
# Where Did My Bench Space Go?

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Imagine you've been handed the keys to your new lab, you walk in and realise your equipment isn't  where it's supposed to be, you don't have the required  utilities and there isn't enough bench space.  isn't? correct, or required

**How could it go so wrong?**

Now imagine you're a maintenance technician and you need to change a filter on a HVAC, in a plant room where the HVAC is mounted 6m in the air with no access platform and the hatch is covered by fire services.

**How did this happen?!**

Time and time again, after a project is handed over from a builder to the client, **there are ‘teething issues’ as the client moves into the building**. These issues often arise as an operational mindset is not applied at the design stage.

By including a range of subject matter experts (SMEs) during the design phase this **ensures that all the operational requirements are considered**. Now this doesn’t mean include a range of different scientists. This means including a panel of SMEs – e.g. representatives from the lab, maintenance, warehouse, QC, QA, equipment preparation, IT, security teams etc.

Before we start asking how we can improve the outcomes, **let’s talk about lab and cleanroom design principles**.

Depending on the type of lab or cleanroom, there a **number of different design guidelines, regulations and standards** architects, engineers and builders need to follow.

For example, **for a PC2 lab**, the two key standards to follow include, the guidelines and checklists for certification of PC2 Facilities under the Gene Technology Act, regulated by the Office of the Gene Technology Regulator (OGTR), also see OGTR Guidelines for Certification of a PC2 Lab, version 3.2 published in 2013, and the Australian New Zealand Standard AS / NZS 2243.3:2022 Safety in Laboratories - Microbiological Safety and Containment.

For **cleanrooms**, ISPE have published several guidelines which are globally recognised, and depending on the local regulating body (i.e. TGA, EMA or FDA), there are additional requirements and regulations – for example, PIC/S guidelines are followed in Europe and Australia.

Another example is **radiopharmaceutical labs and manufacturing**. These facilities follow another set of standards and regulations set out by the Internation Atomic Energy Agency (IAEA) and for Australia, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Ultimately, what this shows us is that **labs and cleanrooms are complex spaces** based not only on user requirements, by on local and international rules and regulations.

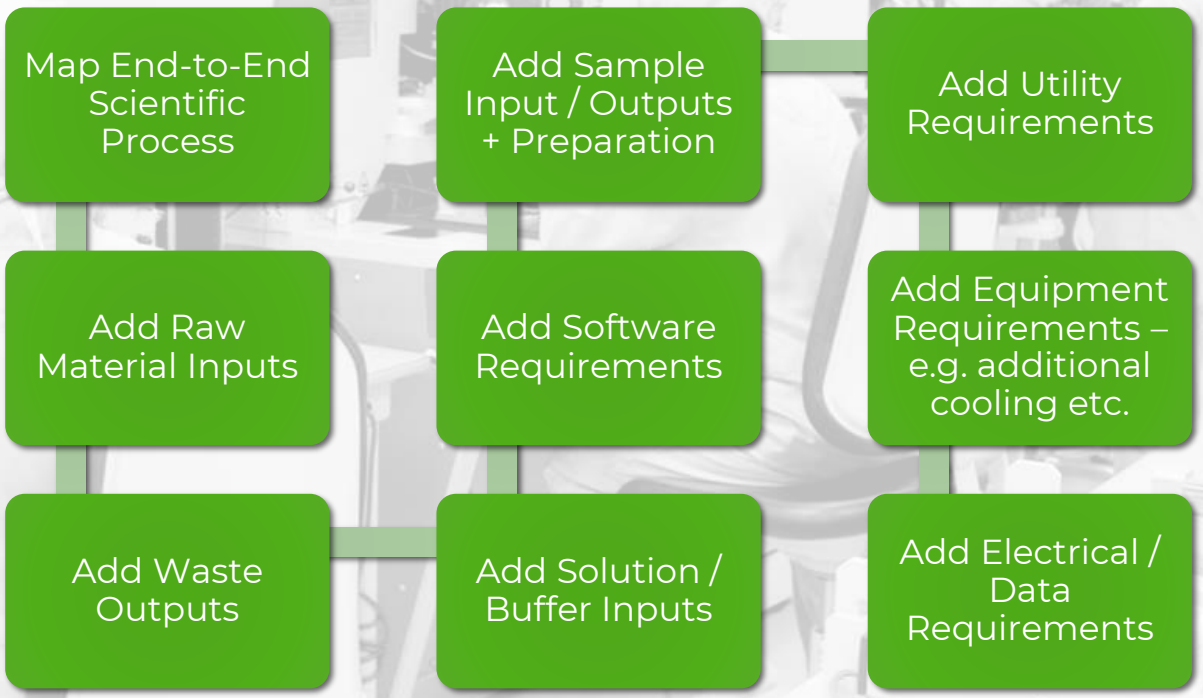
Balancing the regulations with user requirements and expectations can be an intricate process.

So, let’s demystify and simplify how we can improve client outcomes.

# Process Mapping

Before an architect puts pen to paper, the most important activity a project team can do is **create a simplified process map** for the lab or cleanroom operations.

This takes the team back to basics and ensures that everyone understands the process from start to finish. However, note that, project teams usually only look at the lab or cleanroom process rather than the holistic operational process. **For these to consider all facets of operations, process maps should follow these key steps**:



Other considerations that can be added, but may not necessarily be known from the start:

- Documentation and training requirements
- Maintenance / accessibility requirements
- Cleaning requirements
- Validation and/or revalidation requirements
- Storage and warehousing requirements – specifically for consumables & warehousing sizing
- Transport requirements

By creating a process map that considers all the peripheral activities, this gives the architect and project team a holistic view of the process, which in turns, allow them to design a more appropriate facility for the client.

This central process map is used to build the user requirement brief for the facility; however, it is only step one. To ensure that the facility has all the relevant areas, a process map should be created for the following business areas:

- Operational Support Team – e.g. equipment washing and preparation (autoclave), buffer preparation, cleaning etc.
- Engineering & Maintenance Team
- IT & Digital Team – including the Automation Team
- Security Team
- EHS Team
- Warehouse Team
- QC Team (if not included in the lab mapping)

Each one of these teams will have their own process/es and lab/area requirements that needs to be considered when designing a facility.

For example, the **engineering team might need a dedicated engineering warehouse** for utility spare parts or the **QC team might need a sample receipt area** or a dedicated incubator room for sample plates. The **warehouse team might need spaces to segregate waste**, while the IT team may need a significant amount of **space for networking equipment**.

Each one of these requirements takes up a portion of space, and with each addition required by a support function, this takes a section of bench space away from the scientists.

But in reality, there is no science without the support functions!

Once the process mapping activity is complete, **the initial layouts can commence!**

This is where the fun begins.

# Facility Layout & Design Principles

With adaptive reuse projects trending more and more in life science, healthcare and universities, this stage of the design phase can be tricky, especially if the space isn't an easy shape or on a single level.

Other trends that may add to the complexity of facility design, include:

- Open plan lab spaces, with shared utilities
- Shared cleanrooms for multi-products
- Scaling out rather than scaling up
- Flexible and adaptable work-spaces
- Green labs and sustainable designs
- Increasing lab digitalisation, including AI, automation, robotics and machine learning

Although exciting, incorporating all these trends can lead to an expensive fit-out!

It's at this stage where client's need to develop their project design principles which should align with their highest priorities requirements for their lab or cleanroom.

Some examples of design principles may include:

- Labs must have a clear light of sight
- Labs must be designed to handle biological materials
- All furniture must be easily moveable and cleanable
- Maximise storage space while ensuring easy access to materials and equipment
- All surfaces must be easy to clean and disinfect
- Labs must be energy efficient, use lighting control and water saving fixtures
- Collocating equipment into 'hubs' – e.g. freezers or mass specs in one room

Coupling the design principles with the layout, assures alignment between the client and project team, keeping the lines of communication open and transparent, ensuring the best result for all parties.

# Once a first pass of the layout is complete, **it's time for the operational review.**

At this point, the team combines the process map and the layout to confirm that what has been designed is functional for operations.  However, it doesn't stop there. The layout needs to be reviewed by all the relevant SMEs – engineering, warehouse, QC, security, EHS etc. This ensure that there are no surprises later on.

Additionally, at this stage, the builder should also be involved. By engaging with the operations and trades early, this ensure that the facility is operational, again, reducing the risk of variations later during construction. This model is called an Early Contractor Involvement (ECI) model and is becoming more popular with projects on tight budgets and short timelines.

After an initial review of the layouts, some of the frequently provided feedback and questions includes...

- Where is the workshop for the maintenance team?
- The QC lab needs to be segregated, especially for the micro lab
- There has been little to no allowance for technical spaces or service risers
- There are no cleaner's cupboards or low drain points for mop buckets
- There isn't ensure space in the warehouse to store incoming goods
- There is no space to stage or segregate waste into streams (e.g. chemical waste) – this comment can be applied to both the labs and the warehouse space
- Where is the security office? Or reception?
- Where will the automation racks go? And IT infrastructure?
- Do you need a generator or UPS? Where will this go?
- How are we going to wash bins? Do we need a bin washer?
- There aren't enough offices or meeting rooms
- Should we have hot desks or dedicated desks?
- Are there enough lockers for staff?
- The end-of-trip facilities need to be bigger
- Do we have enough parking?

The theme seen with a lot of these questions are surrounding support services. Usually, when a layout is complete, the focus is really on the scientific process and cleanroom / lab design meeting the relevant standards. All the other peripheral requirements are added later.

This does mean that some of the useable lab space is lost to things like:

- Internal cleaner's cupboards
- Waste storage areas
- Utility risers & return ducting
- Material and personnel airlocks / gowning rooms
- Consumable and chemical store rooms

When considering your lab requirements, don't just start with the scientific process in isolation. Too many times, clients have been disappointed because they assumed that had 1000 sqm of space, but it turns into 600 sqm once you add all the peripheral service requirements.

By following this three-stage approach to your initial design:

- Holistic Process Mapping
- Initial Facility Layout and Design Principles
- Operational Review

This ensures that all facets of the process are considered and all SMEs are consulted, from initial raw materials in to final product and waste out.

# Let’s Collaborate!

**EngCor** are **action-orientated, result-driven** engineers who are technical specialists in **process design and life science operations**. We focus on projects, so that clients can focus on operations.
With **10+ years’ experience in capital project delivery and R&D operations**, our services range from GMP / lab projects and operational readiness, utility process design, outsource service preparation and mobilisation, project control and **end-to-end project management services**.

Examples of Services we provide the following services to food, beverage and life science industries:

- Project Management, including capital and operations
- Process Design for utilities and equipment
- Operational Planning and Strategy
- Operational Change Management Strategy Development and Implementation
- Document and Training Preparation
- Alarm Management and Rationalisation
- Outsource Mobilisation including Scope and Contract Preparation
- Asset Management Strategy and Data Preparation
- CMMS Mobilisation

We have a passion for streamline processes and driving efficient operations. Reach out to us at admin@engcor.com.au to schedule a **free call** or visit our website at engcor.com.au

Thanks for reading!

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| Acronym | Definition |
|---|---|
| **AI** | **Artificial Intelligence** |
| **ARPANSA** | Australian Radiation Protection and Nuclear Safety Agency |
| **AS/NZS** | Australian Standard / New Zealand Standard |
| **CMMS** | Computerised Maintenance Management System |
| **ECI** | Early Contractor Involvement |
| **EHS** | Environment, Health and Safety |
| **EMA** | European Medicines Agency |
| **FDA** | Food and Drug Administration |
| **HVAC** | Heating, Ventilation and Air Conditioning |
| **IAEA** | International Atomic Energy Agency |
| **ISPE** | Internation Society for Pharmaceutical Engineers |
| **IT** | Information Technology |
| **OGTR** | Office of the Gene Techology Regulator |
| **PC2** | Physical Containment, Class 2 |
| **PIC/S** | Pharmaceutical Inspection Co-Operation Scheme |
| **QA** | Quality Assurance |
| **QC** | Quality Control |
| **SME** | Subject Matter Expert |
| **sqm** | Square Meter |
| **TGA** | Therapeutic Good Administration |
| **UPS** | Uninterrupted Power Supply |
| **WFI** | Water for Injection |

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