

Incorporating Lean Principles into Pharmaceutical QC Laboratory Design:

building design influencing laboratory behaviours and effectiveness

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1. Introduction

Tanya Scharton-Kersten, Global Head of QC Laboratory Management, Novartis Vaccines and Diagnostics



Figure 1: NVD Lean Lab program overview

In 2010, the Novartis Vaccines Division (NV&D) began a structured implementation of Lean principles in its Quality Control laboratories with the aim of significantly improving internal work processes, communications, customer interfaces and operational performance. Analysts have been trained in basic Lean principles, followed by introduction of 5S for laboratory organization, Visual Management for daily and weekly performance review and finally gradual implementation of effectiveness tools for capacity management and budget processes.

Lean principles were applied in both older legacy facilities and newer state-of-the art facilities. Throughout the Lean Lab program in NV&D it was clear that laboratory design and layout has a strong influence on processes, behaviors and communications. Some designs proactively support lean practices including flow, visual management, standard work and excellence in workplace organization. By contrast, other laboratory designs can require extra time and resource (waste, discourage communication and even impede work flow through the laboratory).

Based on our observations, and with the aim of improving future laboratory design, we developed a comprehensive set of laboratory layout and design guidelines that actively support lean principles and best practices in laboratory operation.

These guidelines were reviewed and refined at an intensive two day workshop on lean laboratory design which included over a dozen participants representing Novartis stakeholders from several different divisions and invited industry representatives. The workshop included submissions and presentations by Novartis participants representing laboratory management, QC analysts and engineers and from recognized industry leaders in lab design and in the application of Lean in laboratory environments. The workshop incorporated breakout and working sessions to develop Lean Lab design guidelines and a re-design exercise for a planned new Novartis laboratory facility (a case study).

This paper presents the main themes and outputs of the workshop including: A Lean vision for QC environments, analyst 'voice of the customer' feedback on existing designs, interpretation of Lean design by three major design-architect companies, Lean design recommendations and guidelines for achieving the Lean vision and workshop feedback.

The guidelines are applicable to existing legacy laboratories (traditional and open space design), renovation of existing laboratories and design of Greenfield laboratory locations. Considerations included generating a common understanding of lean practice in the laboratories and then identifying design features that foster proactive communication, optimize data-information flow and support effective work practices.

2. Lean and Lean in Laboratory Environments

Tom Reynolds, Operations Service Director, BSM Ireland Ltd

2.1 What is Lean?

Lean was first developed in the Japanese automotive manufacturing sector but has since migrated across the globe and into every sector of industry.

It is usually defined as the 'elimination of waste' where waste ('Muda' in Japanese) is anything above the minimum effort, time, resources, movement, materials and space required to add value from the customer's perspective. However this is only a partial definition. The real intent of Lean is to maximize value by minimizing all wasteful practices. This of course includes Muda (i.e. the waste within Processes) but also;

Mura – unevenness (workload volatility)

Muri – overburden (over loading of people or equipment)

Mura and Muri are especially significant in lab environments.

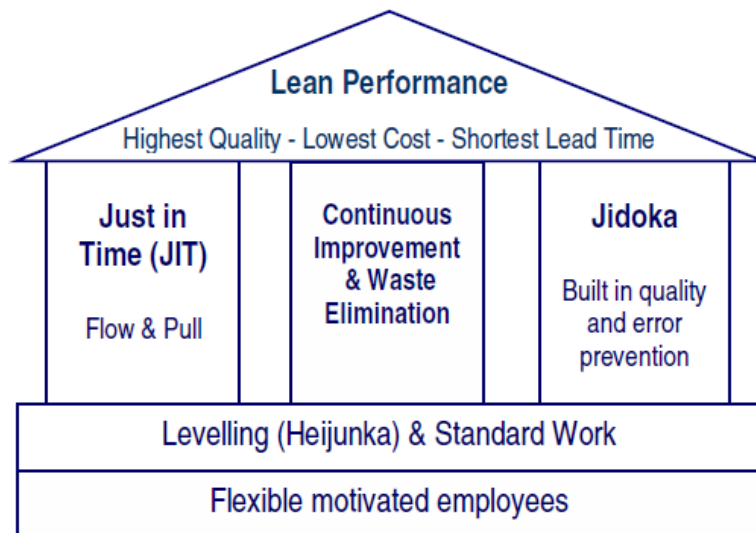


Figure 2: The House of Lean

The principles of the Lean are often illustrated as 'the House of Lean'. The roof represents the goals of Lean, the pillars are the critical 'Lean Practices' required to achieve those goals and the foundation blocks are the key enablers that allow the lean practices to be effectively implemented. For example, Leveling and Standard Work are essential enablers for moving to flow and becoming truly Lean.

Eliminating waste from a leveled flowed lab process, instead of at isolated points creates labs that require less human effort, less space, and less time to add value at less cost with fewer errors and failures than traditional labs. Lean labs are also able to respond to changing customer priorities with fast throughput times.

2.2 Lean in Lab Environments

Laboratories are not the same as manufacturing environments but Lean can and should be applied. The key principles of Lean still apply but there are some unique challenges involved in implementing them in laboratories. However, careful adaptation of the techniques based on a thorough understanding of laboratory processes will deliver significant benefits in terms of productivity or speed or both.

In most laboratories, short term volatility (in overall workload and in the mix of sample types) is by far the biggest lean opportunity. This volatility causes low productivity (during lulls) and/or poor lead time performance (during peaks). Very often the capacity of the lab is not well understood and there is no mechanism to level the workload coming into the lab. If left unchecked this volatility results in the consumption of excess resources and valuable lab space. Lab processes also become stressed leading to constant re-prioritization and 'stop start' progress on individual projects or samples. This reduces effectiveness and adds waste. The rate of failures and rework also often increases. In short Mura (volatility) creates Muda (waste).

Poor utilization of analyst resources (usually in the form of volatility and imbalance in individual analyst workloads) is usually the second largest lean opportunity. Leveling, flow and standard work allow the development of 'productive roles' for the more routine work elements in a lab. Doing the routine well and in a productive manner allows more time and resources to be spent on less routine but more valuable development activities.

Lean in the lab 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 'leveling' 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

3. Lean Laboratory in Practice

Tanya Scharton-Kersten, Novartis & Tom Reynolds, BSM

Prior to the workshop, Novartis and BSM experts had identified and consolidated initial concepts around various elements of laboratory design including: Facility layout, area adjacencies, shared utilities/equipment, consumable storage and access, furniture and equipment layouts. The concepts were presented at the workshop and refined by the multi-functional team in attendance. The original concepts for layout and bench design were validated during the meeting and a new three zone concept for test-review-collaboration emerged based on a review of design options and a case study exercise facilitated by our internal engineering team. The final concepts endorsed by the workshop participants are summarized below.

The Vision: Laboratory areas should be specifically designed to support the key lean principles of Leveling, Flow & Standard Work, 5S and visual management and to minimize 'transport' and 'motion' wastes and optimize space utilization.

Vision to Practice:

- Less internal walls and lab separations (to facilitate sharing of workloads, equipment or resources) 'Open space' design is the baseline unless there is a specific need for a controlled environment. Where separations are required for technical reasons the preference is to use glass to allow visualization of the activities inside.
- Incorporating designated areas and wall space for visual management displays and huddle meetings.
- Incorporating space for visual sample queues (based on the physical samples and/or test documentation).
- Use of Sample centric and / or Test centric cells and cellular bench arrangements (U,L H, Comb & Spline).
- 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.
- Three point consumable storage system:
 - One large central storage location for all QC/micro,
 - Medium sized regional shared central storage close to users,
 - Limited storage with less than one week storage at point(s) of use.
- Manager and supervisor office(s) located within each laboratory with limited glass partitions for visibility and privacy of conversation.
- Data entry / review desks integrated into the test area to support 'real time' data entry and reviews.
- Space and equipment requirements calculated based on leveled demand rates.
- A move away from personal ownership of equipment, bench space or desks.
- Use of a limited number of shared 'hot desks' for non-test and project tasks. In addition to routine testing workloads, labs usually have significant amounts of non-test and project tasks. It is best practice not to mix routine testing and non-test or project tasks in the same working day but also to rotate individuals between testing roles and non-test and project tasks. The use of a limited number of hot desks re-enforces lean behaviors and provides an appropriate space for the specific type of work analysts are involved in on any particular day.

4. The Voice of the Customer

Deborah Bravi (Analyst, IQP Blackbelt), Shirin Heuser (Analyst, Continuous Improvement Manager) and Pamela Thurtle (Analyst, Continuous Improvement Manager), Novartis Vaccines & Diagnostics

The analysts working in a laboratory are key customers of the Lab Design process. We wanted to understand analyst opinion on existing lab designs so that any concerns and operational issues identified could be incorporated into the workshop discussions and the Lean Lab design guidelines.

To this end, a survey to gather feedback on existing laboratory designs was distributed widely to the Quality Control community across several NV&D sites. The scope of the survey included the layout of the rooms, lab furniture configurations and equipment placement. The associates were asked to provide feedback on design elements they liked and/or that worked well and those that were not preferred. They were also asked for their inputs on how to improve the design of future laboratories.

The responses clearly indicated a preference for open space layouts with rooms that are easy to move around in and have good natural light. In addition the placement of equipment to enable sharing between different laboratories was highlighted as an advantage as was the capability to configure dedicated work areas for specific tasks with all the necessary materials and equipment close by. Another consistent theme in the responses was the advantages of having QC laboratories co-located in the same building-structure.

Highlighted issues included perceptions of imbalance between test execution benches and writing spaces inside the laboratory. There was a strong interest in the availability of network connections, particularly with the progression to paperless/electronic systems. Accessibility of consumable and reagent storage locations and improvements in flows through gowning areas/lockers were also raised as issues.

There were also concerns raised regarding the positioning of some Visual Management boards, which were sometimes positioned too close to doors or in small corridors and/or not always readily accessible to the analyst and/or managers.

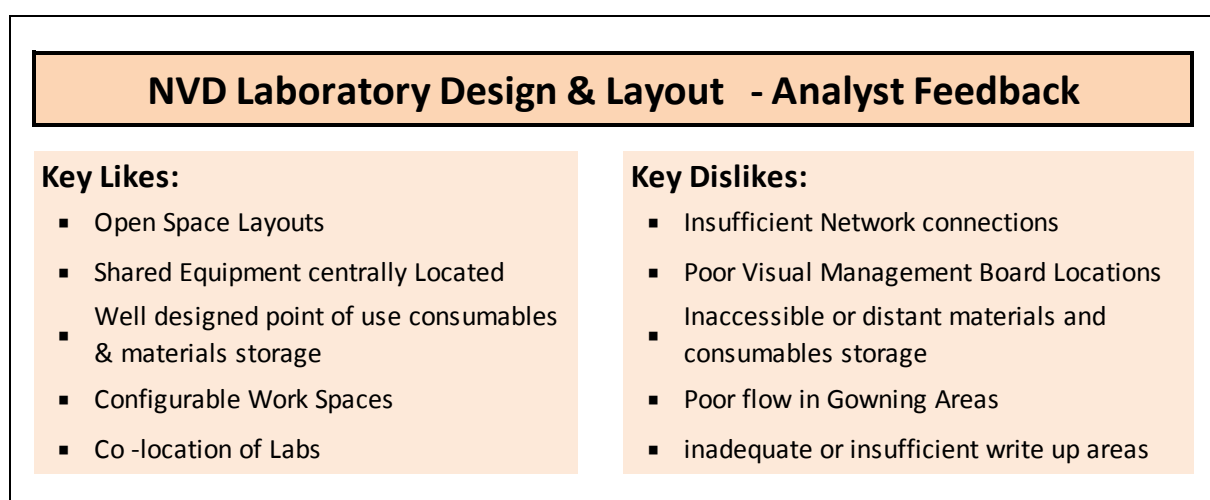


Figure 3: NVD Analyst Voice of the Customer

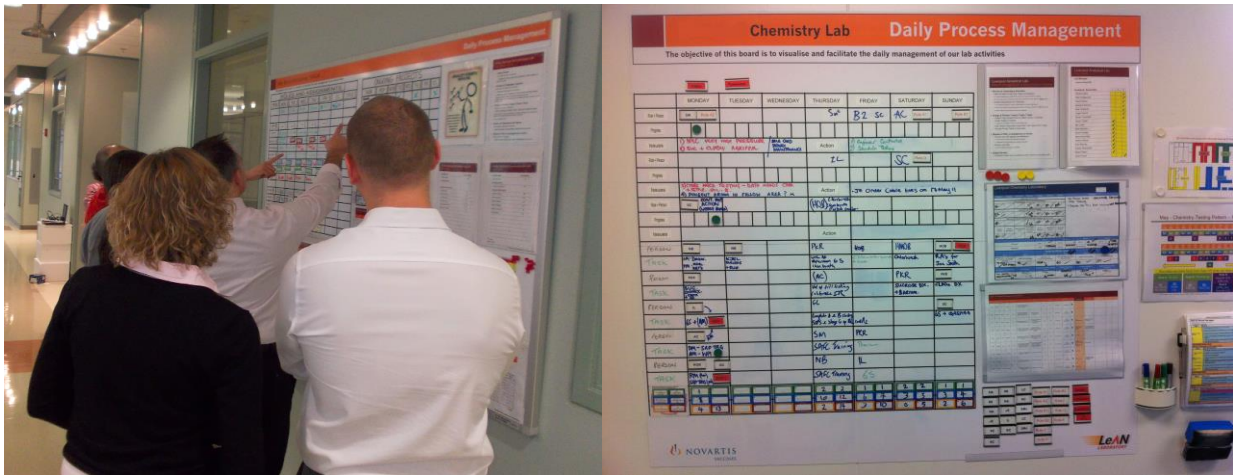


Figure 4: Use of Visual Management Boards and visual material controls in NVD labs



Figure 5: Use of Kanban systems for storage of chemicals and materials in NVD labs

5. The Role of the Design Company

Graham Shoel, Director of Project Planning, Global Engineering, Novartis Vaccines & Diagnostics

‘Effective’ facility design that optimizes original construction investment, cost of ownership /maintenance, and the cost of future operation is an inherent objective of any new or renovation laboratory project. Lean concepts (incorporating lean design and support for lean operation) are often included as part of the sponsor’s User Requirement Specifications aimed at improving ‘effectiveness’. In our experience it is often assumed that the sponsor/user and/or the contracted design or construction organization are experts in Lean design. However an examination of our recent major laboratory expansions highlights a different approach in each country and across contracted vendors. Clearly there has not been a shared common understanding on how Labs can be designed to better support Lean operation.

The workshop aimed to: (1) Capture the NV&D philosophy for lean design and (2) Define guidelines for lab design and layouts that proactively support lean behaviors and processes. As the design vendors are critical components of each new project, several vendors were invited to share their philosophies and considerations for lean design concepts.

The selection of, and relationship with, the design company is key to success. They view the design and operation of a facility from a different viewpoint to client organizations. They have to make the building work from an engineering perspective and this brings both opportunities and constraints to bear.

Novartis invited three design companies, Flad Architects, Jacobs and Foster Wheeler to contribute to the lean laboratories workshop. Each of these designers has been involved on major projects for Novartis in the past 5 years.

5.1 Incorporating Lean in Laboratory Design

Javier Garay, Principal & Jim Gazvoda, Principal, Flad

5.1.1 Key Considerations

The first issue to consider when introducing lean principles into the design and planning of the Quality Control Laboratory environment is defining exactly what “Lean” means to every part of the organization. Quality, Manufacturing, Environmental Health and Safety and Corporate Engineering all need to define together what makes a more efficient and effective use of available resources (people, space and equipment). Variables such as energy use, first cost, operational cost, regulatory compliance, financial justifications, and the quantity and quality of the space all need to be weighed against each other and prioritized with the underlying premise that safety in the laboratory comes first.

Understanding the differences between Manufacturing and Quality Control testing is key the first is a revenue generator, the second is perceived to be overhead. This creates a different level of tolerance for the initial and operational costs for each.

Regional differences may also come into play in facilities in different world locations. Some cultures may require different shift strategies, cross functional training possibilities may be affected, and the reliability of the supply chain could affect the quantity of space allocated to consumable storage, etc.

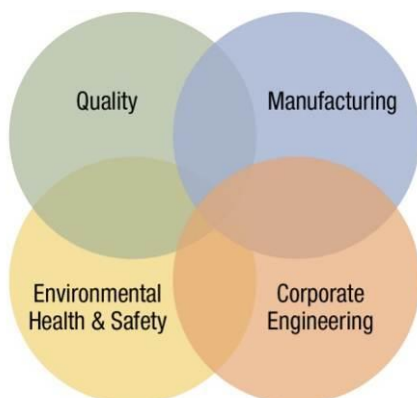


Figure 6: Organizational Alignment

5.1.2 Tools

When implemented as an integral part of the facility design and planning process, the following approaches will ensure that the laboratory environment enables lean practices and behaviors.

Needs Assessment

Two parallel approaches (‘top-down’ and ‘bottom up’) are used to ensure that the quantity and quality of space is exactly what is needed to perform the testing activities.

In the top-down approach, we utilize pertinent metrics such as headcount, benchmarking, and historical data to determine space drivers, functional areas, the amount of rooms, their size, and the amount of equipment that can be placed into each. Subsequently, we analyze how many samples can be tested in the amount of space provided.

The bottom-up approach examines how many batches and how many lots are being manufactured to determine how many tests are required, the equipment needed for each test, and the frequency of equipment use. This information dictates how much space is needed for each test.

The combination of these two approaches creates a holistic picture of both the quantity and quality of space requirements.

BIG PICTURE Approach

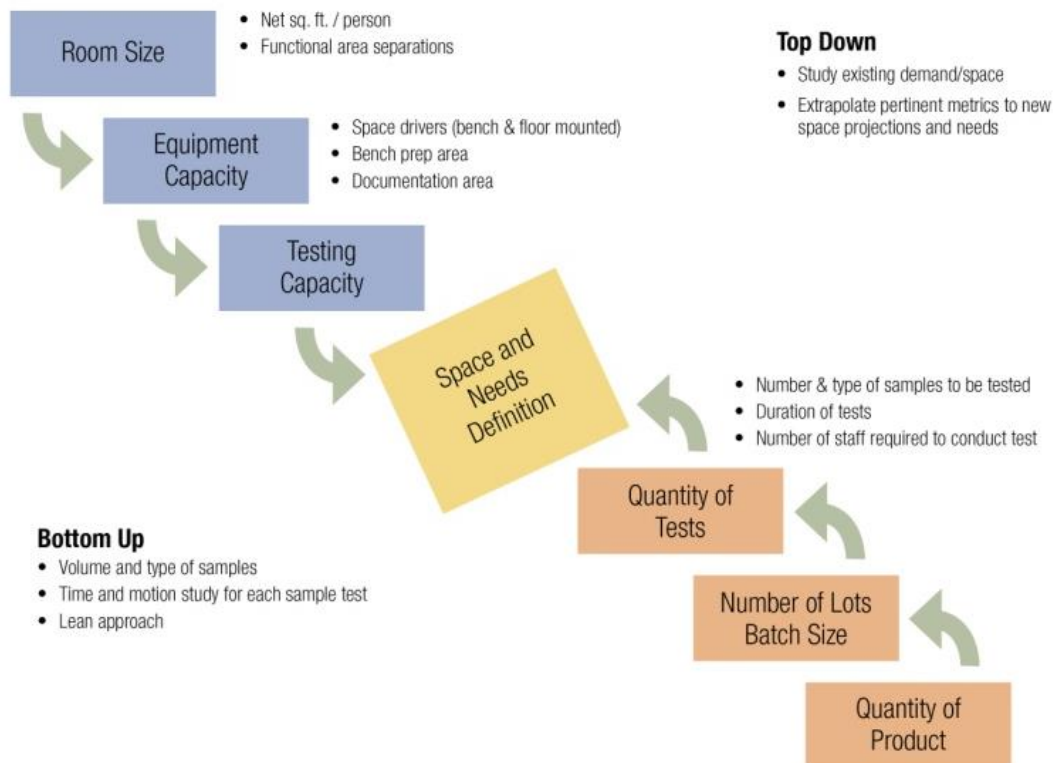


Figure 7: Space Needs Planning Approaches

Activity Location Analysis

A thorough understanding of each team member's activity throughout the day and where that activity takes place is useful in order to understand the patterns of movement and therefore establish the most effective adjacencies possible. This process will reveal important information to enable lean behaviors and practices.

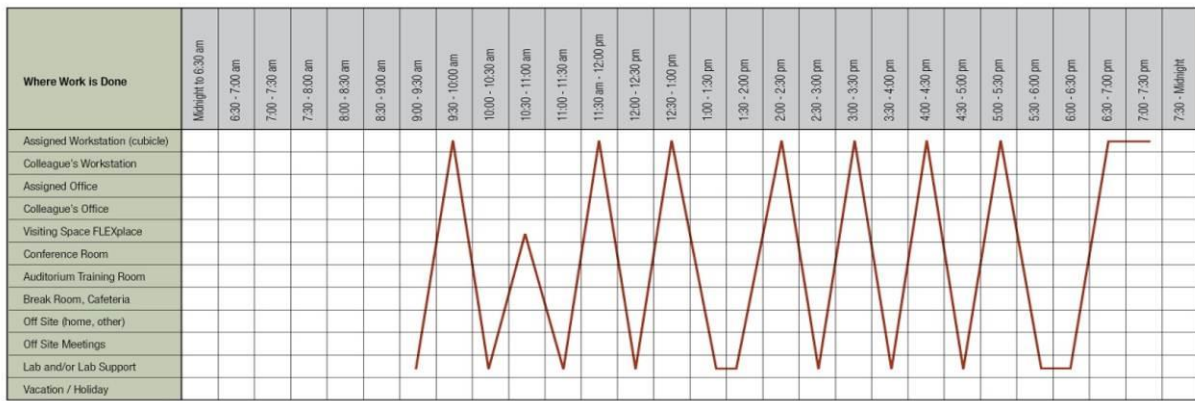


Figure 8: Activity Locations

Equipment Utilization Studies

By capturing equipment utilization data and understanding the importance of the equipment or test to the team's overall mission, we can better understand how equipment should be allocated. This data can then be charted and used to help optimize the allocation and placement of equipment in order to support lean practices. Equipment identified as high value/high use can be allocated directly to the group. Those pieces identified as high value/low use can then be shared among groups. One must also incorporate equipment back-up strategy / risk assessments of specialized assays into space planning and provide flexibility for assay evolution and new technology platforms.

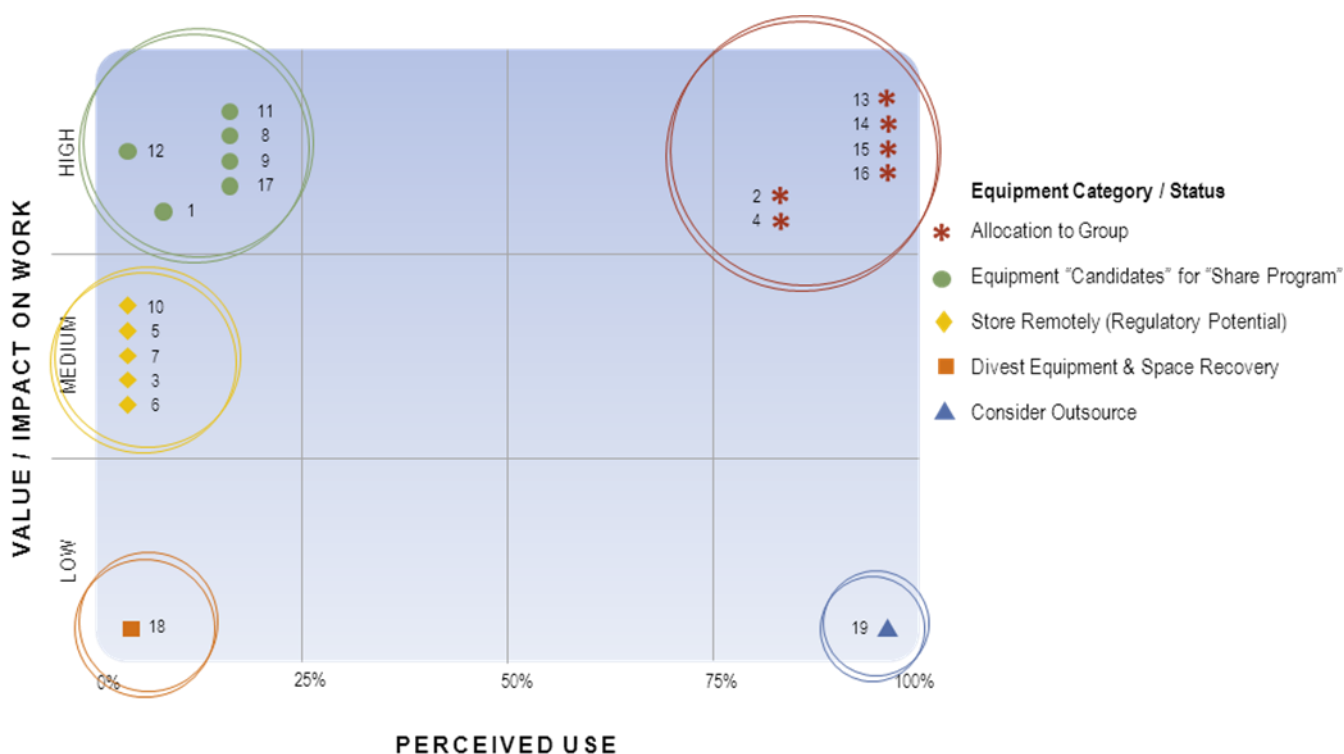


Figure 9: Equipment Utilization

5.1.3 Benchmarking Studies

Benchmarks are commonly used when initially planning and sizing a QC Testing Facility. If used correctly, they can establish range of magnitude criteria for high level estimation. Benchmarks can also assist space justification and lean applications for specific functional space types. When right sizing labs, it is essential to consider a number of variables in the analysis. Benchmark metrics vary for different types of testing areas, such as Microbiological, Analytical and Physical testing. In some labs, the space requirements are equipment driven, while in others it is people driven. It is important to address these differences when applying benchmarks, as one could over size or under size the testing space needs.

Common benchmark metrics include NSF (Net Square Footage) per person (for Primary Lab, Lab Support, and Office type space) and ELF per person (Equivalent Linear Feet) which is the linear measurement of bench and equipment within the lab space.

The testing requirements for Bulk Production sites, Final Product Formulation and Fill/Finish sites also vary. Understanding the actual product types and assays performed will help in selecting the correct benchmarks to use. Some sites may have a combination of these Production activities, but the benchmarks can still assist early space assessments.

It is important to make sure the lab has expansion capability in case the testing demand should change in the future. Consideration must also be given to the use of movable / portable lab furnishings to allow for interchangeability of equipment. Lab automation is also a significant trend in Leaning QC operations.

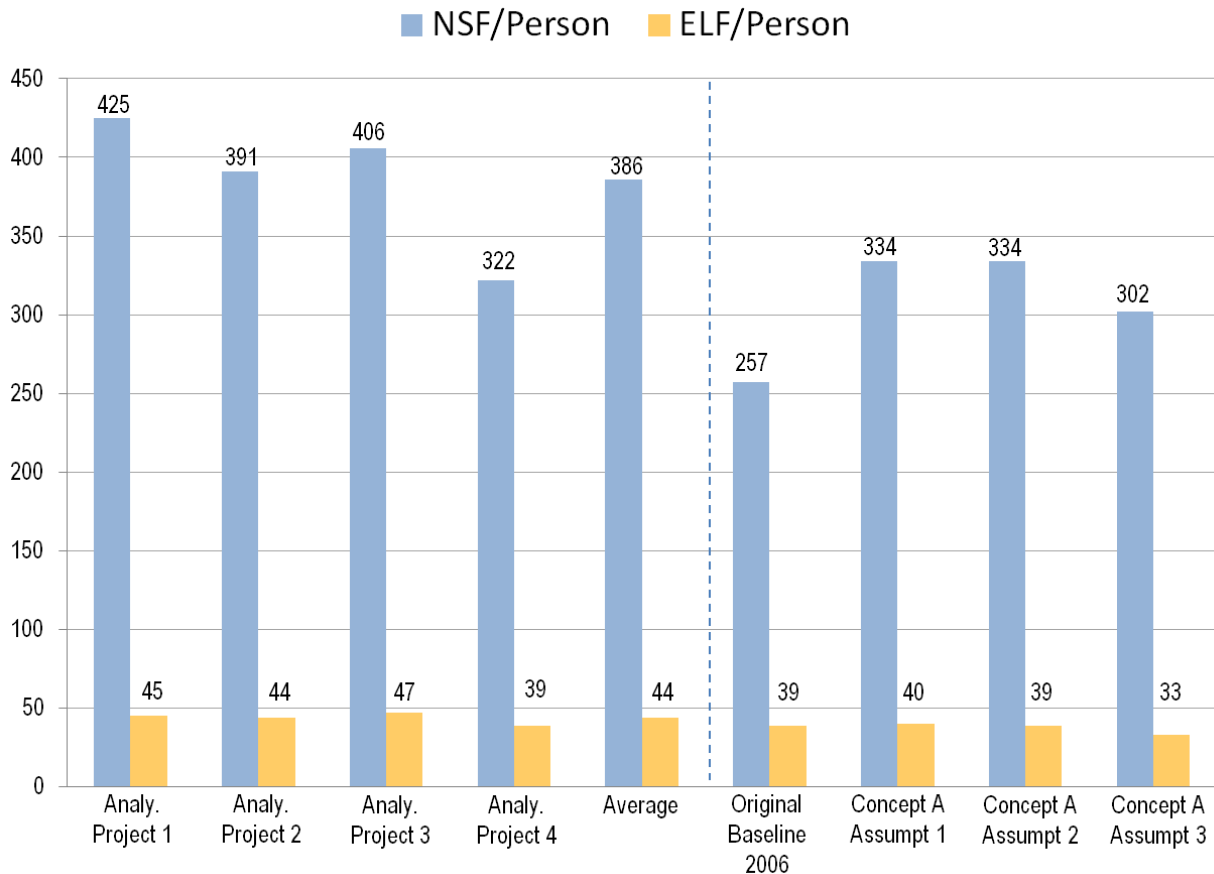


Figure 10: Space / Person Benchmarks

5.1.4 Strategic Planning to Foster Interaction

Equally important to the success of a laboratory design based on Lean principles are the visual connections of different functional and common areas. Views into the labs and office areas, views of conference rooms, dining areas, and circulation arteries support the “visibility” of everyone in the organization and the importance of a cohesive purpose through a sense of community.

Through the use of common spaces, an environment can be created where the different departments are brought together to interact, forming bonds and interdepartmental connections. These interactions help to increase operational efficiency within the facility and to develop trust and collaboration.

By knowing their co-workers, the staff is better able to communicate through networking, collaboration, and problem-solving sessions. Understanding each other as people, rather than by job title, increases teamwork and fosters communication for constructive problem solving during operation.

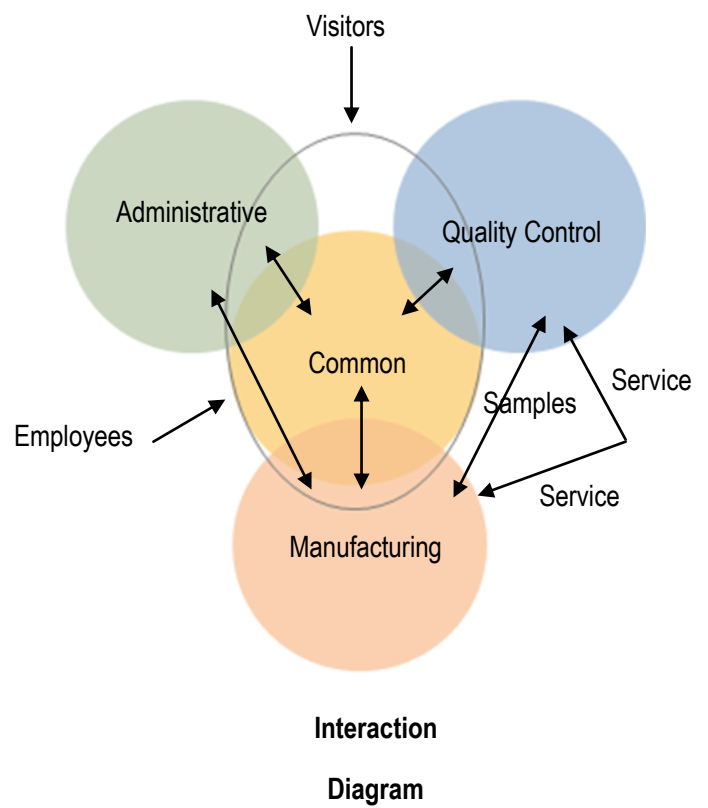
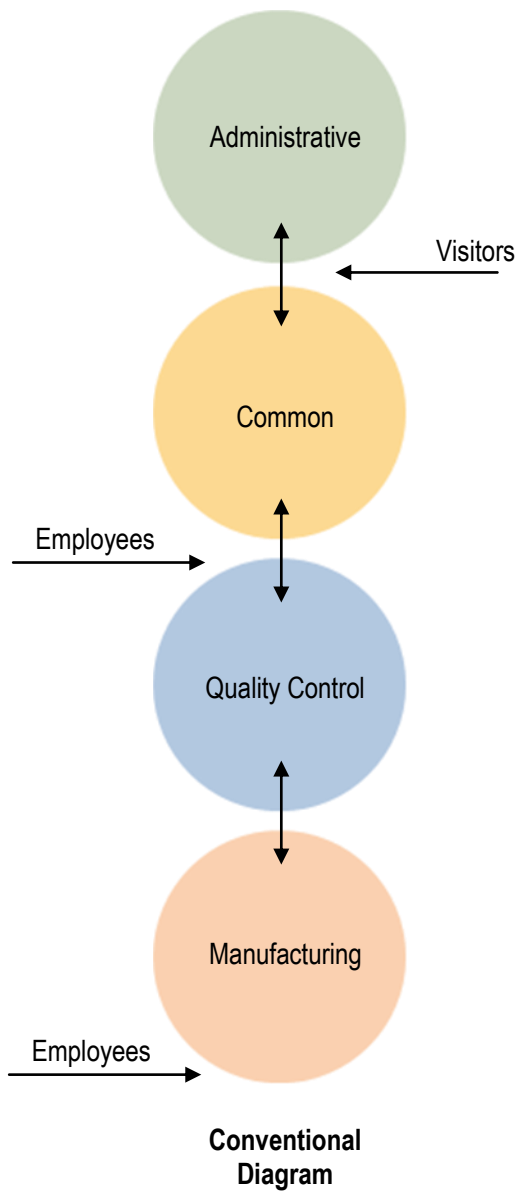


Figure 11: Campus Interaction

5.2 How can Lab Designers contribute to the implementation of Lean Principles?

Pietro Orombelli, Senior Project Manager, Foster Wheeler

Incorporating lean principles into laboratory design is not easy. Lab designers are architects and engineers and they “speak a different language” from lab users; they are unlikely to know how to carry out an analytical test and therefore they cannot make it leaner by themselves.

Equally, a lab operator will typically not know or understand the “engineering language” of drawings, schemes, specifications, etc.

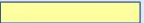

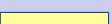

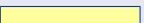




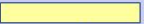

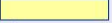

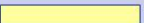

Principle	Procedures Vs Facility Design	Facility design main contribution	
		User	Designer
Eliminate uselessness and wastage	Procedures  Facility Des. 	★★★★	★
Value as determined by the end customer at every step	Procedures  Facility Des. 	★★★	
Identify the value stream	Procedures  Facility Des. 	★★★	★
Allow a flow without interruption	Procedures  Facility Des. 	★★★	★★★
Continuous improvement	Procedures  Facility Des. 	★★★	
Minimize queues and follow the customer priority	Procedures  Facility Des. 	★★★	★★
Level the workload	Procedures  Facility Des. 	★★★	
Manage performance (KPI)	Procedures  Facility Des. 	★★	

Figure 12: Relation between Lean Approach and Design

Therefore communication can be an issue and it's very important to be clear on the requirements and especially in identifying lean aspects that are really related to design.

Lab design can help to support the implementation of lean principles, but in many cases the lab's operating process is much more critical. In the table, we show qualitatively the relative importance of the operating procedures and the lab design on various lean principles.

Even where the design can contribute to the implementation of lean principles, it is essential to highlight the portion of contribution to design that can be originated by the designers and the portion that can be originated by the user.

For example, the minimization of waste is largely driven by the operation procedures used in the laboratory. Conversely, the designers can substantially contribute to optimising the workflow by incorporating the optimal sequence of rooms and corridors into the laboratory layout. Engineers and architects can only make a small contribution to identifying the lab value adding activities, defining the value stream, managing the performance or levelling the lab's workload, but they can help the performance of the lab employees by designing an ergonomic, comfortable and appealing environment. In summary, this table can help to define where to focus discussions on the lean principles between users and designers in the early laboratory design stages.

5.2.1 Flexibility in Lab Installations

Furniture in laboratories must fit with the needs of the activities that will take place in the lab, and not vice-versa. This simple principle may seem obvious but is not always respected.

It is not unusual to find situations where the testing activities are not lean as they could be due to the constraints caused by the furniture arrangement and by the utilities distribution.

Furthermore, the user needs, type of tests, equipment and activities carried out in a laboratory evolve over time and often, a design that was originally perfect, may become obsolete, and may do so quickly. Indeed sometimes it is necessary to revamp a lab area immediately after the conclusion of the construction phase.

To mitigate this issue, in the last 10 years, laboratory designers and furniture suppliers have developed flexible solutions.

Flexibility has been introduced at three levels:

Level 1 - Flexibility at bench level

Traditional benches are fixed and in practice are difficult to relocate (type “a” in the picture). Flexible benches are on wheels to allow a rapid reconfiguration of the lab layout. They can be “detached” (type “b” in the picture) and therefore they need to have a utilities wall behind, or, to be even more flexible, they can be fully mobile (type “c” in the picture) and they just need to be close to the utilities and services distribution.

Level 2 - Flexibility at utilities and services connection

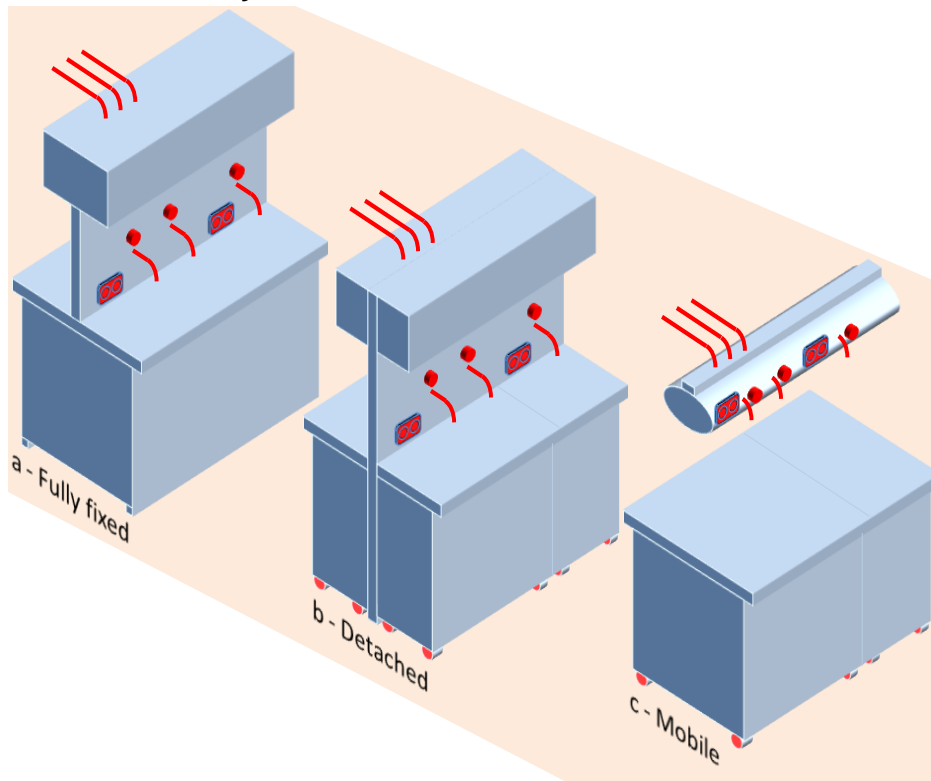


Figure 13: Flexibility in Lab Bench Configuration

The distribution of services such as gases, electrical power, vacuum, water, etc., can be rigidly fixed on the bench in a traditional non-flexible configuration (type “a” in the picture). Alternatively, the services and utilities ‘distribution wall’ can be detached from the bench breaking the rigid connection between bench and services while still having some constraints (type “b” in the picture). Finally, the utilities and services can be distributed from above via flexible connections allowing full flexibility (type “c”).

Level 3 - Flexibility at distribution level

A further level of flexibility can be provided by installing in the lab ceiling void some blind connections to allow the future relocation of utilities and services distribution panels.

Which is the best option?

There is a trade-off between the cost of the furniture and its flexibility. Normally, benches on wheels are slightly more expensive than traditional ones. In the same way, the utilities distribution from high level panels is more expensive than traditional distribution on benches. Nevertheless in most laboratories the cost of these options is negligible compared to the benefit in flexibility. However, the flexible distribution system (blind connections ready in the ceiling void) is justified only when a high frequency of lab reconfiguration is required: for example in non-validated research activities.

5.3 Lean Lab Design from an Architecture/Engineering Perspective

Federico Gabardi, Project Manager, Jacobs & Mike Dockery, Lab Design Consultant, Jacobs

Laboratories are among the most difficult facilities to make energy efficient. Typical labs are three to eight times as energy intensive as office buildings. Crammed with complex equipment, consuming huge amounts of electricity, and requiring complex air-handling and waste management systems, the challenges of creating a green lab can be challenging.

Lean Lab is of course not only about energy. Better, Safer, Greener and Low Cost are the typical drivers for a Lean Lab design and realization.

Better. Activities should be enabled by improved lab design, not inhibited by "traditional" approaches. Labs are not museums or warehouses; they are scientific facilities that must put the people at the center of the design. In other words, the goal of the design is to support the individual user and encourage comfort, productivity, and the exchange of ideas. From the beginning, the design should incorporate modularity, flexibility and adaptability. Examples of this approach are the free-form 'Flexilab' Layout and the "Sidestitial" facility design (see Figure 14).

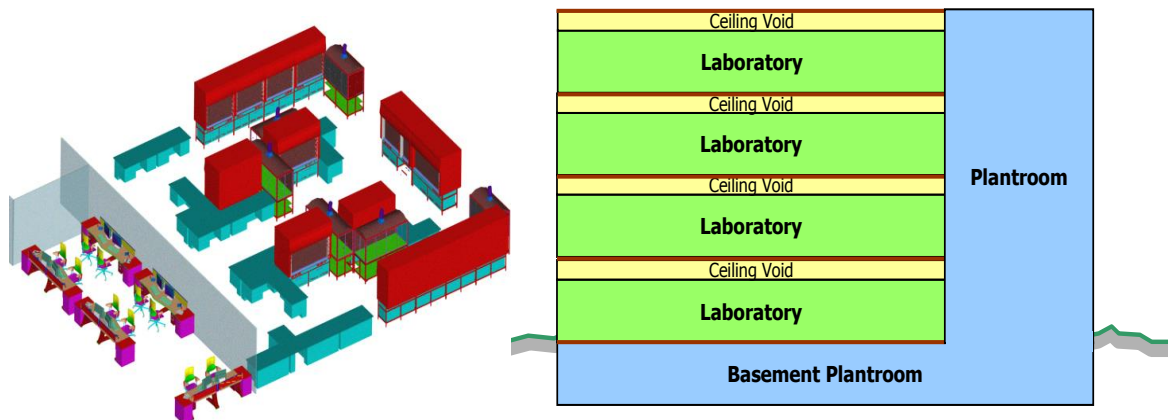


Figure 14: Free-form 'Flexilab' Layout within a "Sidestitial" design

Safer. Lab safety must always be the primary non-negotiable objective. We are obliged to ensure that safety is not inadvertently sacrificed in the quest for energy efficiency and functional expediency.

Greener. The 'Flexilab' Layout allows for re-use rather than replacement. The design principle of "right sizing" is mandatory to reduce energy and HVAC consumption. Other aspects to be considered for a sustainable approach are: reduction in waste, limiting wider environmental impacts, taking a full life cycle view, and maximizing the use of natural resources. Figure 15 shows the energy hub concept used in a recent R&D realization.

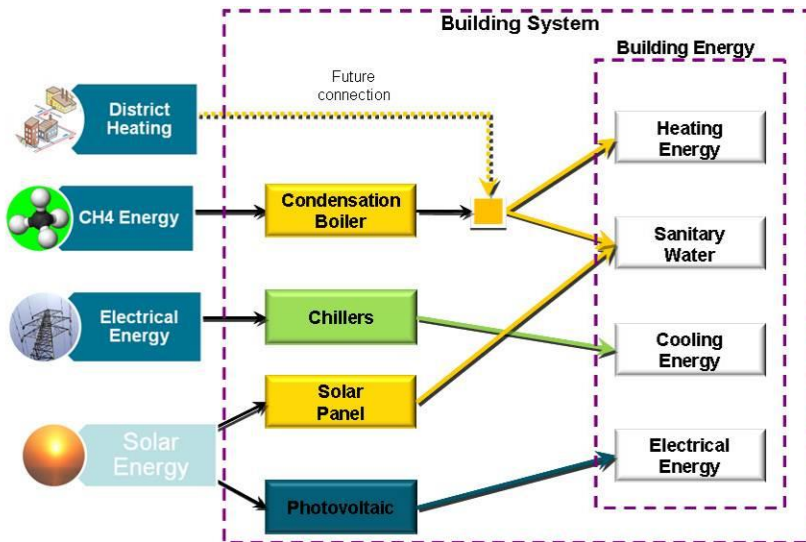


Figure 15: Energy Hub Scheme. Renewable and traditional sources are combined.

Lower Cost. Most labs will typically cost 4,000 - 4,500 \$/m². It is therefore essential that we produce more efficient designs with concepts that deliver more science/testing per m². This could be achieved with a reduction in the use of wasteful, ineffective, inflexible, 'traditional' lab furniture systems, and by replacing with more appropriate alternatives such as moveable carts and shelving for increasingly computer-based analytical and/or automated equipment. This includes the centralization and mechanization of certain types of storage, the modularity in design, right sizing and flexibility for re-configurations and renovations.

In summary, by using a combination of simple changes to lab design 'norms' we can make lab facilities more ergonomic, safer, greener places to work.

6. The (3) three zone concept: Creating Suitable Laboratory work spaces based on the nature of the tasks involved

Luke Kimmel, Associate Director, Global Engineering, Novartis Vaccines & Diagnostics

In order to promote lean behaviors and efficient operation, the analysts' work spaces should be tailored to their daily activities and desired workflow. Utilizing shared spaces where possible and implementing critical adjacencies, a three zone arrangement offers the flexibility to support testing, write up and documentation tasks, non-testing project type work and community interaction. Each zone is designed to support a specific type of work and to promote lean behaviors:

- Zone one embodies the laboratory space for sample testing.
- Zone two encompasses the documentation area where the analysts record results.
- Zone three provides an area for non-testing project work and community interaction.

The key to the success of this arrangement is the adjacency between Zones one and two, they need to be integrated but still require a certain amount of separation in order to create a suitable and safe environment. In order to support Lean best practice, both zones need to be located within the laboratory space. This will eliminate the need to gown out and gown in as the analysts move directly from the testing environment to the shared write-up stations.

The level of separation between Zones one and two needs to be carefully considered to ensure safety protocols are met and sufficient partitioning is provided to allow for the analysts to safely remove their glasses while seated at the shared write up stations to record the results of their tests.

A change in the qualities of the environment between Zones one and two is also desired. Given that the analysts will perform their write up activities within the laboratory area, the visual separation established through the selected materials and color palette of zone two will provide a psychological respite throughout the work day.

Zone three provides a work community space where the analysts can perform computer-based, non-laboratory activities, such as checking email and participating in online training. The space also provides opportunities to connect and interact with coworkers, as well as locker space to store personal items.

All three zones are connected through the elimination of visual barriers. This creates transparency to allow monitoring of the Visual Management Boards in zone two and visibility of personnel in all three zones, giving them the ability to identify issues promptly and without needing to gown in or out of the laboratory space. In addition, the transparency connects the analysts to the rest of the community at the facility through visual connections and access to daylight.

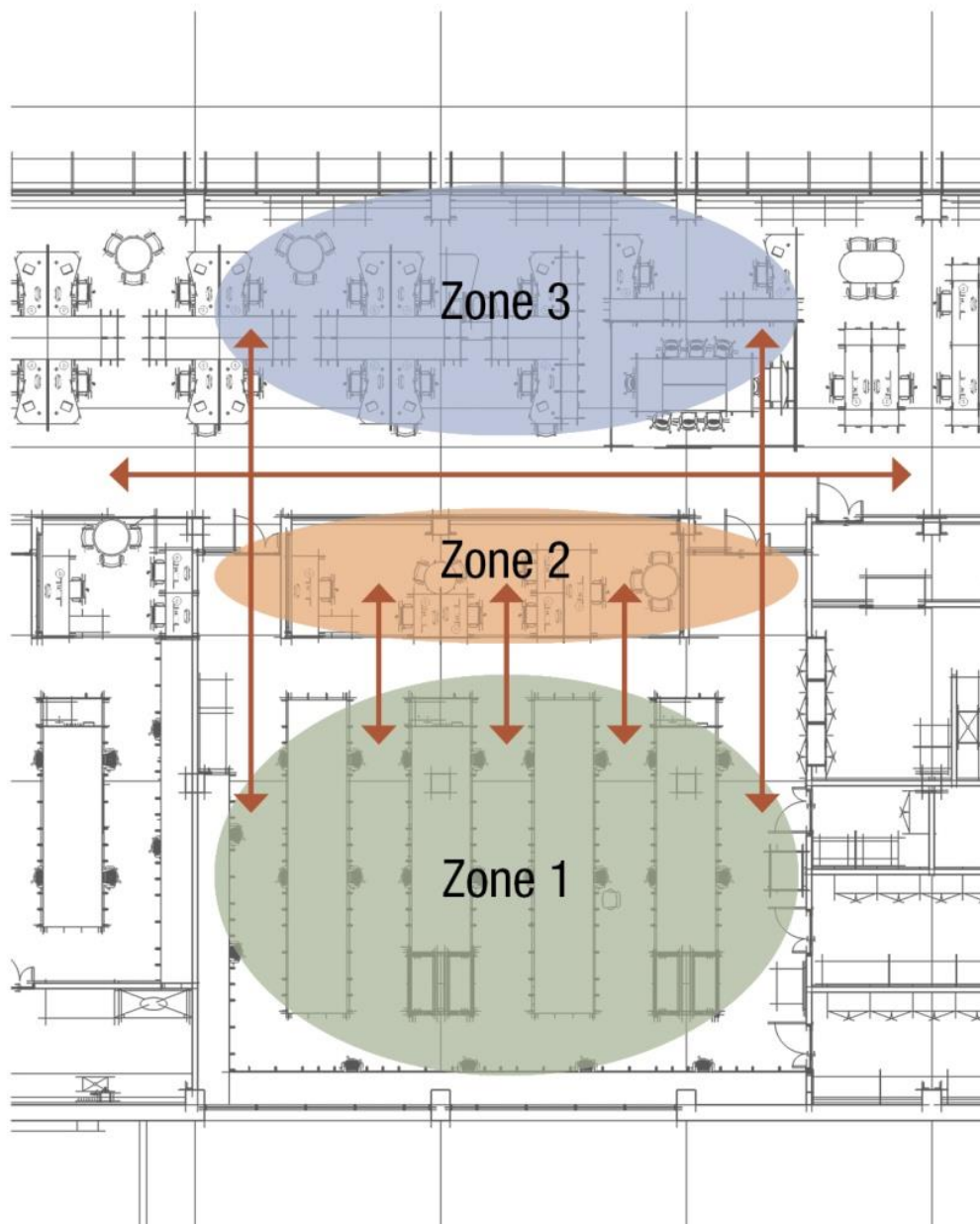


Figure 16: Three Zone QC Laboratory Design Concept

7. Laboratory Location and Layout

Tom Reynolds, Operations Service Director, BSM Ireland Ltd.

7.1 Lab Location & Shared Equipment Areas

The location of individual labs and of services or equipment that is shared between labs, within the overall space, can significantly impact workflow and transport and motion waste. Building Layouts should be designed to:

- Centrally locate shared services and support functions (e.g. sample management / glass wash).
- Minimize throughput times and transport waste by the use of 'pass throughs' and by co-locating or amalgamating 'supplier' and 'customer' labs that can share equipment, storage, samples, analyst resources, test results or information.
- Locate labs close to production areas -this can even eliminate the need for a separate sample management function and will improve flow and communication.
- Co-locate or amalgamate Labs that will share samples, equipment or storage.

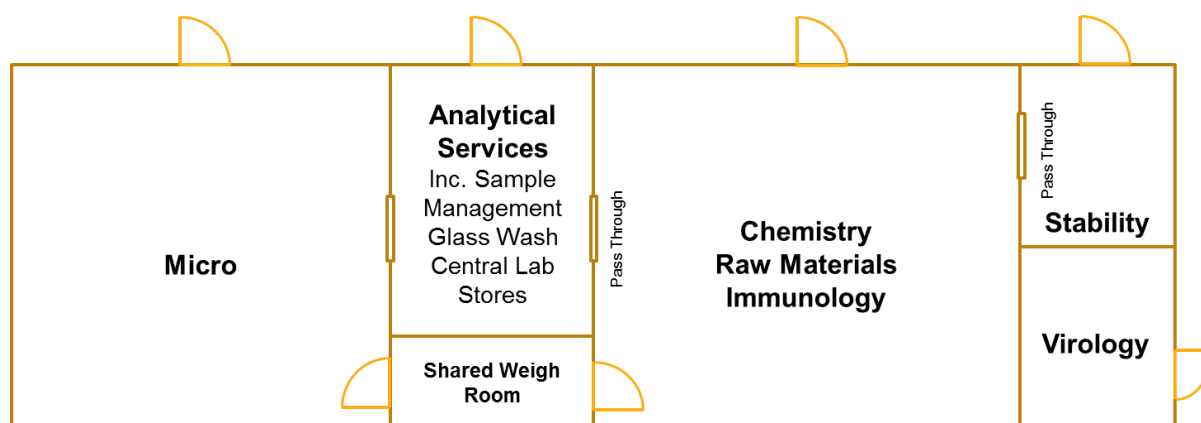


Figure 17: Schematic of Shared Services and Lab Co-location

In this simplified layout, all shared services (i.e. 'Analytical Services') are located centrally between the major 'customer labs'. 'Pass through' hatches are used to minimize transport and motion wastes. Labs that could share workloads, equipment and resources have been amalgamated (e.g. Chemistry, Raw Materials & Immunology). The Stability area, which supplies samples for test, has been directly connected to the labs via a pass through (again to minimize transport waste). To avoid duplication and to minimize travel, equipment that is shared between separated labs is centrally located (e.g. the weigh room).

7.2 Bench Configurations

In a Lean lab process, it is normal that individual tests are combined to make good use of the 'unattended' time inherent in some tests and to help create balanced productive analyst roles. For example a HPLC test run has significant periods in which the analyst does not need to be present. In a Lean lab solution, this test will be combined with other shorter more manual tests to allow that time to be used productively.

Because of the leveling and defined test sequences, these combinations can be fixed and repeated each time the tests are run. This in turn makes it worthwhile to create dedicated work cells for these

fixed test combinations. Bench layout and configuration has a significant impact on how well these work cells operate and on reducing motion wastes.

By far the most common bench configuration in labs today is a straight run which is almost never the optimum configuration.

The key objective in work cell design is to have clearly defined work areas and sample flows with all necessary equipment, services and materials close at hand and with reaches and movement minimized. Achieving this normally requires a bench configuration which 'loops around'. The classic work cell shape is the "U" (also known as the horseshoe) but there are several other alternatives that can achieve the same objectives.

Products, samples, tests, equipment and workloads can and will change over time. Bench layouts and services need to be re-configurable to accommodate this type of change.

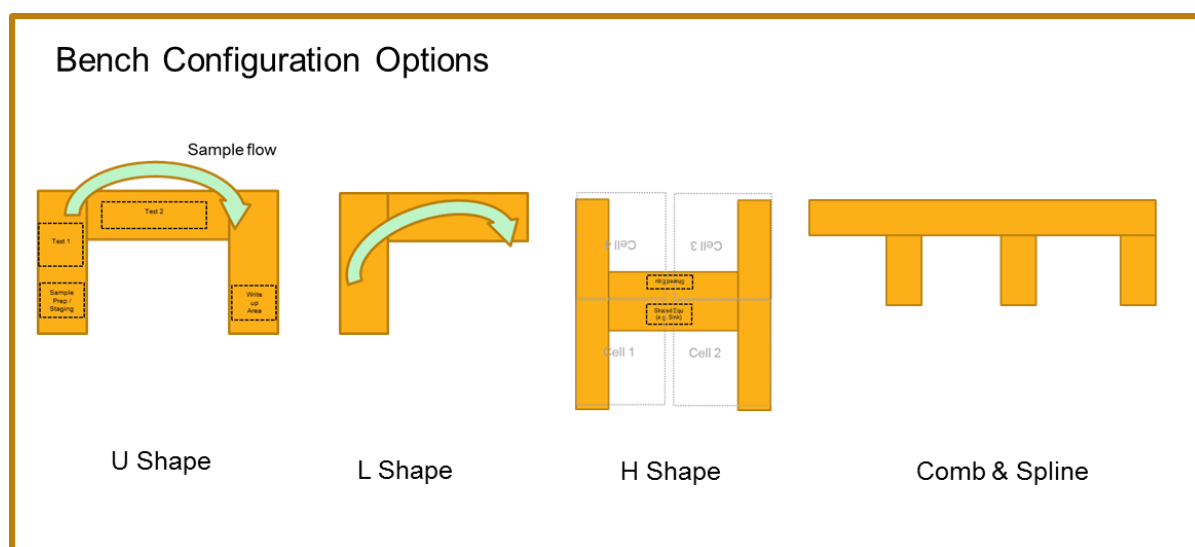


Figure 18: Bench Configuration Options for Testing Work-cells

Arguably, the most versatile and re-configurable option is the "comb and spline" in which the spline can be fixed with services supplied from above and the comb elements are 'movable'. This allows multiple U and L shapes to be easily created and re-configured when required.

8. Consumable Inventory Management and Storage

Tanya Scharton-Kersten, Novartis & Tom Reynolds, BSM

In most Labs, effective management of laboratory consumables (for example reagents, media, gloves pipette tips etc.) is a key enabler for Lean operation. The storage requirements for these materials are an important consideration in the design and layout of labs. Considerable inefficiency and unnecessary costs can result from analyst hoarding or unnecessary multiple storage locations. Poorly managed inventory management processes can also result in materials running out or needing to be ordered on short notice or expiring due to oversupply. Effective stock management systems can increase analyst productivity and work satisfaction, reduce the resources spent on inventory management and reduce test delays.

The Consumable Inventory Management (CIM) process should itself be based on lean principles with an objective of minimizing:

- 'Stock outs' & 'Write offs'
- The cost of inventory
- Inventory management effort
- Space requirements.

Achieving these objectives normally involves:

1. Minimising the number of Stock Locations for individual materials.
This reduces stock counting effort and helps to improve accuracy. It also helps to minimize the overall inventory volume and reduce the risk of write-offs. There is however often a 'trade off' between minimizing the number of stock locations and having materials available at the point of use.
2. Controlling and Minimizing inventory volumes:
 - a. By calculating maximum and safety stock levels, re-order points and reorder quantities based on recent historical usage data.
 - b. By reviewing and revising these in a timely fashion when activity drivers change.
 - c. By reducing vendor lead times and minimum vendor batch sizes where possible.
3. Minimizing the effort required to replenish stocks at the point of use including:
 - a. Reducing Travel by locating lab and site stores centrally.
 - b. Reducing Transaction and Documentation effort by using Kanban controls or scanning systems instead of manual computer entry or documentation based systems.
4. Minimizing inventory ownership duration:
 - a. By using a 'Consignment' stock approach.
5. Minimizing inventory management effort via:
 - a. Vendor Managed inventory processes & Vendor clustering
 - b. Kanban systems to trigger re-ordering and/or fixed re-order quantities as appropriate.
6. Minimizing transaction and documentation effort via.
 - a. Transfer of ownership at one point only (preferably electronic) with no subsequent recorded transactions or documentation.

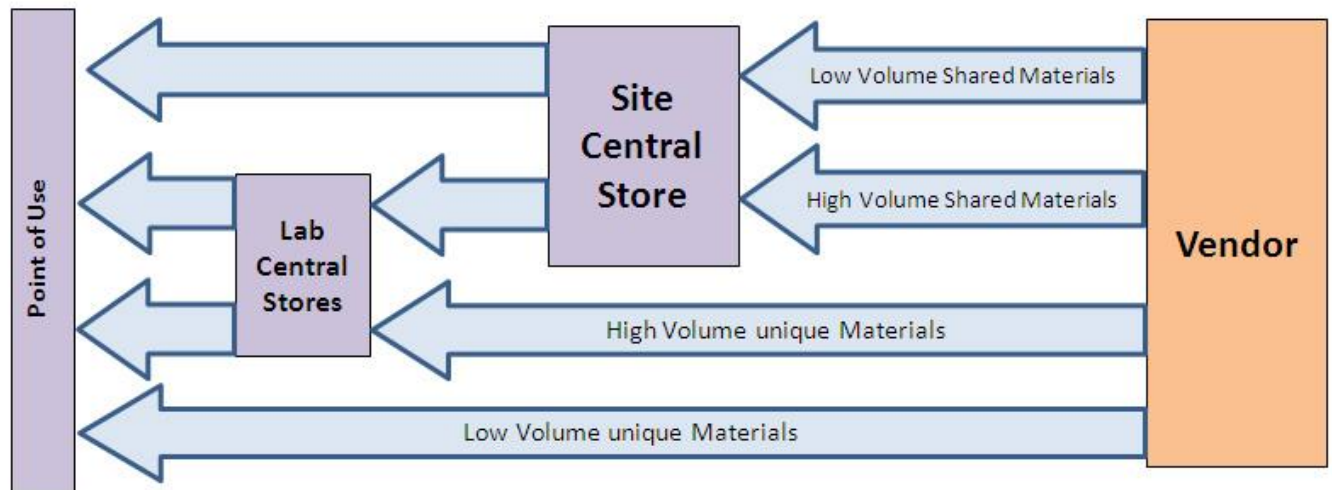


Figure 19: The 'three' point inventory management system

- Typical CIM strategy with varying approaches for different material classifications:
 - There is limited storage at the point of use - typically a day to a week's worth of material and often in the form of a two stock container Kanban (i.e. one container open and in use and one un-opened). Replenishment happens after first unit has been exhausted and the second unit opened. The empty stock container itself can be used as the Kanban signal.
 - Low volume shared materials i.e. materials that are used by several labs are delivered to a site central store and later moved directly to the point of use in a specific lab on receipt of a Kanban signal.
 - High Volume shared materials are delivered to a site central store with transfers to lab central stores on foot of Kanban signals or on a fixed weekly or monthly basis as appropriate. Materials are transferred from the lab central store to the point(s) of use based on Kanban signals as above.
 - High volume unique materials i.e. materials that are not shared between labs are delivered directly to the site central stores with transfers to the point of use as before.
 - Low volume unique materials are delivered and stored directly at the point of use in a specific lab.

The usage volumes and volatility pattern of individual materials is critical to determining the appropriate CIM strategy for that material (i.e. the number of stocking locations and use of Kanbans):

- Less usage volatility requires less safety stock and enables the use of Kanban controls.
- More usage volatility requires more safety stock and potentially a demand forecasting process. Kanban approaches do not work well when the material usage patterns are very volatile (i.e. where material requirements are subject to significant peaks or seasonality).
- Combining the requirements for individual labs (for shared materials) will reduce the overall demand volatility (central limit theory), the safety stock required and the number of transactions needed.

9. Workshop Validation and Feedback

9.1 Jeanne Sirovatka, Associate Director Supply Chain, Sandoz

No matter what you are doing, there comes a time when you are going to want to take things to the next level. Implementing Lean and achieving Operational Excellence in today's laboratory is imperative for short and long term success. Frequent changes in business needs are the norm for most Labs and Operational Excellence can be achieved, maintained and improved upon by taking advantage of the flexible, efficient and open concept laboratory design.

One of the key drivers in the generics pharmaceuticals business is the ever-changing business priorities. There is no doubt that designing flexibility into the laboratory engineering systems will also enhance operational efficiency.

Sandoz operates in a highly competitive marketplace and there is no better time to implement the Lean lab design concepts in our QC laboratories as we are currently going through a breakthrough transformation project to apply lean processes in our labs.

Participating in the Lean Laboratory Facility Design workshop was a fantastic opportunity to learn the many factors that influence an efficient laboratory design including operational business models, test volumes, workflow, types of workstation, automation, and quality of life in the laboratory. All of these should be evaluated during the design and planning phase as critical factors which will drive the culture change and lean behavior to create flexible, adaptable and expandable laboratory space.

Throughout this valuable workshop, different vendors and architects demonstrated how maximum flexibility, adaptability, and expandability could be easily achieved through efficient utilization of the open space concept. Transparency could be maximized through extensive use of glass instead of walls, enhancing the Novartis values and behaviors. Ultimately, the open space concept makes the laboratory more durable and creates a desirable work environment. Flexible laboratories could be easily reconfigured as instrumentation and workload varies, enhancing the overall laboratory environment and throughput speed. Design features will maximize adaptability within the laboratory include layering, reserve riser space, and accommodations for future capacity. An open lab plan will also provide the resiliency required to create innovative ergonomics and efficient, easily modifiable workstations. Ultimately, the open plan concept will enhance space and staff utilization, supervision and the overall QC business unit performance.

9.2 Christophe Peytremann, Global IQP Champion, Novartis Pharmaceuticals

The cross-divisional Lean Lab workshop was really a great chance to discuss lab design concepts. The topic and timing were perfect knowing the numerous new labs and expansion projects planned in our Pharma business unit. This workshop convinced us that lean must fully integrated in lab design from a very early stage by all project stakeholders/functions. This workshop also helped us to go beyond the most obvious opportunities usually identified such as those related to sample flow and analyst motion. We look forward to pursuing cross divisional collaboration on this topic. Following the workshop we communicated a coordinated philosophy to assessing current state via a scored checklist (Figure 20) and showed teams how 6S and flexible design are key components for all future laboratory set ups (Figure 21).

Lean Lab principles	Lean Lab approach	Assessment of the impact on Lab design	
Pull to Demand	Demand & Business needs are embedded in the Lab design	Understand future testing demand pattern (volume and complexity); # batches and tests (mean, max), by technologies, etc	
		Demand and capacity calculations - overall, by product group, by workcentre (hplc, GC, fume hoods), used to size the lab	
		Bottlenecks and areas of potential future growth / capacity expansion identified, layout flexible to accommodate changes in lab size	
		Flexibility to accommodate short term demand changes and demand variability, e.g. movement of analysts between labs	
Vision based approach; Blue Sky and Practical Vision	Lab design enables the lab vision and generates tangible benefit	Understand how the lab design meets the VoC / VoB; fast TpT, testing rhythm, TpRate, tests per FTE and testing costs	
		Strong understanding how the lab design supports and enables the Lean Lab vision	
		Lab design can accommodate latest QC initiatives (paperless, compliance, GLP, etc.)	
		Lab design represents latest 'state of the art' thinking based on SME, industry best practices, etc.	
Create Continuous Flow	Flow - value add versus non value add steps. Lab design minimizes motion, transport, inventory, waiting time, delays, etc.	Lab Location versus production (proximity to the customer and suppliers)	
		Work-teams structure	Structure (e.g. teams organized by main testing flows and products groups, POO)
			Lab design suitable for multiple testing teams; team size (number of FTE per testing team 5 to 8)
		Material Flows	Sample flow optimized (sample receipt- prep - testing - release); unidirectional, minimum distance, minimum number of steps, minimum non value added steps (walkthrough)
			People motion is optimized (e.g. Spaghetti diagram)
			Preparation activities are integrated optimally, e.g. Test kitting, buffer preparation, cleaning
			Sample administration and storage are integrated in to the flow
			Consumable / Glassware location is at the point of use to avoid non value added steps and delays
			Utilities (water, gases, extraction, fume hoods) are located at the point of use
			Reagents location is at the point of use to avoid non value added steps and delays
			Waste removal activities (used materials, samples, HPLC drains, etc.) are minimized
			Other materials & supplies are located to support good flow
		Equipment layout (Flow vs Functional layout)	Flow layout assessment (pro's and con's evaluated)
			Functional layout assessment (pro's and con's evaluated)
			Clear to see how the equipment layout fully supports lean work flow
		Information Flows	Test Documentation (TM, SOP, etc.) generation, location supports lean work flow
			Sample doc'n, results and record sheets supports lean work flow
			Lab has good proximity to QA to support fast release and deviation closure

Lean Lab principles	Lean Lab approach	Assessment of the impact on Lab design			
Waste Elimination	Lab design improves productivity of space, equipment capacity and people	Equipment capacity utilization	Layout can support different shift patterns (5/1, 5/2, 5/3) without loss of efficiency		
			Key equipments:- <i>HPLC</i> <i>GC</i> <i>Fume Hood</i> <i>Dissolution</i>	Equipment : product ratio is optimal for dedicate v multi-purpose use (optimized setups)	
				Equipment : analyst ratio is optimal for shared v dedicated use (avoid delays)	
				Equipment utilization % is optimal for flexibility and efficiency	
				Requirements for asset care (cleaning, setup, maint, calibration, qualifications); spares, etc	
		Workbench, ergonomics	Length and size of workbenches are ergonomic, equipment located to maximize working area, sufficient area for the expected testing in progress		
			Shape (straight, U-shape, L-shape) support optimal flow		
			Space around workbench provides safe and efficient use of space		
		Workbench and desk space	Defined workbench vs desk usage is reflected in the space allocation		
			Overall space per analyst is within acceptable range (30 to 40m2 per analyst)		
		Storage Space (glass, reagents, chem, consumables)	Storage based on usage	Workbench storage is minimized (eliminated)	
				Designated storage areas are replenished frequently (potentially from external supplier (VMI))	
			Storage space optimization for good access and utilization; use of novel storage solutions e.g. Carousel		
Visualization	Lab design includes Implementation of visual, interactive, line of sight management	Lab is open plan (open space with minimal (solid) walls and barriers to line of sight			
		Visibility of work flow (sample, materials, chemicals, waste, etc); Kanbans, 2 bin, etc			
		Visibility of lab performance is integrated, clear signals possible to highlight problems			
		Ability to sustain 6S - bench and storage design (open, transparent, easy-clean, stain resistant, etc)			
		Planning & Scheduling	Visual environment for the testing teams to work		
			Visual equipment allocation or reservation		
		Whiteboard and waste-boards for each team - problem solving area included			
Lean Leadership	POO environment; ownership, self direction, team working	Co-location of the team leader, specialists and QC head in the lab; promotes strong interaction on daily basis			
		Layout supports team working environment			
		Layout supports ownership of 6S			
		Layout supports ownership of asset care			

Figure 20: Lean Lab Layout and Design Checklist

Lab Fitment

Flexibility and 6S designed-in



Figure 21: Lean Lab 6S and Flexibility

10. Recommendations & Conclusions

Tanya Scharton-Kersten, Novartis & Tom Reynolds, BSM

While Pharmaceutical QC Laboratories are different from manufacturing environments they are none the less operational entities. They have a major impact on the release of product and are often significant cost centers in their own right. Lean principles can and should be applied in order to optimize lab processes and operational performance. The design, layout and placement of labs can have a significant positive or negative impact on the implementation and sustainability of lean processes and behaviors within the lab.

Laboratory areas should be designed to:

1. Support Levelling, Flow & Standard Work

Levelling, flow and standard work are key lean lab principles. Building design to proactively support them normally involves:

- » Less internal walls and separation of labs – this promotes flexible operations and the sharing of workloads and resources to level short interval workloads.
- » Incorporating space for sample management and visual queues – visualisation of workloads is a core concept of lean.
- » Use of Sample centric and / or Test centric cells and cellular bench arrangements– Cellular workspace design facilitates the combination of tests to create balanced productive analyst workloads and standard work and reduces travel and motion wastes.
- » Allowing space for visual management systems of laboratory performance -for example daily and weekly meeting boards to allow visualization of work to be performed in the short term and of Lab performance over time.

2. Support effective use of peoples time

- » Integration of write up, review and approval areas - this enables efficient and timely documentation and review of tests supporting both flow and levelling of workloads.
- » Use of a limited number of adjacent but separated 'hot' desks for project work and non-test tasks.
- » Adjacent collaboration areas and meeting rooms.

3. Minimise 'transport' and 'motion' wastes

- » Location of Labs close to manufacturing (simplifying sample management & chain of custody).
- » Co-location or amalgamation of Labs that will share samples, equipment or storage.
- » Central location of shared lab services (e.g. glass wash).
- » Central location of equipment or storage that will be shared within a lab.

4. Minimise space & equipment requirements

- » Space and equipment requirements should be calculated based on levelled demand rates rather than peaks.
- » There should be a move away from personal ownership of equipment, bench space or desks - Analysts should operate as true teams sharing resources and workloads.

5. Maximise future configurability,

- » Via Flexible bench configurations and (semi) configurable services (air / extraction etc.)
- »

6. Support effective laboratory inventory management

- » Via limited and defined storage at the point of use.
- » Central lab storage for shared materials or high volume unique materials.

7. Support effective performance management

- » By incorporating areas for visual management displays, huddle meetings etc.

8. Foster lean behaviours & communication

- » Via centrally located, glass walled offices for Lab Managers and Supervisors.
- » Extensive use of glazing to visually link lab areas.

9. Support excellence in workplace organisation and cleanliness (5S)

- » Via open or glass fronted cabinetry.
- » Limited and defined storage through the lab.
- » No drawers.

11. Final Thoughts

Tanya Scharton-Kersten, Global Head of QC Laboratory Management, Novartis Vaccines and Diagnostics

By bringing together designers, users and lean experts, the NVD Lean Lab Design Workshop generated innovative approaches to incorporating support for lean processes and behaviors in the design and layout of lab spaces. These went far beyond the obvious opportunities related to sample flow and analyst motion and have had a significant impact on Novartis thinking and approach to lab design. It has allowed us to develop guidelines that will help ensure that all new builds and refurbishments include design elements and approaches that pro-actively support our Lean Lab initiatives.

We are sharing the outcomes to generate continued interest and discussion amongst the wider pharmaceutical laboratory community with the intent of inspiring better laboratory designs from the point of view of both the laboratory user community and business partners.

I would like to thank all the workshop participants for their invaluable contributions.

The work presented represents the outputs of a workshop and continued dialogue and inputs of a larger team recognized by the authors for their contributions to the final paper as presented:

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