

# Pharmaceutical API Plant

Designing a concept Lab Design from a green field site

## Challenges and Objectives

Our client, a global pharmaceutical corporation, is overseeing the build of a multiproduct API facility in the Far East which will be capable of manufacturing their current and future product portfolio.

The requirement is to develop a concept design for a QC laboratory with optimum internal layouts within a defined footprint i.e., what is the best layout and flow sequencing for that footprint which will give the best optimal returns from an efficiency perspective.

The concept designs need to include flexibility such as configurable and reconfigurable benches, flexible work areas, cells and work surfaces that will be the norm in the lab design of the future. The new plant needs to be configured for faster turnarounds, shorter campaigns from small to medium volume throughput. The Lab will incorporate high containment, micro, environmental and development testing requirements.

A further goal of this project is to design the lab areas to support the key Lean principles of levelling, flow & standard work, 5S and visual management and to minimize 'transport' and 'motion' wastes and optimise space utilisation.

Applying Lean in a Laboratory shifts the focus of improvement initiatives from individual tests or activities to the flow of samples and data through the total lab process. It uses 'levelling' techniques to address workload volatility and generates flow by creating 'defined test sequences' that move samples quickly through all required tests and reviews. Test activities are combined into balanced, productive, repeatable analyst roles that use people's time well (standard work). A lab design and layout that actively supports these principles will increase the effectiveness and sustainability of the Lean processes.

## Approach

The project incorporated a series of virtual workshops with the client's internal team and support staff both in Europe and in the Far East together with an analysis of a 5 year manufacturing plan and all relevant testing requirements and production data. A set of master data was accumulated for the new facility identifying the process steps, lots, demand, capacity, utilisation, lead

times, cycle times etc. from a manufacturing perspective and matching of existing lab testing schedules to the new facility. Over 360 documents relating to product build and testing were made available to our team.

We incorporated the following Lab design considerations in the development of the different layout options:

- Designated areas and wall space for visual management displays and huddle meetings.
- Internal walls and lab separations.
- Space for visual sample queues.
- Central location of equipment that will be shared within a lab.
- Open or glass fronted cabinetry and shelving to promote good housekeeping and support 5S activities.
- Central storage locations.
- Managers and supervisor office(s) locations.
- Data entry / review desks integrated into the test area.
- Space and equipment requirements calculated based on levelled demand rates.
- Use of limited number of shared 'hot desks' for non-test and project tasks.

High level Value Stream maps (current and future state) were developed for their existing lab processes which were used to identify constraints and improvement opportunities for the new layouts.

## **Project Output**

A dynamic capacity model was built to determine the resources required to support the QC laboratory testing based on the manufacturing plan for the period 2023-2028 and applying different lead-time throughput scenarios. This model enabled the team to identify all test equipment and analyst resourcing requirements and highlight the spikes and troughs in the demand for all key resources. It identified capacity constraining equipment that required most attention which then enabled the team to design a layout that ensured maximum efficiency of those pieces of equipment. With the help of the modelling, it assisted the validation of Capex investment required to meet the needs of the test laboratory and avoid unnecessary investment.

Value Stream Maps were completed of the QC testing process and this helped to establish critical constraints for consideration in layout design. A series of layout concepts for the QC laboratory were then presented that would support the testing requirements and future opportunities for growth.

A final concept layout was agreed and was fed back to the client project management team for further consideration. The final concept Lab layout incorporated the following key characteristics:

1. Support of levelling, flow, and standard work.
2. Support of effective use of time.
3. Minimized transport and motion wastes.
4. Minimized space and equipment requirements.
5. Maximised future configurability/future proofing.
6. Foster Lean behaviours and communication.
7. Support excellence in workplace organisation.
8. Support post COVID 19 regulations e.g., bench spaces, resource allocations and appropriate shift patterns.