# CONSTRUCTING SCIENCE

SETTING GUIDANCE FOR LIFE SCIENCES LABORATORIES

## OPERATIONAL READINESS

# CONTENTS

# 1 INTRODUCTION

This guidance offers practical resources to how successful Operational Readiness can be achieved and it is aimed at all parties engaging with new science laboratory facilities – from design and construction professionals to facility owners, operators and managers, as well as the science teams who will occupy the building as tenants.

# DEFINING OPERATIONAL READINESS

## Operational Readiness is the process and endpoint at which the tenant can start delivering science within a laboratory facility.

This guidance offers practical resources to how successful Operational Readiness can be achieved and it is aimed at all parties engaging with new science laboratory facilities – from design and construction professionals to facility owners, operators and managers, as well as the science teams who will occupy the building as tenants.

It marks the end of the facility design and construction phases and the shift to an operational phase. Operational Readiness forms a discrete stage of the project and entails all preparatory activities necessary to 'ready' the space and systems for science work to start.

The concept of Operational Readiness is not well understood by design and construction teams. With a stand-alone project, the industry is geared towards achieving completion of construction works, even with the introduction of 'soft landings', and regards this point as the culmination of a project. However, there may be many more weeks of necessary 'readiness' work before scientists can actually start.

Within a fully operational facility, programmes for modification and upgrade because of new equipment or following tenant churn, means Operational Readiness for re-fitted space forms a routine responsibility of the facility/tenant operational management team.

## In that respect, Operational Readiness can be defined both as a discrete end-stage of a project, and an ongoing process and responsibility of operational teams.

The complexity, duration and cost of Operational Readiness will be determined by the scale and complexity of the space and the science that will be undertaken, where a large-scale single new facility may take many months to bring to this point, but a small re-fit within an existing operational building, less so.

The general direction of increased automation of lab equipment will reduce validation and on-site testing, and widespread introduction of product/logistics tracking technology could accelerate moving-in and stocking timelines. It is important that programme, resource and cost implications of Operational Readiness are included within overall project planning, for completeness.

It encompasses, among others:

- **The recruitment, training and occupation of the facility by operational staff**
- **The development and adoption of operational practices and safety protocols**
- **Equipment/system relocation, purchase and installation**
- **Commissioning, qualification and validation**
- **Stocking of the facility for daily use, including consumables and PPE**

# PROJECT MANAGEMENT

Operational Readiness requires a close project management regime, due to the interrelationships between a number of different workstreams. It cannot be an afterthought of design, as decisions made throughout the project will affect the ability to perform some of the tasks of OR successfully.

# DEFINING THE WORKSTREAMS AND SETTING UP

Defining the workstreams is dependent on the relationship between the tenant and the landlord (if applicable).

Below, is a non-exhaustive list of the workstreams that would comprise the Operational Readiness project, each of which is expanded further in this report:

- Equipment selection and procurement
- Commissioning, qualification and validation
- Training
- People and waste flows
- Material onboarding
- Business systems alignment
- Cleaning: preparation and regime
- Automation and IT
- Regulatory

It is best practice to appoint a workstream leader for each of the workstreams above. Typically, these people will need to undertake the project in tandem with their day-to-day workload. For this reason, buy in from all stakeholders is essential.

At the same time, a Project Initiation Plan (PIP) as documentation will help to elevate this process. The PIP should include the project's scope and define the roles and responsibilities of each of the workstream leaders, as well as an outline set of milestone targets.





## RECOMMENDATION

- Define the workstreams
- Appoint a workstream leader for each one
- Ensure this is communicated and signed off to ensure buy in from all stakeholders.

BEST PRACTICE

# MANAGING OPERATIONAL READINESS

## A number of project control documentation can be used regularly to enable the transition into Operational Readiness.

These documents are not dissimilar to any project management process, but we outline the key ones below:

### PROJECT SCOPE AND BUSINESS CASE

A consolidated project scope is a key document that outlines what is included within the project parameters, the project budget and the reason behind the project. Depending on the circumstances, the business case could be included in the documentation, and it is suggested that it is developed with all the workstream leaders.

### STAKEHOLDER MANAGEMENT PLAN

The stakeholder management plan is a document that outlines how the project will manage the expectations of each stakeholder. It forms a good exercise to ensure that the hard and soft requirements of the project are captured and that there is a plan to proactively communicate with the stakeholders.

### PROGRAMME SCHEDULE

A programme schedule, typically in the form of a Gantt chart outlines the methodology of the project in a visual way, with particular attention to the interdependencies of tasks. There are several online tools that enable seamless cooperation between teams.

## SETTING OUT A PROGRAMME SCHEDULE

Most laboratories that have been successfully turned operational tend to have followed a similar process:

- **Outline brief**
- **Specification of requirements / business case**
- **Design**
- **Construction**
- **Commissioning**
- **Validation (if required)**
- **Operation**
- **Occupation**
- **Review / post-occupancy evaluation**

Each stage should be tested against the brief and specification to ensure compliance.

# OPERATIONAL CONSIDERATIONS

## COMMERCIAL CONSIDERATIONS

Principally, operational readiness approach should be embedded within the project's budgeting and procurement approaches wherever appropriate. The will be different considerations for different clients and different projects. A number of potential considerations are listed below:

1. **Commissioning** – consider the strategy/ approach for commissioning management: is an independent Commissioning Manager required? Will this be purchased as a separate package through the main contractor or through the client team as a consultant. It is also important to ensure that the budget envelop allows for this, either within the measured works cost plan, or the fee budget.

2. **Main Contractor attendances** – Any attendances needed from the main contractor during the operational readiness and familiarisation phases that will begin around Practical Completion of the Building Contract. These might include additional mechanical or electrical support post completion. This should be procured through the packages during procurement, together with any post PC coordination and management from the Main Contractor.

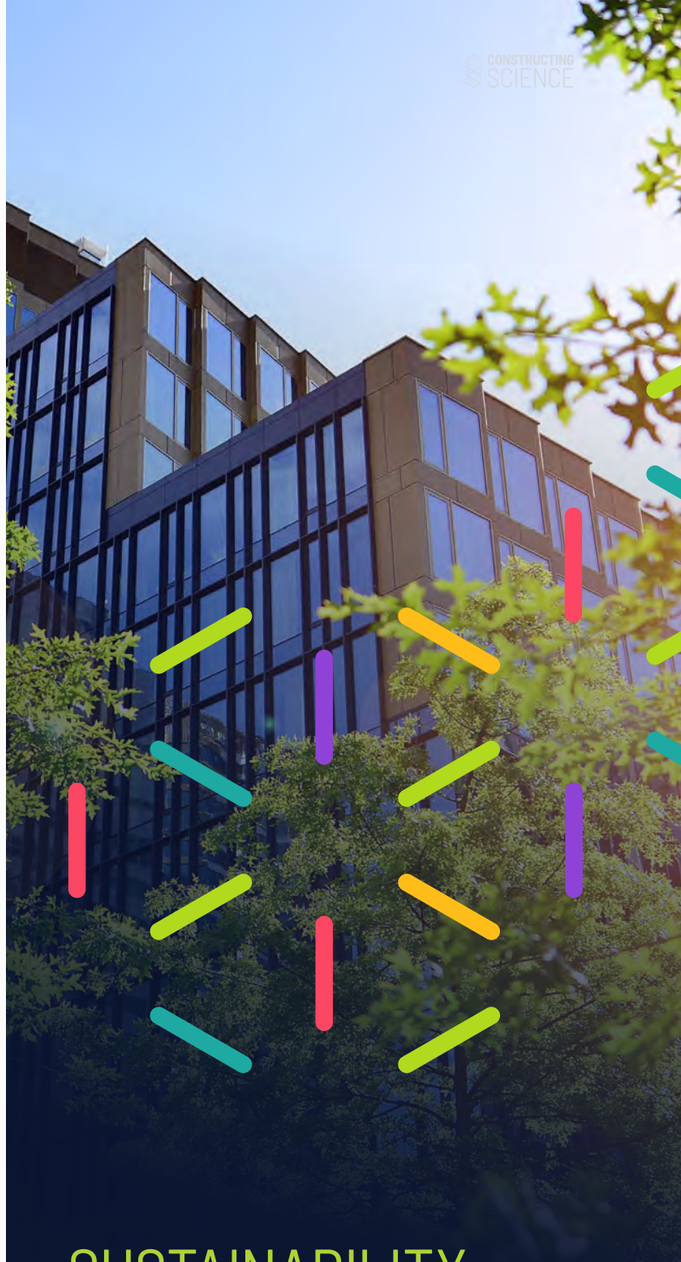
3. **Training** – in labs with significant equipment, training is likely to be needed, particularly if new research flows or automation has been introduced. Often this can be bought through the equipment supplier, but needs to be specifically priced and funding agreed for this element of the works.

4. **Contractual** – There may well be some overlap between the operational readiness phase and snagging and defects correction works that are being undertaken at the same time. Access and arrangements for this should be reviewed and clearly set out in the general preliminaries document so that the Post Practical Completion regime for the Contractor is clear and workable with the planned operational readiness process

5. **Contractual definition** – where operational start is a more critical date than Practical Completion, consideration can be given to incorporating this into the contract as a defined term, linking it to incentive and damages clauses if appropriate.

### The main point is to start with the end in mind.

This means understanding any budget implications early on, particularly in relation to training, spares, maintenance, early access, infrastructure, testing and so on. These requirements then need to be translated carefully into procurement to ensure the requirements are clear and the requiste resources and expertise are clear and incorporated.




## SUSTAINABILITY

Sustainable development is not achieved through a design stage model or calculation — it must be observed, measured or experienced when a building is in use. Operational Readiness is therefore critical to ensuring that the sustainability potential of the building can be maximised from lowering energy bills to offering wellbeing benefits.

## GUIDANCE FOR LANDLORDS

- To ensure sustainability is verifiable, progress should be measured against independent and internationally recognised methodologies to evidence and validate the outcomes to be achieved.
- Sustainable buildings tend to require longer-term engagement than those a decade ago. If pursuing WELL certification, operational data must be collected and submitted annually. The embodied carbon of maintenance and retrofits must be measured and reported. Biodiverse landscaping must be managed to maintain the benefits to nature throughout the building lifecycle.
- The Design for Performance methodology provides landlords with detailed energy data through submetering, facilitating easier identification of HVAC faults and comparison against initial design targets. This data also highlights areas of high energy consumption, prompting discussions around implementing energy efficiency measures to address these issues, whilst also supporting billing.
- Continual building performance monitoring enables operational efficiency and optimises long term value.

## GUIDANCE FOR TENANTS

- There is a plethora of sustainability certifications in the built environment. These can be specific, such as CycleScore, or general, such as BREEAM. Navigating the terminology, rating systems and value of certification schemes can be challenging, so it is important that these are well understood.
- If a tenant is aiming for net zero carbon, they must measure and reduce the energy consumption as well as optimise the embodied carbon of any fit-out.
- To enable the fit-out of a shell space to achieve sustainability certification, it is necessary to request comprehensive information from the landlord, including the route to compliance for the base-build.
- The availability of detailed energy data through submetering encourages responsible tenant equipment usage patterns.





# WORKFLOW & SCIENTIFIC PROCESS

Planning for laboratory workflow ensures the tenant will maximise benefit of facilities, equipment and tools. Workflow planning should therefore be led by the occupier/tenant and enabled by laboratory design.

Ahead of dividing sections and planning for large equipment the occupier will need to define research activity, identify appropriate tasks and protocols, select equipment and plan for personnel movement.

When planning the workflow, first divide the laboratory into areas with different access control in order to avoid contamination and secondly, restrict the access and equipment sharing for contamination-sensitive activity. Where contamination is not huge issue, plan for special organisation to ensure best productivity including sharing equipment, proximity of related activity and central ad easily accessible position for consumables and reagents.

For example, general supplies and large equipment necessary for different activity and often shared should be placed in central, easily accessible areas. However, if the lab includes tissue/cell culture or "omics" work, the most important consideration for design and workflow planning is avoiding contamination. Therefore, separate rooms or labs with one entry point should be used for such activity. These spaces should include designated equipment and consumables, space for protective clothing and changing area and separate sinks.

If laboratory activity includes both work with patients/volunteers/animals as well as their samples, lab design needs to ensure that live participants and samples do not have common pathways in the lab. Access to rooms where collection or analysis of samples is done needs to be restricted to selected staff. Also, layout should include separate processing and storage solutions for "raw materials" and early stages of sample processing.

One should also consider and plan for future activity. As R&D intensive businesses, mature labs need to address a need for increased capacity and/or change of research focus and activity. For example, addition of automation to workflow will influence capacity/ time requirements of automated processes and consequently influence layout of the space.

Finally, have a conversation with the occupier about often forgotten non-research activities and tools for scheduled tasks of lab maintenance, cleaning, ordering consumables, audits and documentation maintenance.

# EQUIPMENT

# Definitions

Technical equipment plays a major role in science and significantly shapes modern science facilities. Within this guidance, 'technical equipment' is defined as:

- Process systems - such as provision of lab-grade water or process extract ventilation;
- Science-enabling equipment - such as fume hoods or autoclaves;
- Scientific equipment provided by the tenant - typically bench-top and small items.

For new-builds and re-fit projects alike, technical equipment is conventionally allocated into a 'Group', dependent on which party procures and installs it, as follows:

- Group 1 – specified by client/occupant, supplied and installed by the contractor (builder)
- Group 2 – specified and supplied by client/occupant; 'free-issued' to contractor for their installation
- Group 3 – specified and installed by client/occupant, typically after the building contract works have completed





# Scope of guidance

## Although life sciences firms and laboratories vary widely, much of the technical equipment is common.

Our top 10 items are:

1. Fume hood – ducted (Group 1) and recirculating (Group 2)
2. Microbiological safety cabinet – ducted (Group 1) and recirculating (Group 2)
3. Refrigerator (Group 3)
4. Ultra-cold freezer (Group 3)
5. Incubator (Group 3)
6. PCR (Group 3)
7. HPLC (Group 3)
8. Microscopes – typically compound, fluorescence, confocal, electron (Group 3)
9. Glasswasher (Group 3)
10. Large autoclave (Group 1)

Our guidance applies to these plus other common items, noting that this list will evolve as automated and robotic laboratory equipment/systems become more widespread.

Preparation of an equipment list and categorisation of equipment into a Group should be done at early stage of a project (whether new-build or re-fit), as the physical, spatial and service impacts of equipment/systems necessarily form primary design considerations.

- Spatial footprint and optimal location within a demise.
- Access and installation paths including via goods lift
- MEP services (power, ventilation, process cooling, water and gases).

Equipment list (i.e. for a pre-let tenancy) or assumed equipment list (for speculative provision) are key documents and should be understood by all parties – landlord, design team, contractor and tenant to ensure appropriate provisions are made at the right time.





# Checklist for equipment Operational Readiness

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

These activities are essential for a science start; 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, so 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 get familiar with new equipment and systems, and appropriate SOPs 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/SOPs 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, to 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 surrounds, so once installed, they tend to remain in place for long periods of time 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 becomes an ongoing responsibility of the operational team.

# DELIVERY LOGISTICS AND SITE INSTALLATION

Relocating a laboratory can be a daunting and time-consuming task. If you work in a laboratory, it's not something that you will likely have to do on a regular basis.

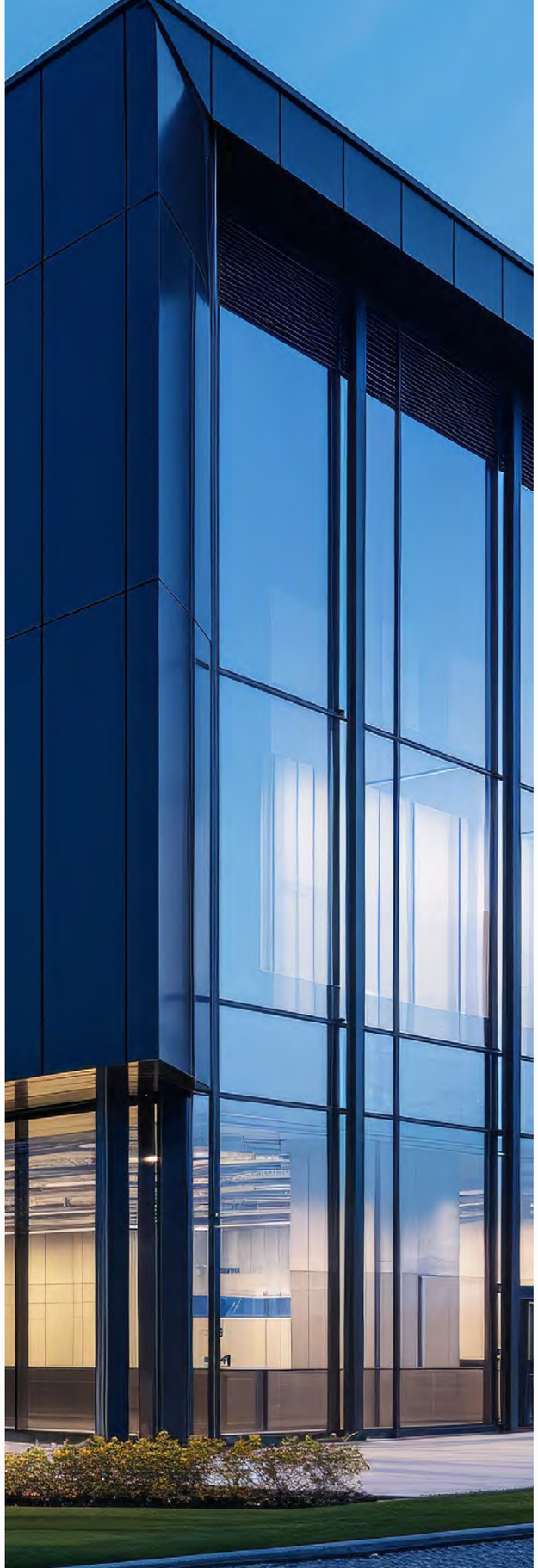
One of the most common questions that we get asked is "What does it take to relocate a laboratory?" or "How do you plan a laboratory relocation?". This question needs to take many variables into consideration:

- How large is the laboratory that is relocating?
- Is it a regulated laboratory?
- Do you have anyone in your own team that is both experienced enough and has the time to complete the planning of the laboratory move?
- When are you relocating?
- Do you have hazardous chemicals and samples to relocate?
- How much of your equipment needs some level of decommissioning/ recommissioning/ validation?

Ultimately, no laboratory relocation is completely the same. However, there are several planning constants in most laboratory relocation projects:

1. **Identify who will be your lead contact within your organisation, as well as ensuring the correct size and skillset of the internal support team.** It's important to have a key contact to liaise between any external stakeholders and your internal team. Having multiple main or lead contacts involved can lead to mixed messaging, poor communication and an inefficient project strategy. Likewise, if there are a lot of internal tasks of a varying nature to complete then leaving the tasks all to one person might be too much, especially if they still have their day job to do.

2. **Start planning early.** In our opinion of "best practice", once you have established that you are relocating your laboratory you should get the wheels in motion and come up with a high-level project plan. Whether this is planning internally or reaching out to a specialist to assist and advise, it is never too early to start discussions. Getting all the costs and timescales for various required aspects, ensuring you have all the correct and up to date information and finding suitable suppliers and specialists can all take a lot of time and effort.



A couple of documents that will make the initial planning of the relocation for an experienced laboratory relocation project manager a lot easier are:

- A full and sufficiently detailed equipment asset list
- A full chemical / COSHH list

The equipment asset list will be a great start, followed by completing an assessment and data capture of any equipment requirements. A lot of equipment cannot just be unplugged, packed and relocated, which is especially true for a GxP laboratory. Getting all the requirements into a master document will ensure that all the equipment decommissioning/ recommissioning/ validation requirements are in an orderly list for costs to be obtained by various suppliers and specialists.

A full and accurate chemical / COSHH list is vitally important to ensure that any relocation is completed both safely and legally on public roads.

If you don't have complete equipment lists where some equipment decommissioning / recommissioning / validation is required, or chemical / COSHH lists, then a specialist company should be able to offer this data capture and inventory service for you.

3. **Many laboratories will have LN2 cryo storage units, freezers and/or fridges to relocate.** The contents of these are likely to be the most important items that will be relocated, as they are often irreplaceable if damaged or lost. There are several ways that these can be transported from your current to your new laboratories. Specialist laboratory relocation companies should be able to advise of the safest, lowest risk, greenest and most cost efficient way to relocate your cold chain materials.

4. **Understanding relocation timings is critical.** As part of the planning phase it is vital to understand how long it will take to complete the full relocation and most importantly, the amount of downtime that is likely. Modern day laboratories are often very fast paced environments, and any laboratory downtime will be detrimental to ongoing research and laboratory operations.

5. **Budgeting for the relocation.** A laboratory relocation project can be expensive, especially for highly regulated laboratories and where there is a lot of high end/analytical equipment. Getting some early budget quotes for all the elements that might be required allows for the likely budget to be understood and ringfenced.

6. **Plan for the unexpected.** Although a laboratory relocation can be perfectly planned, there is always something that can get in the way of the perfectly planned project. What happens if you relocate all your fridges and freezers and one or more of the compressors fail? What happens if the connections to the LN2 feed are not correct and the LN2 cannot be connected to fill up Dewars once relocated? Has the pressure been tested and validated for the HPLCs to function correctly? What happens if the build and fit-out is delayed and there are a large number of equipment engineers and relocation teams already booked in? A company that specialises in planning and relocating laboratories should be aware of, and understand, all of the possible pitfalls and more importantly how to plan for and mitigate them.

Considering equipment early on is critical – need to prioritise equipment with long lead items. There are pieces of equipment that are off the shelf and not critical.

# COMMISSIONING, QUALIFICATION AND VALIDATION

# COMMISSIONING

# QUALIFICATION AND VALIDATION

Commissioning is the act of bringing the building systems required for the operation and function of the laboratory to an operational state. In a typical building these systems can include ventilation, heating/cooling, the BMS and other components, but in a laboratory building it often includes specialist equipment such as fume extract, laboratory gases, and Environmental Monitoring Systems (EMS).

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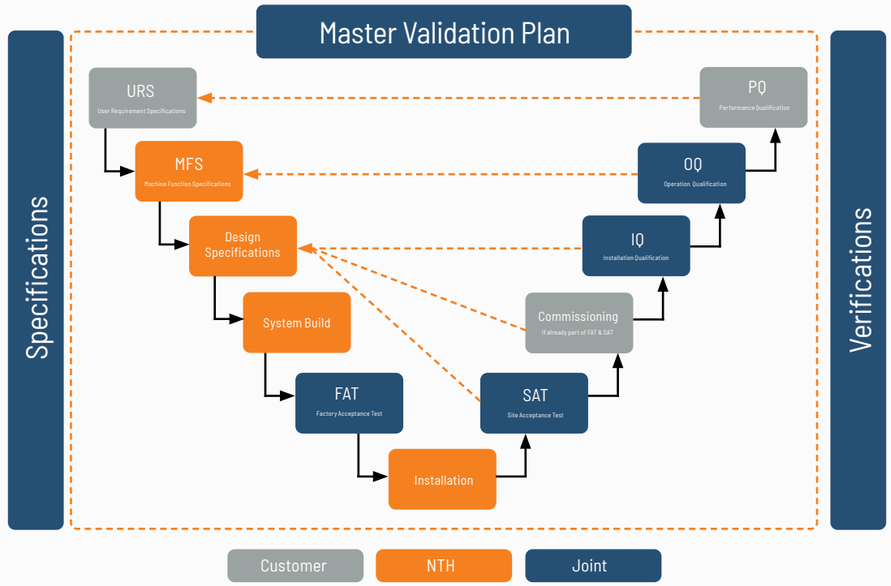
Commissioning should be considered throughout the design and construction phases of a project with a commissioning plan being developed either in design or early construction phases. The plan should identify all the steps needed to commission the facility and specialist equipment, including and Factory Acceptance Tests (FATs) and Site Acceptance Tests (SATs).



# IN-OPERATION CONSIDERATIONS

- Wayfinding and signage
- Specialist waste
- Training
- Storage
- Goods in/out and internal logistics
- Familiarisation of the tenant with the FM team

# TRADE EFFLUENT CONSENT

Trade effluent is any liquid waste that is discharged into a public sewer from a business, industrial or trade process, excluding surface water and foul drainage from domestic functions such as toilets, showers and kitchens.

Consent to discharge trade effluent must be obtained from the local sewerage undertaker for the area which will contain conditions to control the quality and quantity of discharge and may limit or require elimination of persistent or potentially harmful substances.

Liquid waste from laboratory or support areas is classified as trade effluent and requires discharge consent if it is being disposed of via the public sewer system. Typical sources of trade effluent in lab buildings include lab sinks, autoclaves, glasswash etc, and therefore most labs will require a consent. The producer of the effluent is responsible for ensuring that the consent is in place prior to discharge, and for compliance with the terms of the consent. In many cases this will be the individual tenant's responsibility, although in some cases there may be a building-wide arrangement in place.

The application for trade effluent consent should be submitted well in advance of commencing operations. For example, Anglian Water recommend making an application approximately six months before trade effluent discharge will commence. Information to be provided in the application typically includes details of the process(es) giving rise to effluent, any on-site treatment, the volume, nature and composition of the effluent, and details of the drainage system and proposed discharge point.

It should be noted that the sewerage undertaker is not obliged to issue a trade effluent consent and can refuse to accept trade effluent flows or require the effluent producer to pay for upgrades in order to accept trade effluent. For example, if the public drainage system does not have capacity for additional volume, the producer may be required to pay for upgrades to the drainage network or local water recycling centre to increase capacity before the discharge can commence. This can significantly extend the time between application and receiving consent to discharge.



# RISK ASSESSMENTS


The initial phase in making risk-based decisions relies on the completion of risk assessments, which identify, evaluate and prioritise the risks present within the facility, and enable the key stakeholders to make the final decisions on the appropriate risk mitigation measures to be implemented at the facility.

Key to this is identifying the hazards and threats, and understanding the likelihood and consequences associated with the risks prior to determining risk acceptability and deciding on the required mitigation measures. It is essential that every key stakeholder agree on the risks that need to be addressed in the overall facility, and how best to address those risks.

- Consider the introduction of a lab manager to the project early on.

In laboratories risks may stem from the following:

- The nature of the material present in the facility. For instance, a low infectious dose requirement and the severe consequences associated with infection by most viral haemorrhagic fevers (e.g. Ebola virus) are such that any work with these agents will inherently pose a significant bio-risk to laboratory personnel.
- The scientific procedures carried out. It is important to understand what procedures are routinely conducted since this can significantly affect the relative risk identified in a comprehensive assessment. For example, work conducted with an agent may be determined to represent a moderate risk, but the risk may increase if larger amounts of the same agent are routinely handled, such as in vaccine production facilities, or if work activities change that could increase potential exposure, such as if aerosolisation studies are to be conducted. Conversely, an agent that may present a relatively high risk under certain conditions may actually represent a much lower risk if smaller amounts or attenuated strains are primarily used, such as in a clinical setting.
- The risk of exposure to staff working in the facility. Some activities can increase the potential to aerosolise hazardous agents, and procedures or policies can unnecessarily place workers in contact with others who may be contagious.

- The risk to the environment or persons outside the facility. Handling hazardous materials can pose a great risk to the users as well as the surrounding community. It is the inherent characteristics of the agents and the procedures being conducted in the facility that will determine the likelihood of infection and extent of a release into the surrounding human and animal populations.
- The risk of theft of hazardous materials. An individual or group of individuals, either associated or not associated with the facility, may wish to steal materials to use themselves or to sell to others for the purposes of causing harm.
- The risk to the facility and the users from outside threats. An individual or group of individuals may wish to sabotage the facility. Historical examples include animal rights activism or other types of government or ideological protests.

Once the risks associated with the work conducted at a facility are understood and characterised, it is necessary to evaluate and prioritise the risks to ensure safe and secure operations, as well as the best use of available resources.

Determining whether a risk is high, moderate, or low, and whether the risk is acceptable or not, is a subjective process that can vary between individuals and facilities depending on local laws, culture, experiences, management perspectives and even current events.

# CONSENTS

A range of permits, licences and consents will be needed to become operational, depending on the type and range of scientific activities proposed. Given that securing consents can be a length process, they need to be scoped and enacted early. The FM/ operational management team need to consider these early and a consents tracker tool can help.

## COMMON PERMITS, LICENCES AND CONSENTS INCLUDE:

- Landlord consent - for building modifications associated with a science fit-out
- Town planning consent – for external plant and flues, ancillary functions (chemical store)
- Trade effluent licence – for waste effluent discharged from the building laboratory drainage system
- Consents and permits associated with specialist waste streams
- Home Office licence – needed for pre-clinical facilities
- NACTSO – for licenses associated with facilities with enhanced security requirements
- HSE – for specialist functions that involve hazardous environments or equipment (chemical/solvent storage, specialist gases, fume extract and exhaust systems, and activities that require DSEAR assessment

# MAINTENANCE AND FACILITIES MANAGEMENT

The maintenance and facility management of science facilities is at the core of the operational effectiveness and longevity of a facility.

# OPERATIONAL LOGISTICS

The facility viability long term is measured by a seamless ability to maintain the building systems and day to day services. It is the highest point of contention between the users and the management. While user/ tenant areas are mostly the responsibility of the user groups, the public spaces represent a 'risk' to the activities of users and a potential for crossovers and handling errors.

The logistic component in science facilities is significantly larger than the typical commercial ones. This logistic component increases the more advanced the R&D and/ or manufacturing activities are. It includes waste and storage management but also a highly regimented delivery flow, all of which requires products and tenants' separation including line clearance and control. All material flows are subject to risk assessment and regulated with Biosafety and Biosecurity drivers defining protocol. Furthermore, the dependability of building systems including cooling, electrical supply and stable IT systems is critical to research activity.

Maintaining these facilities will require a high functioning and professional management team.

A holistic and risk assessed planning approach is required for all life sciences facilities based on GCLP, GMP and GDP compliance (subject to sector and usage), striking the balance between user and public areas without risking operational needs. This requires a combination of physical and procedural planning and a periodic effectiveness assessment.

Accessibility, segregation, and programming are fundamental – while facility system maintenance, plant and equipment replacement may cause major disruption, an established strategy and planning will mitigate these issues. The main daily disruptor is the flow of goods through the facility. The operator should aim to strike a balance between prompt accessibility to materials coming in and samples / product coming out as well as optimising space usage, especially temperature-controlled rooms/ equipment. This involves an in-depth study and analysis of the warehousing and loading area zoning, and the layout will affect daily operations and the safety of the goods.

# SEGREGATION OF WASTE

It is a legal requirement to ensure hazardous waste is disposed of correctly by licensed waste carriers, meaning waste segregation is important for ensuring the correct onward disposal method is used. Additionally, the correct segregation of waste is important when considering laboratory safety and cost of disposal.

Organic and inorganic waste must also be segregated and stored appropriately prior to disposal.

Common waste streams are:

- Sharps including syringes, pipette tips
- Clinical and offensive waste including infectious, cytotoxic and anatomical waste
- Solvent/chemical waste
- Recyclable waste such as packaging materials
- WEEE

Waste streams must be easily identifiable using appropriate containers, ensuring contents of each container can be identified if required for consignment and waste transfer notes.

Standard Operating Procedures must be finalised by operators regarding the handling of all waste streams ahead of Operational Readiness and appropriate waste producer licences granted.



# WASTE STORAGE

All materials and waste flowing in and out of the building must be 'safe to touch'. In other words, it will be the users' responsibility to ensure the safety of the staff handling these materials (e.g. double bagging without contaminants on the outside of the waste etc).

In support of the proposed tenant accommodation, facilities for the safe delivery, storage and waste collection of hazardous and non-hazardous materials should be provided. Sizes for storage and waste facilities depend on the processes in the laboratories and must be further defined with the tenants for detailed space requirements.

# DELIVERIES

The design of a facility should allow for a minimum of short-term storage of deliveries that ranges from standard office consumables to pathogens and samples to hazardous materials.

The ability of the facility management team to control material flows is especially important when dealing with early-stage companies, due to their intrinsic “operational weakness”.

# MATERIALS RECEIVING

Materials and samples entering the facilities should be handled in accordance with user SOP’s and chain of custody guidance .

A clear responsibility definition is required for landlord and user responsibilities.

Items to be considered are Cold and Cryo short term storage, additional space and time frames. Levels of resilience and handling protocols will have to be developed.


# CLEANING

As they are home to R&D, clinical testing and analysis facilities, cleaning is critical in laboratories. Best practice cleaning protocols ensure hygiene standards are maintained at all times. This not only improves the accuracy, reliability and repeatability of results but heightens safety for laboratory personnel, enhances workflow efficiency and extends the lifespan of sensitive equipment and instruments.

The range and complexity of potential hazards in most laboratory environments dictates special provision for the health and safety of cleaners. Changes of cleaning staff, including supervisors, may be fairly regular, and the need for induction safety information and instruction may be significant.

Laboratories can be highly specialised, particularly within the life sciences sector. Many laboratories rely on expensive and highly sensitive equipment and instruments, which means a one-size-fits-all approach to cleaning doesn’t always work. Establishing specialised cleaning procedures for different equipment helps lab personnel choose the right methods. This simultaneously extends the longevity of equipment and improves data.

# MANAGEMENT AND BUSINESS SYSTEMS INTEGRATION

Achieving effective integrated building systems is a vital factor in assisting the operation of a successful laboratory facility. Key to achieving this success will be ensuring the right level of input and consideration to integrated systems are given from early in the design process right through to commissioning and handover.

## Benefits include:

- Providing enhanced levels of safety for the facility occupants
- Potential to improve energy management and achieve running cost and carbon savings through active monitoring and fine tuning of systems
- Reduced downtime and a more proactive approach to maintenance through quicker response times to system faults
- If a holistic approach is adopted from the outset, a more seamless integration of new equipment over the lifetime of the facility can be achieved.

# GUIDANCE FOR LANDLORDS

- Provide a building management system (BMS) which can communicate with third party BMS and user equipment through proprietary communication protocols such as Modbus or BACnet.
- For multi-tenant buildings, consider the need for multiple points of interface between tenants and the landlord systems.
- For tenants where interruption to their operation is critical, they may wish to have visibility of the operational status of landlord-installed plants, such as air source heat pumps (ASHPs), air handling units (AHUs) or heating/cooling circuit pumps. The landlord-installed BMS should be capable of providing this information via a local panel within the tenant demise without the need for major upgrade works to their BMS.
- If pursuing WELL certification, operational data must be collected and submitted annually. The embodied carbon of maintenance and retrofits must be measured and reported. Biodiverse landscaping must be managed to maintain the benefits to nature throughout the building lifecycle.
- The landlord should provide clarity around tenant interfaces, including their location, purpose and any integration requirement. This could include tenant heating/cooling metering or electrical power monitoring.
- Laboratory buildings typically operate on a 24-hour basis, often with reduced occupancy overnight. The landlord will need to work with the tenants to ensure the right safety protocols and interfaces are achieved. For example, activation of a trapped person alarm in passenger or goods lift will need to report to location which is continuously monitored by personnel either within the building or by a third-party.

# GUIDANCE FOR TENANTS

- The journey to achieving successful integrated building systems begins early in the design process. Regular reviews with recorded outcomes are recommended throughout the design stages. If the landlord design is running in parallel (e.g. if a building is being developed for a specific tenant) then the landlord design team should form part of this group.
- Understand monitoring requirements for critical laboratory equipment such as:
  - Ultra low temperature (ULT) freezers
  - Fridges
  - Isothermal vessels
  - Cold rooms
- Developing a critical alarms matrix to understand the alarm levels associated with different monitored activities and using this as a basis for forming an effective cause-effect strategy.

# IT AND AUTOMATION

Preparing for the management and IT systems integration of lab space into a shell and core project will require advanced knowledge of several key areas:

- Internet service provider availability and redundancy both within internal routes as well as site provisioning from carriers.
- System resiliency of the building network supporting key BMS systems used for critical monitoring including local and building power resiliency (i.e. UPS).
- Building provision for mobile signal coverage including site survey, and whether base station equipment has been provisioned within the building, and that system is capable of extension into tenant areas utilising existing landlord backbone cabling system.





## GUIDANCE FOR LANDLORDS

- Consideration should be given at an early project stage based on target tenant base for the scale.
- Ensuring space, resilient power, data, leak detection and cooling provisions are available for tenant comms rooms.
- Consideration of space saving opportunities for tenants by provision of risers suitable for network racking.
- Consideration for segregated tenant IT risers to suit tenant data protection and security requirements for WAN connectivity.
- Provision of landlord WAN for supporting shared spaces within the building including loading bays, bin stores and other key back of house spaces.
- Provision of space allowances on rooftop areas for future tenant network equipment
- Provision of space allowances for tenant systems

## GUIDANCE FOR TENANTS

- Enquire as to whether the building has achieved WiredScore accreditation and to which level as an indication of the overall connectivity space and redundancy provision
- Assess the resiliency of networks supporting key building monitoring systems such as the BMS (not typically covered in WiredScore assessments)

# RESOURCING REQUIREMENTS

# BRIEFING AND URS

User Requirement Specifications (URS) are lists of equipment and instrumentation requirements that enable facilities and procurement teams to review the operational needs of a user group within an organisation and purchase new equipment/ instrumentation as required.

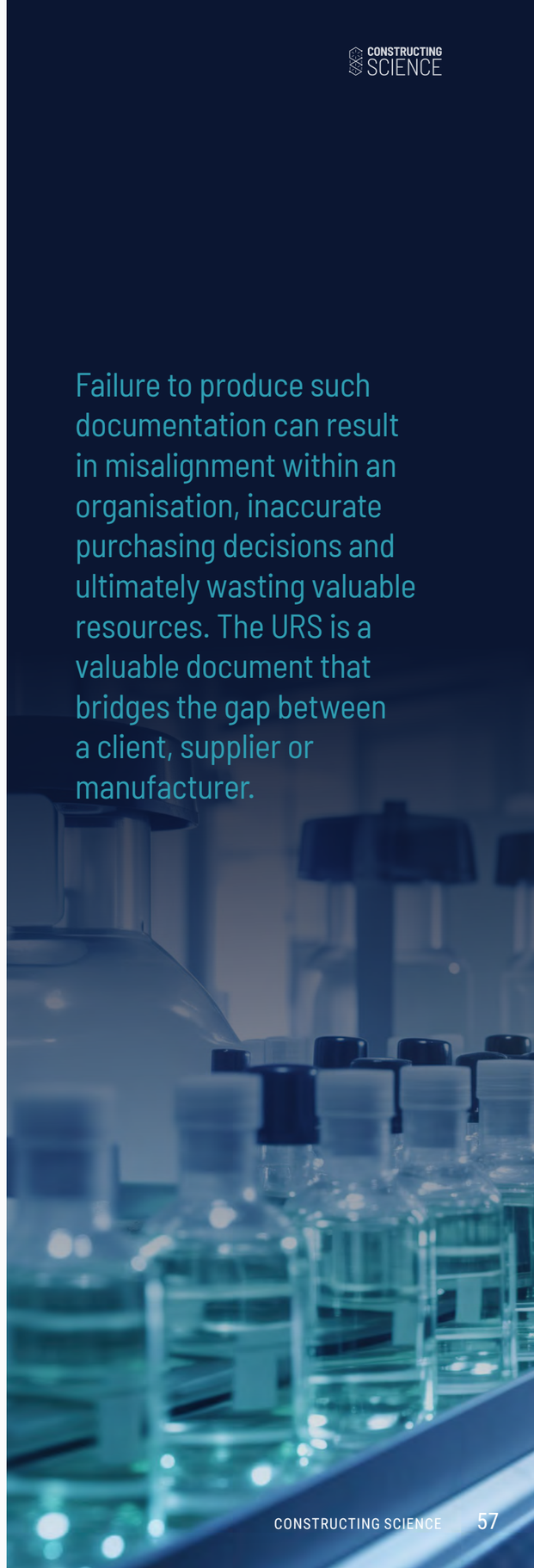
Commonly referred to as asset or capital equipment lists, a URS is typically prepared by the users, operatives and support teams from each department or workstream that frequently utilise the equipment and instruments specified.

These specifications provide a consolidated solution to support the wider operational overview of an organisation such as regulatory requirements, validation activities such as operational qualifications, install qualifications or maintenance.

Each URS includes a variety of information and data sets that are typically broken down into the following:

- Name of equipment or instrumentation
- Manufacturers serial code numbers
- Intended use and technical requirements.
- Technical capacities such as weight, volumes, and maximum loading.
- Technical space requirements such as dimensions, location, and installation requirements.
- Technical accuracy inclusive of decimal measurements, electrical; mechanical; plumbing; structural, and vibrational requirements that could affect performance. This will include compatibility of surrounding infrastructure and utility requirements associated with operations.
- Environmental accuracies and fluctuation requirements such as temperature, humidity, noise, moisture, daylight, lighting, ultraviolet, containment, pressures; electromagnetic or radioactive.
- Operational cleanliness which could affect positioning; performance; spillage or bunding.
- Technical instrument or equipment-specific requirements that are nuanced or a singularity such as rotations per minute (RPM). This includes operating times of the equipment, process-driven working shifts, and patterns of operators, calibration; software and/ or data management requirements.
- Material requirements specific to the operational needs of the equipment or instrument.
- Construction and/or contact of the instruments such as non-contact, conductive, or requirements to appropriately seal or close an item.
- Installation, delivery and commissioning.
- EHS and health and safety protocols associated with the equipment or instrument.
- Operation and Maintenance Manuals (O&M) including electrical diagrams, warranties, insurance; calibration certifications and part listings; shipping and instructions on installation and movement.

Failure to produce such documentation can result in misalignment within an organisation, inaccurate purchasing decisions and ultimately wasting valuable resources. The URS is a valuable document that bridges the gap between a client, supplier or manufacturer.



## CHANGE CONTROLS

Laboratory change control is a formal systematic management process or governance to monitor the changing requirements of laboratory operations activities such as processes, equipment and systems that may affect a procedure or service. A set of controlled, documented and authorised actions will be developed to ensure a change does not negatively impact product quality or compliance and includes the prevention of potential risks, accidents or unintentional consequences. The goal is to ensure and document a system-validated state is maintained.

When approaching change control, the following should be included in the process control.

- Regulatory submissions
- Integration of new software, building management systems and equipment management systems
- Standard operating procedures (SOPs) and lab processes.
- Records, training and qualifications of operatives.
- Management of stock, inventory and services.
- Project programmes and scheduling
- Utility and infrastructure validations

This process can be broken down into five steps of control.

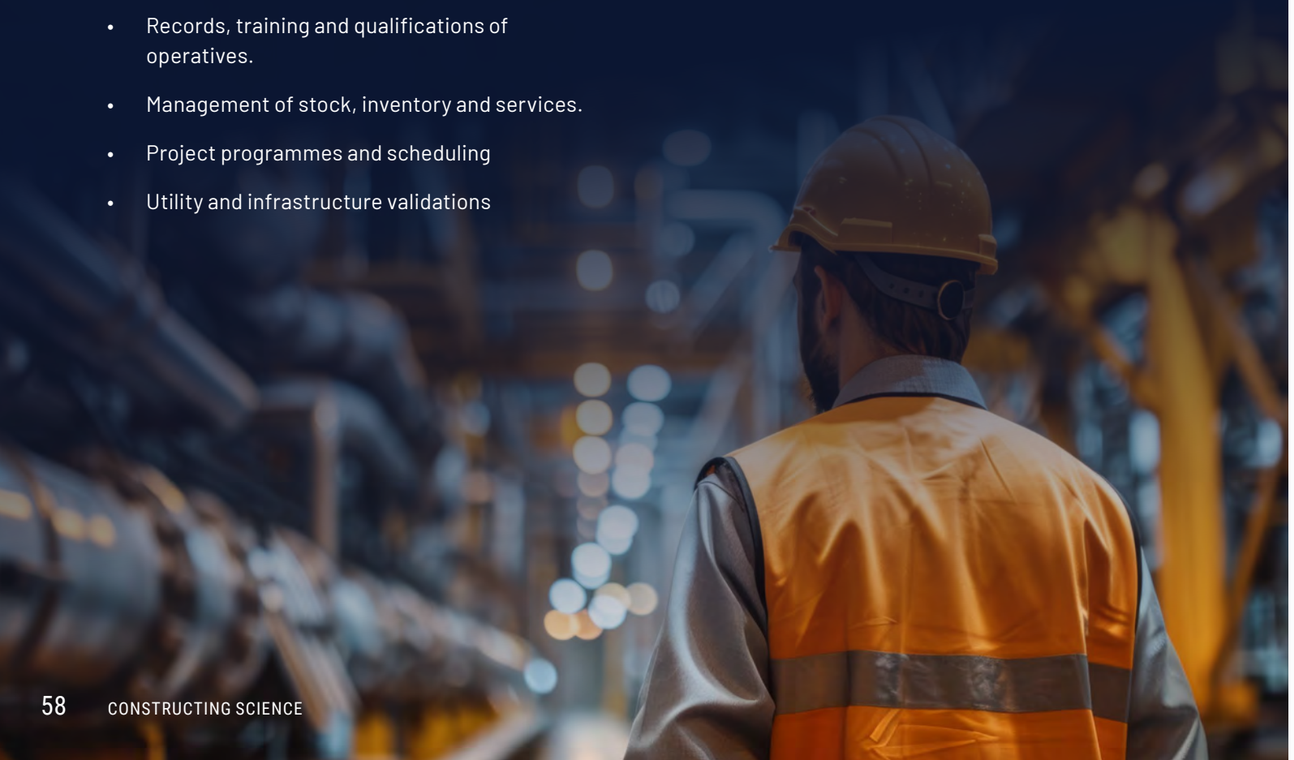
**1 Initiation**
A change request is logged.

**2 Assessments**
This change request is evaluated.

**3 Analysis**
Go No Go Process on approval of change request.

**4 Implementation**
The change request is implemented or vetoed.

**5 Complete**
The change request is closed out.







# STANDARD OPERATING PROCEDURES (SOPs) AND RISK ASSESSMENTS

The standard operating procedure is a detailed step-by-step set of instructions for performing experiments driven by routine operation requirements that involve hazardous materials (chemical, physical, biological, or radiation) or carry out experiments utilising equipment or systems that pose a hazard.

The SOP indicates the key risks associated with an activity and how these can be controlled. SOPs created by organisation personnel are specific to the lab department or tenants with those who have received appropriate training.

SOPs are a great tool to guide personnel in the right direction for completing activities efficiently and as part of a quality management process, generally improving compliance within the laboratory. SOP steps should be clear, concise and easily accessible by the operatives expected to support a process or accomplish a specific goal.

SOPs must outline the following responsibilities:

Laboratory personnel – requirements to complete appropriate training to operate within the environment or use a particular equipment type.

- Routine inspection and maintenance of the hazard.
- Record adverse events or flag non-conformance or malfunctions.
- Notification of responsible persons to act appropriately such as required cleaning or maintenance.
- Acknowledgement statements – agreement of full adherence to SOP requirements.

The Laboratory Manager

- Provide suitable information, instructions and training to operate in hazardous areas.
- Safe working procedures, calibration and decontamination procedures.
- Coordinate routine inspection and maintenance duties of all lab personnel.
- Investigate any reported problems.
- Organise the maintenance, repair or servicing by trained authorised personnel.

A SOP document needs to establish the author and have a written record of the inception of the document. Any queries that arise can be easily directed towards the appropriate operative or author. The approval process should be documented to ensure that only fully approved SOPs are live within a lab space. The final copy must be approved by the PI or Lab Manager.

The steps of an activity will need to be granular enough that someone starting fresh or learning a new process can follow them safely. Use of all equipment and materials must follow procedure, including operations and use variations. Weekly inspections and routine maintenance must be adhered to in addition to monthly cleaning and decontamination protocol.

The following hazard types are included within SOPs:

- Chemical / COSHH inventory – chemical classes and banded SOP.
- Biological hazards
- Radioactive materials and radiation equipment.
- Laser safety

Processes within a laboratory will change over time. SOPs' authors must take time to make updates as new information becomes available, recording improvements as procedures develop. Updating and improving SOPs should become a fundamental part of the lab culture. SOPs will need to be reviewed and updated for approval. A revision note must be applied to every document to ensure the latest version is being viewed with all appropriate reference literature.

SOPs must be kept on-site / within the premises of the activity. Routine inspections may request the visibility of the SOP with copies of the documentation available. To optimise the SOPs' use, the process should be broken into sections with specific steps and bullet pointed for clarity to support user.

The following information should be provided within the SOP and following ISO & BS Standard requirements.

- Administrative information about the facility/ department
- Identification of the procedure – title / ID numbers / versions / revisions
- Author
- Page numbers
- Safety instructions
- The date of issue
- Individuals involved in documenting and approving SOPs
- Reviews, approvers and functions

Some laboratories will include health and safety information within the body of the main SOP whilst others may provide a separate document focused on safe operations. Risk assessments must be delivered to all personnel responsible for working within a lab space with hazards. A hierarchy of safety controls is a good way of determining which actions will minimise risk and best control exposures.

The five levels of safety control hierarchy are:

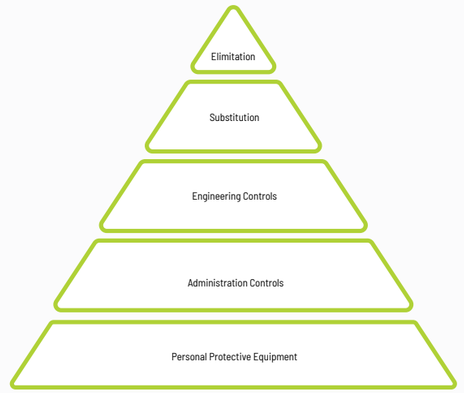
### 1 Elimination
Physically remove the hazard.

### 2 Substitution
Replace the hazard or operational type.

### 3 Engineering controls
Go No Go Process on approval of change request.

### 4 Administrative controls
Advise different ways of operatives working.

### 5 Personnel Protective Equipment
The change request is closed out.



# QUALITY ASSURANCE

Quality Assurance (QA) is integral to a laboratory process whereby close monitoring or supervision of the practice, process or function is undertaken to take course corrective measures as required to ensure the quality of the output is maintained throughout its cycle.

Quality assurance is a systematic approach with responsibilities of ensuring health and safety, quality of the environment, research and products inclusive of procedures such as SOP and risk assessments, clear lines of communication, record archive tracking and training for team members.

Quality Management Systems (QMS) can be adopted within laboratory facilities to monitor internal and external requirements. QMS data sets provide an easily accessible library of information that can be shared with periodic auditors or inspections as required.

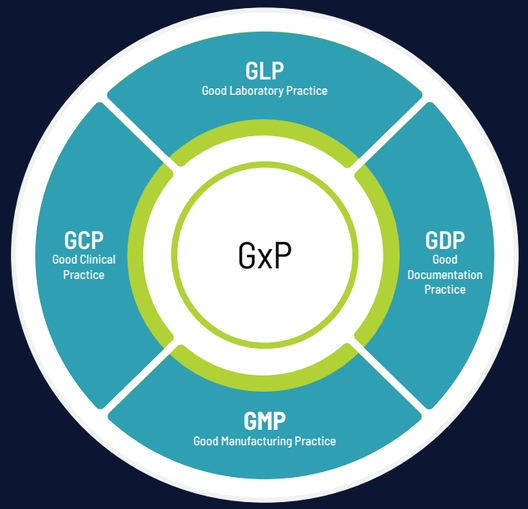
A comprehensive QMS includes trackable changes of all controlled procedures; clearly defines SOP and risk assessment documentation and authenticates requirements for agencies such as the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA) or US Food and Drug Administration (FDA).

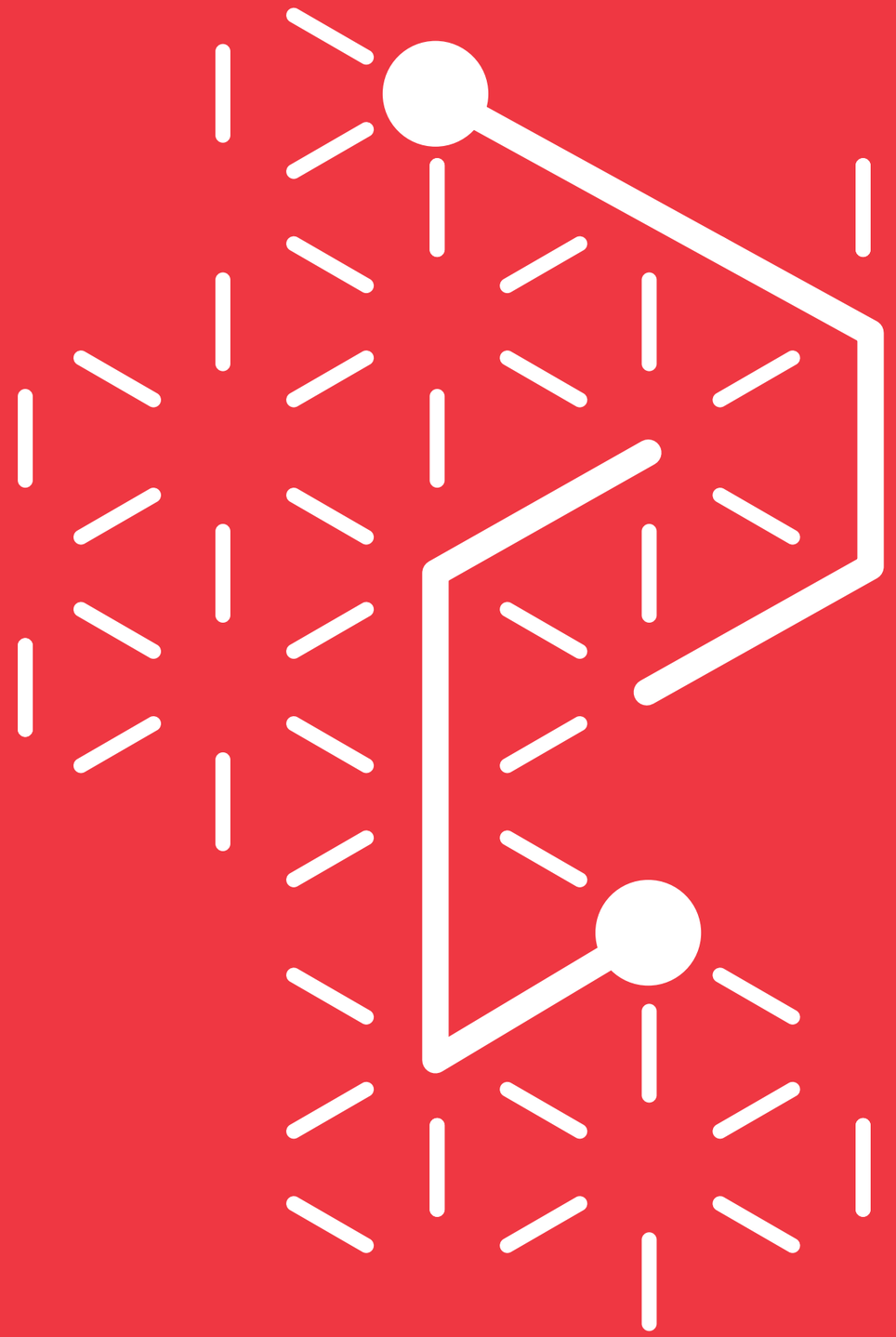
GxP refers to an umbrella of good practice guidelines and quality assurance regulations to ensure life science products; pharmaceuticals; medical devices; food and beverages and cosmetics are safe for living organism use. The 'X' within the acronym merely exchanges depending on the discipline requirement. Adhering to GxP guidelines ensures suitable use and public safety, and reinforces the ethical positioning and law-abiding requirements.

The merits of GxP compliances allow for improvements to precise and benchmark data sets, high product quality and safety, improved efficiencies and streamlined processes, continuous improvements in QMS, and ultimately competitive market access.

The following good practice falls under GxP:

- Good laboratory practice (GLP)
- Good manufacturing practice (GMP)
- Good clinical practice (GCP)
- Good documentation practice (GDP)





# GLOSSARY

| | |
|---|---|
| Factory Acceptance Tests (FATs) | Factory Acceptance Tests are a series of tests and inspections conducted at the manufacturer's facility to verify that equipment or systems function correctly and meet specified requirements before they are shipped to the customer. |
| Site Acceptance Tests (SATS) | Site Acceptance Tests are similar to FATs but are conducted at the customer's site after the equipment or system has been installed. SATs ensure that the equipment functions correctly in the actual operating environment. |
| Quality Management Systems (QMS) | Quality Management Systems are formalized systems that document processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organisation's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. |
| Standard Operating Procedures (SOP) | Standard Operating Procedures are detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are essential for ensuring consistent quality and compliance. |
| Medicines and Healthcare Products Regulatory Agency (MHRA), | The Medicines and Healthcare Products Regulatory Agency is a UK government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. It regulates the manufacture, distribution, and supply of these products in the UK. |
| The European Medicines Agency (EMA) | The European Medicines Agency is a decentralised agency of the European Union responsible for the scientific evaluation, supervision, and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. |
| US Food and Drug Administration (FDA) | The US Food and Drug Administration is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, and cosmetics. |
| Personnel Protective Equipment (PPE) | Personnel Protective Equipment refers to protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection. PPE is used in various settings, including healthcare, construction, and manufacturing. |
| Exhaust Ventilation (LEV) | Local Exhaust Ventilation is an engineering control system designed to reduce employee exposure to airborne contaminants such as dust, mist, fumes, vapou0&Mrs, or gases in a specific location. LEV systems capture contaminants at or near the source and exhaust them outside the work area. |
| Operation and Maintenance Manuals (O&M) | Operation and Maintenance Manuals are comprehensive documents that provide detailed instructions on the operation, maintenance, troubleshooting, and repair of the constructed asset, equipment or systems. These manuals are essential for ensuring longevity and efficient performance. |
| Hazard Identification HAZID | Hazard Identification is a systematic process to identify potential hazards that could cause harm to people, property, or the environment. It is the first step in the risk management process and involves recognising all the hazards associated with a particular activity or process. |

| | |
|---|---|
| Hazard and Operability HAZOP | Hazard and Operability Study is a structured and systematic examination of a planned or existing process or operation. The HAZOP method is used to identify and evaluate problems that may represent risks to personnel or equipment, or prevent efficient operation. It focuses on identifying deviations from design intent and their possible causes and consequences. |
| Process hazard Assessment (PHA) | Process Hazard Assessment is a systematic approach to identifying and analysing the potential hazards associated with the processes. The goal is to understand the risks and implement measures to prevent accidents and ensure safe operations. |
| Functional safety | Functional Safety pertains to the part of a system's overall safety that depends on the correct functioning of safety-related systems and other risk reduction measures. It involves the automatic protection system that mitigates hazardous events. |
| Safety integrity level (SIL) | Safety Integrity Level is a measure of safety system performance, in terms of the probability of failure on demand. It is used in the context of functional safety standards and denotes the required risk reduction level provided by a safety function. |
| Layers of Protection Analysis (LOPA) | Layers of Protection Analysis is a risk management technique used to evaluate the risk and effectiveness of various protection layers in place to prevent or mitigate hazardous events. LOPA involves a semi-quantitative analysis to ensure that the layers are adequate to reduce risk to acceptable levels. |
| As low as reasonably practicable (ALARP) | As Low As Reasonably Practicable is a principle in risk management where risks are reduced to a level that is as low as reasonably practicable. This involves balancing the cost and difficulty of risk reduction measures against the benefits of risk reduction. |
| So far as is reasonably practicable (SFAIRP) | So Far As Is Reasonably Practicable is a legal standard used in health and safety legislation. It requires that measures to control risk should be taken to the extent that they are reasonably practicable, considering the severity of the risk, the state of knowledge about the risk, and the cost and feasibility of risk reduction measures. |
| Building Services Research and Information Association (BSRIA) - www.bsria.com | The Building Services Research and Information Association is a UK-based association providing research, consultancy, test, and training services in construction and building services. BSRIA focuses on improving the built environment through advanced research and providing authoritative information and guidance. |
| User Requirement Specifications (URS) | User Requirement Specifications are detailed documents that outline the requirements of the end-users for a system, product, or process. URS documents describe what the users need and expect from the system, including functional and performance criteria. |
| COSHH | Control of Substances Hazardous to Health is a UK regulation that requires employers to control substances that are hazardous to health. This involves assessing the risks, implementing control measures, and ensuring that exposure to hazardous substances is adequately controlled to protect worker health. |

# CONCLUSIONS

Operational Readiness is a crucial process that marks the end of the facility design and construction phases and the shift to an operational phase. It is a discrete stage of the project that entails all preparatory activities necessary to ‘ready’ the space and systems for science work to start.

This includes the recruitment and training of operational staff, the development and adoption of operational practices and safety protocols, equipment/system relocation, purchase and installation, commissioning, qualification and validation, and stocking of the facility for daily use. It is important that the program, resource, and cost implications of Operational Readiness are included within overall project planning.

Operational Readiness requires a close project management regime, due to the interrelationships between a number of different workstreams. It is essential that every key stakeholder agrees on the risks that need to be addressed in the overall facility, and how best to address those risks.

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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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## CUSHMAN & WAKEFIELD

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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## EEDN

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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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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 pharma 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.

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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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The business activities of LBIC clients include gene and cell therapy, drug discovery and therapeutics, medical diagnostics and med tech, clean technology, analytical services and consultancy. LBIC's excellence in operational service provision in bioinnovation has enabled it to develop strong brand recognition, and the endorsement and reputation of the RVC contribute to LBIC's unique value proposition, providing a strong platform for its future planned expansion.

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CONSTRUCTING SCIENCE