"Work smarter, not harder"

Lean methods come to the lab…at last!

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Is "lean lab" just a management trend du jour or something which you need to carefully consider? The successful introduction of lean manufacturing into industrial production was completed years ago and is now an indispensable part of today's highly competitive markets. The argument "Lean's not for us in the chemicals, pharmaceutical and food sectors – we're too highly regulated" simply doesn't hold water! The aerospace industry is also highly regulated – but lean can be found everywhere within it. Compared to the manufacturing industry, however, the lab and lab operations alike have a number of very specific challenges that need to be accommodated. While the key principles are the same, a number of aspects need very special handling.

The idea behind 'lean' is "to create value with no (or less) wastage." The aim is to achieve optimal alignment between all of the processes required within the value chain and to avoid any activities that are unnecessary (wastage, Japanese "muda").

When incoming work surpasses the capacity of the lab to handle it or the analysis results or approvals come in too late and the lead time (total working time) is exceeded, then it is high time to take a long look at lean theory. And to do so before investing in new resources (equipment, premises and personnel). Another opportunity presents itself if you're planning a new building or extension and want to use lean ideas to implement the project. The general aim here is now to look at the magic triangle of high quality, low costs and rapid lead time and to seek out the idea balance.

The following sections list the elements/modules with which processes can be designed and optimized to fit the "lean" ideal.

Module: Housekeeping and Workplace Optimization with 5S

The 5S method is viewed as being the most important core method in the field of lean production. The term, which has its origins in Japanese manufacturing theory, refers to specific strategies for workplace optimization. The goal of a 5S program is to design workplaces so that personnel can perform work without any interruptions, while avoiding searching, waiting around or time-consuming fetch and carry, thus ensuring that work can proceed without wastage. A clean and well-organized working environment is also seen as the basis for quality work – this is especially true for the laboratory sector.

Module: Value Stream Mapping/ Process Analysis

Value stream mapping is a method for performing a systematic survey of the current state of a process plus all of its relevant key figures. The resulting visualization (current map) can be used to illustrate wastage very clearly. The goal is to optimize the overall production process in terms of its lead time.

A key figure in value stream mapping is the proportion of cycle time to the overall lead time. Even though the total lead time may be two weeks, for example, the cycle time may be just one hour. Within this process, value is created only by the hour in which the analysis is worked on. Some of the remaining time is consumed by unavoidable yet necessary steps that indirectly create value, such as sample preparation, buffer production or equipment calibration, which can certainly be optimized or substantially reduced. But plain and simple wastage from waiting, fetching and searching must be reduced to zero! By using the modified seven "mudas" (Japanese term for wastage or waste), you can then proceed to investigate all of the steps in the process so as to visualize their potential for optimization.

Ancillary activities such as the wash-up room, sample transportation, buffer production and autoclaving also offer specific potential, since it may be possible to organize them as centralized services. This serves to reduce the lab workload to benefit value creation. For types of analysis rarely performed, the option of outsourcing this work to a trusted external lab can be investigated – or to procure culture media largely externally, for example, and make greater use of disposable items (see Fig. 1).

- **Module: Scheduling and Planning**
  Smoothing and leveling are the lean keywords here. Translated to a lab context, this equates to investigating whether series can be established or whether a day/week takt cycle can be introduced without endangering the lead time. The aim is to guarantee a certain default workload so as to level out over-/undercapacity. The "work in progress" (WiP) must be visualized and discussed briefly every day with employees as part of the daily stand-up meeting. While shift work in the lab may be a topic to an extent, coverage from "6 (AM) to 6 (PM)" is nowadays a necessary minimum. When hiring new staff, take care to ensure that Saturday is classed as a normal working day and that no opt-out is possible for shiftwork (see Fig. 2).

- **Module: Workflow**
  The goal here is to arrange work equipment in a way that is more likely to facilitate a seamless transition between the individual work steps. An even better approach is to form "cells", i.e. the creation of functional areas such as water analysis. Such a cell offers a localized place for all analysis work – including the necessary equipment requalifications. In practice, therefore, this means that analysis, reporting and documentation are kept close together. In the future, the trend towards the paperless lab will gain further traction, especially in light of the fact that as much as 50% (!) of work in highly-regulated sectors involves documentation activities. More attention needs to be paid to e-reader/tablet applications (see Fig. 3).

Fig. 1 Value stream mapping, process analysis

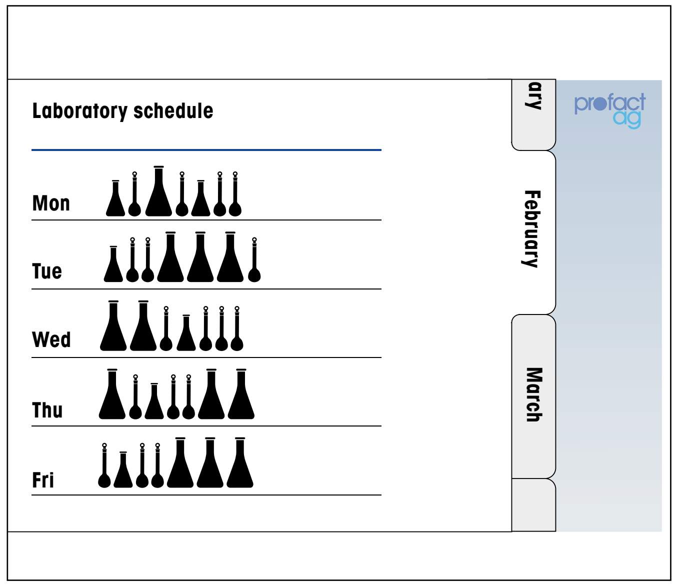

Fig. 2 Weekly plan, task list

- **Module: Production Control with Key Figures (KPIs) and Visualization**
  Key performance indicators (KPIs) are an indispensable management tool One typical measurement is lead time, e.g. from sample receipt at the lab (journal entry) to sample release in working days, plotted against the factory calendar (see Fig. 4). The "right first time" value can also be calculated: this expresses in-spec parts to overall production as a ratio. Translated to lab-speak, this gives the proportion of analyses that are error-free first time around. Another KPI presents OOS (Out of Specification) results, and namely those caused by the lab itself, such as measurement errors, equipment errors, operator errors, etc. This regular monitoring of laboratory performance forms the basis for the following activities, such as root cause analysis for deviations (in performance, not in analyses!) and the activities necessary in continuous improvement to achieve goals such as CIP. And if you're in management, you need to "Do the gemba walk"! Get the information directly from within the process.

Module: Apparatus and Equipment

This involves regular inspection of lab apparatus. This establishes whether reliability is OK, whether the equipment is responsible for any OOS cases, whether maintenance agreements are appropriate, whether critical wear parts are held on-site – or is obsolescence management being practiced? Does the market offer innovations that could accelerate our processes? Examples here include using one device capable of measuring both conductivity and TOC, the use of an autosampler to minimize set-up times or the latest generation of laboratory balances, which now themselves include many kinds of lean features.

In the context of Industry 4.0, major efforts are now being made by suppliers to provide active support for digitalization and networking. Almost all data in the lab are now logged electronically, for example. Measured values are one example: once recorded, they can no longer "escape"

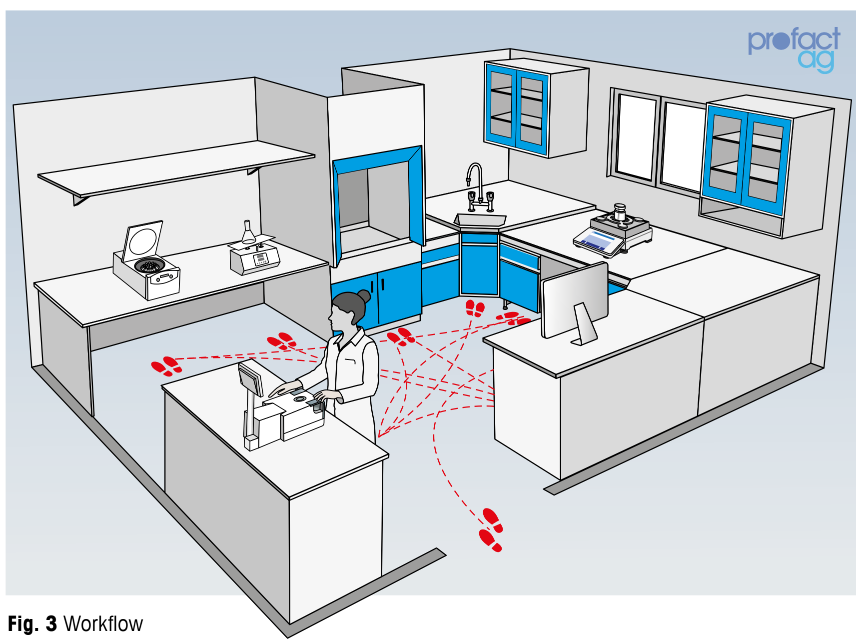

Fig. 3 Workflow

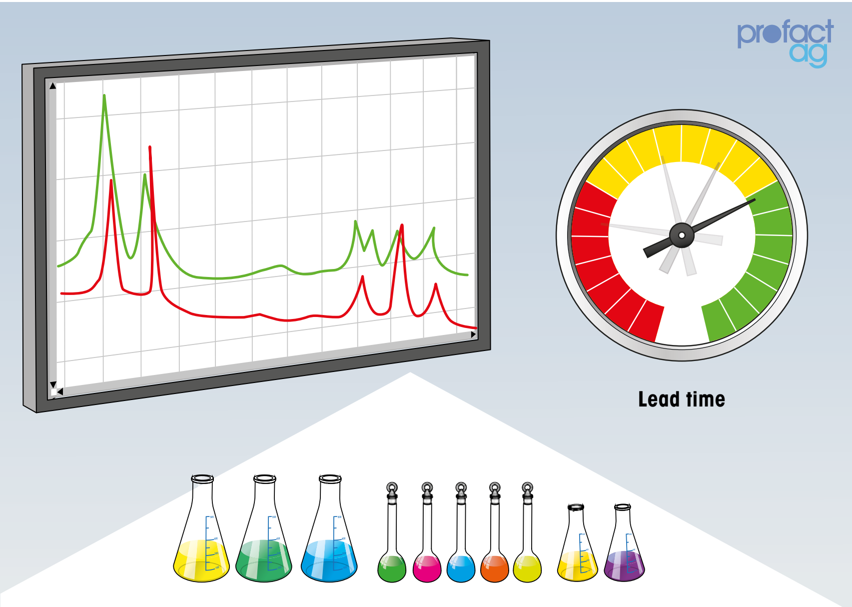

Fig. 4 Key performance indicators

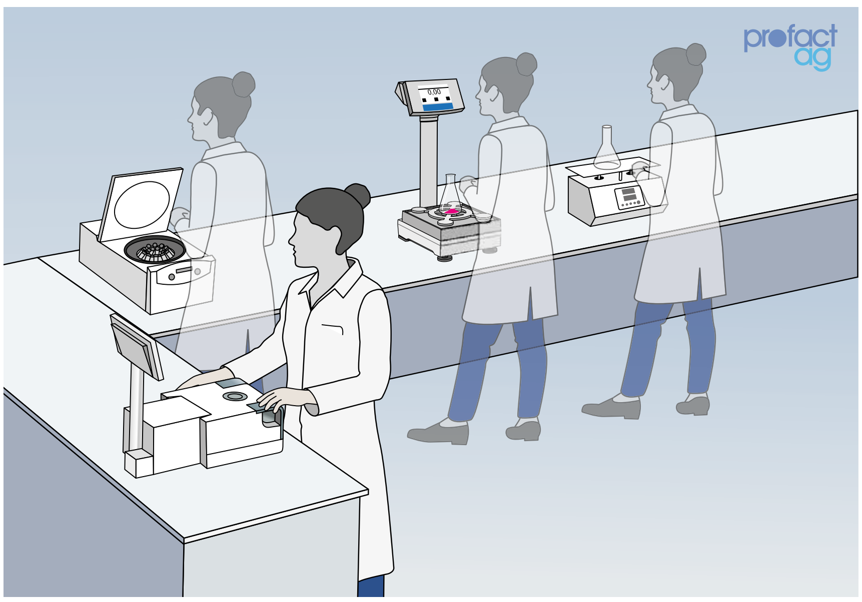

Fig. 5 Training/Continuing Professional Development

The concept of "lean" comes from Japan (although under a different name) and has its origins in the Toyota Production System (TPS), which was successively developed following the Second World War – and was originally born of necessity. While mass production in Western companies was focusing on breaking down the manufacturing process into many smaller work steps (Taylorism) and maximizing the quantities produced on large-scale production lines so as to keep per-unit costs low, Toyota instead made the decision to concentrate on optimizing production processes, and the flow of materials and information. There was simply neither money nor space for new, large-scale plant and warehouses capable of storing large stocks of materials and components. Expensive materials needed to move fast along the value chain. As a result, Toyota developed the expertise needed to synchronize flows and achieve continuous improvements in terms of quality, lead time and resources.

but are stored in multiple systems such as SAP or LIMS (Laboratory Information Management System), etc. Applications include the simple measurement of dimensions in packaging control, for example, through to HPLC systems that apply the measured value directly within the software. The time-consuming updating of Excel tables or handwritten records can then finally be consigned to history. Currently in development, the AnIML (Analytical Information Markup Language) standard seems very promising. One should never underestimate complexity, however: we only need to think back to the heyday of CIM (computer-integrated manufacturing) in the 1990s – and what then became of it. Even today, the goal of fully-integrated information processing has yet to be achieved.

Module: Training/CPD and Multi-Skilling

Employees with inadequate training will be unsure of themselves and may well require more time to complete an analysis, may make unnecessary errors (OOS, repetitions) or may even balk at attempting a scheduled analysis ("I've never done that before"). Employee freedom in the sense of "I'll go and pick an analysis to do that I like doing or can do really well" – and not the analyses required by the takt – also needs to be questioned. As lab leader, you also need to ask yourself questions about matching analyst expertise to methods/apparatus. The "multi-skilling" approach permits a degree of flexibility in the event of planned/unplanned absence. That said, equipment ability/competency is maintained only by regular work with the apparatus. The opportunities offered by e-learning should also be utilized for continuing professional development (see Fig. 5).

Module: Consumables and Lab Chemicals

Indirect goods such as consumables and laboratory chemicals must be properly managed. An ABC or XYZ analysis can be used to classify the products so as to optimize this management. The ABC analysis determines the contribution to value from each good, while the XYZ analysis quantifies the demand/consumption flow in terms of time. This reduces stocks of "slow sellers" while allowing "fast movers" to be managed using kanban methods. Following the core principle of this lean method, staff are responsible for replenishing materials picked from the warehouse. The bad habit of "take the last one and hope no-one notices" should therefore be a thing of the past (see Fig. 6).

Module: CIP

The continuous improvement of the states achieved by implementing CIP/kaizen methods is of central importance to sustainability and ongoing further development. This is also an important topic when the laboratory wishes to obtain "lean" certification. Facilitators must be proficient in commonplace problem-solving techniques. Green and black belt training courses are now available either in-house or on the market.

We can sum up by recalling a piece of advice from change management: as a rule of thumb, if you need to leave your comfort zone, then you need change management! Seek professional coaching from the HR development unit or externally and support the transformation towards lean in your laboratory.

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Erwin Studer holds a degree in mechanical engineering and has spent much of his professional life in the pharmaceutical industry. Alongside work in factory planning, he became involved in laboratory planning and construction very early on in his career. Today, he is one of several partners leading a practice-oriented team of engineers and business management professionals who provide consulting services to manufacturing companies, predominantly within Europe. His team offers specialized methods and tools for boosting efficiency that affected employees can use to achieve proactive, measurable and sustainable solutions to problems in the lab, in production and in the wider production environment.

Fig. 6 Kanban inventory control

Glossary

5S Method for workplace organization. 5S stands for: Sort, Systematize, Spick and Span, Standardize, Self-Discipline

CIP Continuous Improvement Process, Japanese "kaizen", "change for better"

KPI Key Performance Indicator

Muda Japanese for "wastage", cf. the 7 traditional mudas

Gemba Japanese for the "place where value is created"

Gemba walk Japanese, similar to "management by walking around"

Obsolescence Non-availability due to the discontinuation of (usually electronic) parts or the cancellation of software upgrades.

ABC/XYZ analysis The ABC/XYZ analysis is a materials management technique for improving the classification of inventories held by a business.

Kanban Kanban is a method for inventory and production control that is based on the "pull principle" and which defines the system as a self-contained control loop.

Green/Black Belt Certified training as a facilitator/change agent

Six Sigma (6σ) Six Sigma is simultaneously a management system for process improvement, a statistical quality goal and a quality management method.

Change Management Organizational development approach for implementing new strategies, structures, systems, processes or types of behavior.