sciences ecosystem to supercharge innovation, drive inward investment and build skills and talent across the sector in the UK.

Working in close partnership with London's world-leading universities and national ecosystem stakeholders, MedCity creates powerful networks and partnerships to fast-track R&D, with a specialist focus on diagnostics, digital health and cell and gene therapy. As life science experts, MedCity also facilitates the development of life science space in London to support the growth of research intensive businesses.

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MISSION STREET

Mission Street is a specialist investor, operator and developer focused on the delivery of creative solutions for the evolving Science and Innovation sector. We have a rapidly growing development portfolio, with more than 1,200,000 sq ft of committed projects in strategic locations within Oxford, Cambridge and Bristol.

The company is led by a specialist management team with extensive experience developing and operating Science and Innovation buildings and campuses and integrating these into their ecosystem. We believe that sustained economic prosperity will be underpinned by growth and investment in scientific and emergent 'knowledge economy' industries. Our Mission is to become the partner of choice for the UK's research and innovation sector, supporting the entire lifecycle from discovery to R&D and manufacturing.

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OBERLANDERS

Oberlanders are a multi-award winning AJ100 architectural practice with studios across the UK. Growing from their roots in science & technology, they provide bespoke strategic design services to a multitude of sectors from occupier refurbishment projects to master planning entire communities for living and working. With a rich mix of experience and skills nuanced to each and every project, they design to a client's needs rather than a signature style.

They are committed to creating sustainable, energy-efficient architecture that provides healthy and comfortable spaces where people can thrive. By committing time upfront to listen, pushing the art of thoughtful design, and keeping to their word through honest and transparent communication, they add tangible value to projects. Their passion for what they do leads to the creation of more than just buildings, it creates relationships, trust, and exceptional outcomes.

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RAMBOLL

Founded in Denmark in 1945, Ramboll is a global engineering, architecture and consultancy company that operates across 35 countries with over 16,000 employees.

We combine deep local insight and experience with a global knowledge base to create sustainable societies and drive positive change for our clients, as we transition to a more sustainable future. Ramboll UK has a dedicated science design team and an impressive track-record of delivering leading-edge science facilities for academic, institutional and commercial clients across the UK.

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CONSTRUCTING SCIENCE