Reprinted from
PHARMACEUTICAL ENGINEERING
THE OFFICIAL TECHNICAL MAGAZINE OF ISPE
SEPTEMBER/OCTOBER 2014, VOL 34, NO 5
©Copyright ISPE 2014
www.PharmaceuticalEngineering.org

Incorporating Lean Principles into Pharmaceutical QC Laboratory Design

by Mike Dockery, Federico Gabardi, Javier Garay, Jim Gazvoda, Luke Kimmel, Pietro Orombelli, Christophe Peytremann, Tom Reynolds, Tanya Scharton-Kersten, Graham Shoel, and Jeanne Sirovatka

This article presents a case study based on an international workshop hosted by Novartis Vaccines to prepare guidelines for incorporating lean principles into pharmaceutical quality control laboratory design.

Novartis Vaccines (Novartis) has applied a structured implementation of lean principles across Quality Control (QC) laboratories in Europe, India, China, and the United States. The aim has been to significantly improve internal work processes, communications, customer interfaces, and operational performance.

As a result of this critical effort, analysts have been trained in basic lean principles, 5S organizational strategies were introduced, and visual management was implemented for daily and weekly performance reviews. In addition, the QC team gradually applied effectiveness tools for capacity management and budget processes.

As different QC teams – operating in both legacy and new state-of-the-art facilities – implemented lean principles, it became clear to Novartis that laboratory design and layout have a strong, direct influence on processes, behaviors, and communication.

While some designs proactively enable and support lean practices, such as flows, visual management, standardized work, and excellence in workplace organization; other design solutions result in teams spending extra time and resources. In the less than optimal facilities, the very layout and design of the space introduces waste, discourages communication, and even impedes workflow throughout the laboratory.

Based on these observations and aiming to improve future laboratory designs, Novartis developed a draft of comprehensive laboratory layout and design guidelines that would support lean principles. The guidelines were then reviewed, refined and augmented in an intensive two-day workshop that brought together key Novartis stakeholders with the industry's leaders in laboratory design, planning, and lean operations.

The mechanics of the workshop allowed the team to first develop a common understanding of lean practices in laboratories in order to identify design features that foster proactive communications, optimize data information and support effective work practices. The team identified and consolidated initial concepts around facility layout, critical adjacencies, visual management, shared equipment, consumable storage access, and furniture/bench and equipment layouts. Once a common understanding was achieved, the team broke out into three to four person work cells to develop a case study re-design of a new Novartis quality control laboratory facility.

As a result of the workshop, a three-zone concept for laboratory design emerged along with a solid set of layout guidelines that are applicable to existing legacy laboratories, newer state-of-the art facilities, and future "greenfield" laboratories.

Lean in Laboratory Environments

Lean is a philosophy and a concept of operations that focuses on the elimination of waste and the application of leveling, flow, pull and standard work. 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 (overloading of people or equipment)

Mura and muri are especially significant in lab environments.

Even though QC laboratories are not the same as manufacturing environments, the key principles of lean still apply and should be implemented in their operation and space planning. However, there are some unique challenges involved in implementing lean in the laboratory environment that require careful adaptation of the techniques used in manufacturing. When these adaptations are based upon a thorough understanding of laboratory processes, lean implementation 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 batches or samples. This reduces effectiveness and adds waste. The rate of failures and rework also often increases. In short, mura (volatility) creates muda (waste).

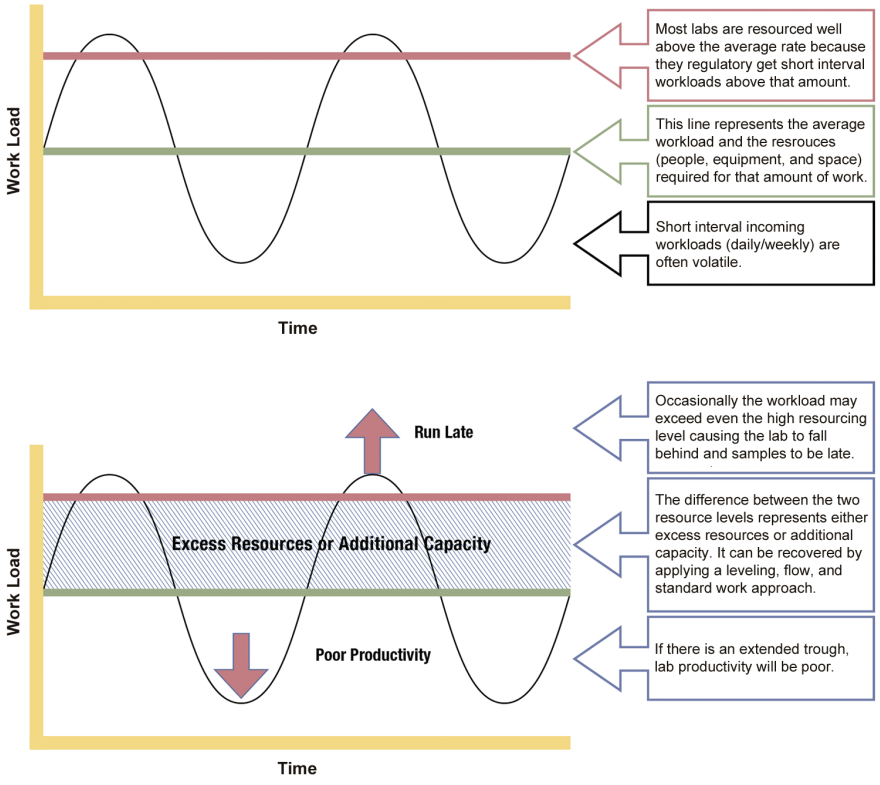
Poor utilization of analyst resources (usually in the form of volatility and imbalance in individual analyst workloads) is usually the second largest lean opportunity. Leveling, flow and standard work allow the development of 'productive roles' for the more routine work elements in a lab.

Applying lean principles in a laboratory environment 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, and repeatable analyst roles that use people's time well (i.e., standard work).

A lab design and layout that actively supports these principles will increase the effectiveness and sustainability of the lean processes.

Defining Lean for an Organization

The primary issue to consider when introducing lean principles into the design and planning of the QC laboratory environment is defining exactly what lean means to every part of the organization. Quality, manufacturing, environmental health and safety, and engineering need to define together what makes an efficient and effective use of avail-



If a lean approach is used there is no need to resource above the "Leveled demand rate" – this reduces space and equipment requirements

Figure 1. The impact of volatility.

able 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 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 as overhead. This creates a different level of tolerance for the initial and operational costs of each. Regional differences also may 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.

Space Needs – Quantity and Quality of Space

Implementing lean principles in QC laboratory environments starts with determining the right *quantity* of space required to effectively carry out testing operations. In addition, identifying and implementing the ideal adjacencies between the different testing, office, write-up, and support spaces of a facility will ensure the right *quality* of space is provided in a way that enables lean practices and behaviors. Finally, a clear understanding of the equipment required, how it is used, who uses it, and how often is essential to maximize the use of resources.

- **Needs Assessment** – a thorough assessment of space needs includes both a top-down and a bottom-up analysis. The combination of these two approaches creates a holistic picture of the quantity of space required. Benchmarking studies are also used when initially planning a facility.
  - 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.
- **Benchmarks** are commonly used when initially planning and sizing a QC testing facility. If used correctly, benchmarks can establish range of magnitude criteria for high level estimation. Benchmarks also can 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 they are 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 Net-Square-Feet (NSF) per person for the primary lab, lab support, and office spaces, as well as Equivalent Linear Feet (ELF) per person, which is the linear measurement of bench and equipment within the lab space.

For example, benchmarks were used to determine if reducing a 12-person biochemistry testing area from 260 NSF/person to 162 NSF/person was not only feasible, but also functional and safe. In the end, the benchmarks showed that for this specific operation, the appropriate range was 216 NSF/person. In the process,

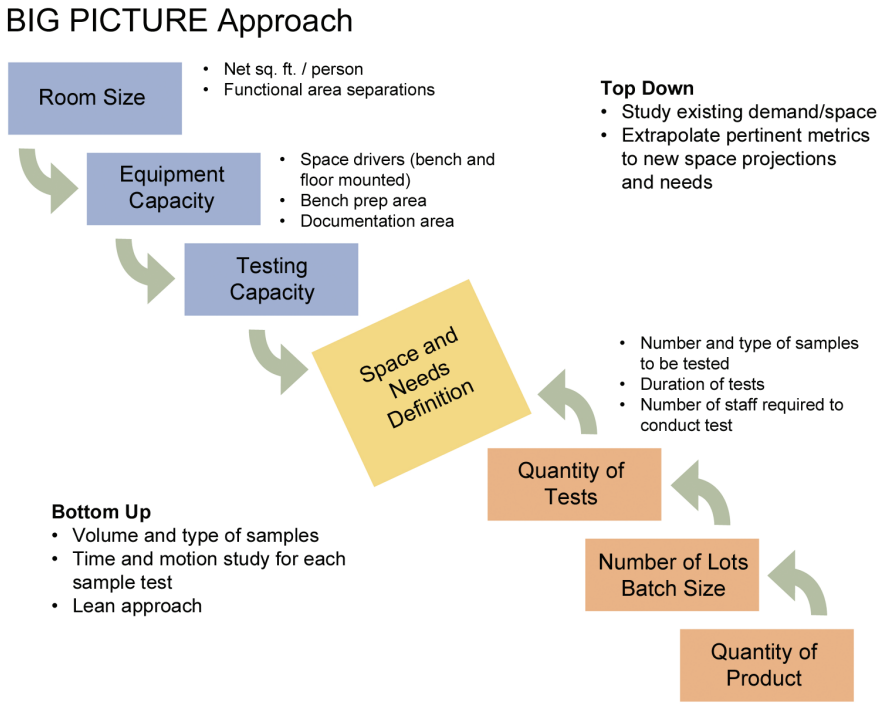


Figure 2. Space needs planning approaches.

the ELF/person was only reduced from 429 to 385.
- An important consideration in determining space needs is **lab expansion**. It is important to ensure the lab has expansion capability in case the testing demands should change in the future.

- By mapping the locations of each team member's activity throughout the days/weeks and where that activity takes place, an **Activity Location Analysis** provides a thorough understanding of the patterns of movement and can help establish the most effective adjacencies possible.

  Equipment Utilization Studies capture data that can provide an understanding of the importance of each piece of equipment to the team's overall mission. Through such a study, a QC organization can better understand how equipment should be allocated. This data can then be charted – from most frequently used and most critical, to least used and non-essential – and used to help optimize the quantity, type, 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 also must incorporate an equipment back-up strategy and risk assessments of specialized assays into space planning and provide flexibility for assay evolution and new technology platforms.
- Consideration must 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.

Lab Location and Shared Equipment Areas Within the Facility

The location of individual labs and of services or equipment that are shared among labs within the overall facility can significantly impact workflow, material transportation, and traffic flow. 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 passthroughs and by co-locating or amalgamating "supplier" and "customer" labs that can share equipment, storage, samples, analyst resources, test results, or information.
- Locate labs adjacent to production areas, simplifying sample management and facilitating improved flow and communication.
- Co-locate or amalgamate labs that will share samples, equipment, or storage.

Creating Suitable Laboratory Work Spaces

For Novartis and the nature of the tasks involved, creating suitable laboratory work spaces involved the utilization of a three-zone concept. In order to promote lean behaviors and efficient operation, the analysts' work spaces are 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 practices, both zones need to be located within the laboratory space. This will eliminate the need to gown in and out 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

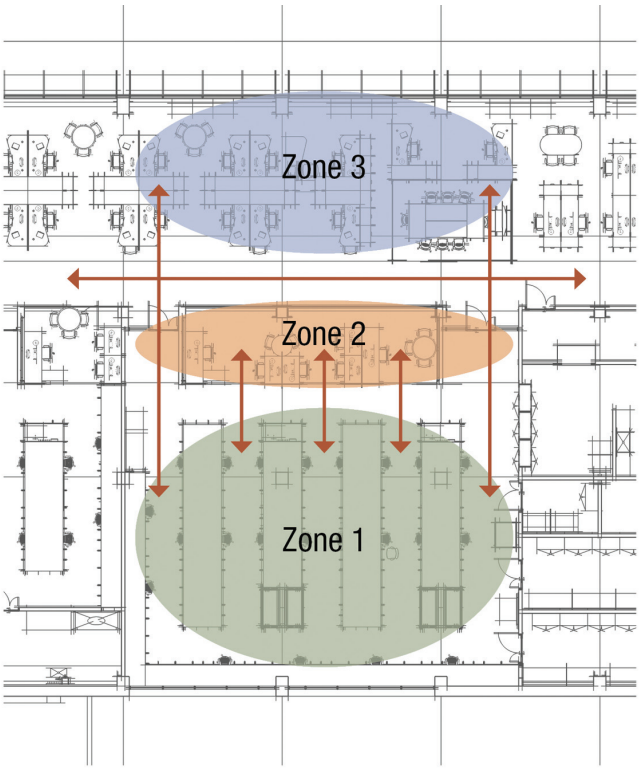


Figure 3. Three-zone QC laboratory design concept.

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 co-workers, 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.

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. In turn, this 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 can reduce 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.

Arguably, the most versatile and re-configurable option is the "comb and spine" in which the spine 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.

Enabling Flexibility

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 as 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 a design that was originally perfect may become obsolete. Sometimes obsolescence can come about so rapidly it is necessary to revamp a lab area immediately after the conclusion of the construction phase.

To mitigate this issue, in the last ten years, laboratory designers and furniture suppliers have developed flexible solutions at three levels:

- **Level One – Flexibility at Bench Level** – traditional benches are fixed and are difficult to relocate in practice. Flexible benches are on wheels to allow a rapid reconfiguration of the lab layout. They can be "detached" and therefore need to have a utilities wall behind them (although it should be noted that this solution may be more expensive). To be even more flexible, the benches can be fully mobile, only requiring being in close proximity to the utilities and services distribution that can be pendants hanging from the ceiling. This option could be less expensive and well suited to lean principles.
- **Level Two – Flexibility at Utilities and Services Connections** – the distribution of services, such as gases, electrical power, vacuum, and water can be rigidly fixed on the bench in a traditional non-flexible configuration. 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. Finally, the utilities and services can be distributed from above via flexible connections allowing full flexibility.
- **Level Three – Flexibility at Distribution Level** – a further level of flexibility can be provided by installing some blind connections in the lab ceiling void to allow the future relocation of utilities and service distribution panels.

With all these options, which one is best? There is a trade-off between the cost of the furniture and its flexibility. Normally, benches on wheels are slightly more expensive than tradition-

al 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. In any case, GLP implications should be considered when reconfiguring the labs layout.

Consumable Inventory Management and Storage

In most labs, effective management of laboratory consumables 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 analysts hoarding or unnecessary multiple storage locations. Poorly managed inventory processes also can result in materials running out, needing to be ordered on short notice or expiring due to oversupply. Effective stock management systems can increase analyst productivity, increase work satisfaction, reduce the resources spent on inventory management, and reduce test delays.

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

- "Stock-outs" and "Write-offs"
- Cost of Inventory
- Inventory Management Effort
- Space Requirements

Achieving these objectives normally involves minimizing the number of stock locations for individual materials, controlling inventory volumes, minimizing the effort required to replenish stocks at the point of use, reducing travel by centrally locating lab and site stores, reducing inventory ownership duration, minimizing inventory management effort, and reducing transaction and documentation efforts.

Energy Efficiency in a Lean Laboratory

Laboratories are among the most difficult facilities to make energy efficient. Typical labs are three to eight times as energy intensive as office buildings – filled with complex equipment, consuming large amounts of electricity, and requiring complex air-handling and waste management systems. Better, safer, and more economical are typical drivers for lean laboratory design and realization; however, sustainability should not be ignored.

The strategies which can be adopted for an energy efficient laboratory are the reduction of demand, the harvesting of free energy, the recovery of waste, and the increase of efficiency; the HVAC system should be designed taking into consideration the indoor environmental quality.

Adaptability and flexibility should be the drivers for design of an energy efficient lab; the HVAC system must be flexible and adaptable to accommodate changes without significant modifications.

Guidelines

The initial Novartis concepts for lab design and layout were validated and refined by the multi-functional team at the workshop and an agreed set of guidelines were established. In addition, a new three-zone concept for test-review-collaboration emerged based upon a review of design options and a case study exercise.

The final high level guidelines endorsed by the workshop participants direct that laboratory areas should be designed to:

Support Leveling, Flow, and Standard Work – leveling flow and standard work are key lean lab principles. To proactively support these fundamental work balance concepts designers should:

- Incorporate fewer internal walls and less separation of labs – this promotes flexible operations and the sharing of workloads and resources to level short interval workloads.
- Incorporate space for sample management and visual cues – visualization of workloads is a core concept of lean.
- Use 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.
- Allow 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.

Support Effective Use of Time

- Integrate write up, review, and approval areas to enable efficient and timely documentation and review of tests supporting both flow and leveling of workloads.
- Use a limited number of adjacent, but separate "hot" desks for project work and non-test tasks.
- Include adjacent collaboration areas and meeting rooms.

Minimize Transport and Motion Wastes

- Locate labs close to manufacturing (simplifying sample management and chain of custody).
- Co-locate or combine labs that will share samples, equipment, or storage.
- Centrally locate shared lab services (e.g., glass wash).
- Centrally locate equipment or storage that will be shared within a lab.

Minimize Space and Equipment Requirements
- Space and equipment requirements should be calculated based on leveled 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.

Maximize Future Configurability
- Employ flexible bench configurations and (semi) configurable services (air/extraction, etc.)

Support Effective Laboratory Inventory Management
- Implement limited and defined storage at the point of use.
- Establish central lab storage for shared materials or high volume unique materials.

Principle	Procedures vs. Facility Design	Facility Design Main Contribution	
		User	Designer
Eliminate uselessness and waste	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 4. Relationship between lean approach and design.

Support Effective Performance Management
- Incorporate areas for visual management displays, huddle meetings, etc.

Foster Lean Behaviors and Communication
- Centrally locate glass walled offices for lab managers and supervisors.
- Employ extensive use of glazing to visually link lab areas.

Support Excellence in Workplace Organization and Cleanliness
- Utilize open or glass fronted cabinetry.
- Limit and define storage throughout the lab.
- Eliminate drawers.

Implementing Lean Principles in Quality Control Laboratories

By bringing together designers, users and lean experts, the Novartis 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 them to develop guidelines that will help ensure that all new builds and refurbishments include design elements and approaches that pro-actively support lean lab initiatives.

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.

Authors

The development of Novartis Vaccines' lean lab guidelines were spearheaded by a team of users and consultants. These experts came together as a group to share their experiences and understanding through the joint authorship of this article. Primary contributors included:

Mike Dockery, Jacobs, Lab Design Consultant
Federico Gabardi, Jacobs, Project Manager
Javier Garay, Flad Architects, Principal
Jim Gazvoda, Flad Architects, Principal
Luke Kimmel, Novartis Vaccines, Associate Director, Global Engineering
Pietro Orombelli, Foster Wheeler, Senior Project Manager
Christophe Peytremann, Novartis Pharmaceuticals, Global IQP Champion
Tom Reynolds, BSM, Operations Service Director
Tanya Scharton-Kersten, Novartis Vaccines, Divisional Quality, Sponsor – Lean Laboratory Program
Graham Shoel, Novartis Vaccines, Director of Project Planning, Global Engineering
Jeanne Sirovatka, Sandoz, Associate Director, Supply Chain