Lean Principles of Performance Improvement

A variety of performance improvement techniques, such as Lean, have already proved their worth in other business sectors and are ideally suited for adoption by the biopharmaceutical industry.

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‘Lean’ is just one of a number of continuous improvement techniques that have found favour within industry over the past decade or so. At its most basic level, it can be defined as performance improvement brought about by the identification and elimination of waste, and the principles of Lean have been applied widely in the manufacturing sector as a way of improving operational performance. However, the uptake of Lean in the more scientific and laboratory-based environment of the biopharmaceutical industry (and indeed most similar lab-based industries) has been slow. Given the current pressures on the biopharmaceutical industry to perform and provide value for money, perhaps now is the time for it to embrace these principles to a greater degree.

As touched on above, Lean involves the identification and elimination of waste to bring about performance improvement. One of the key ways it does this is by defining and reviewing process flow within an area, department or organisation. It looks at the processes in detail to find the causes of delay, rework, bottlenecks and so on with the aim of eliminating them. The definition of waste in Lean is anything that adds costs without adding value (that is, non value-adding activities), and it should be the aim of any organisation to minimise non value-adding activities, while maximising the value-added work that it does.

SOURCES OF WASTE

Within the biopharmaceutical environment, waste can be looked at in all areas – whether it is biopharmaceutical research, the drug development process or the manufacture of final products. While Lean has traditionally been applied to the manufacturing sector, there is no reason why the principles cannot be applied to many different areas of an organisation, including the non-traditional areas of drug research and development.

Within the research and development area, the most obvious source of waste is the continuation of research projects and the continued development of potential drugs past the time at which they can be identified as unsuccessful or non-commercial. This is wasteful in terms of both cost and resources. Running a research or development project on a non-commercial compound, target or candidate drug wastes money; however, it also wastes other resources including equipment and – perhaps most importantly given that it is a knowledge-based industry – it wastes the time, skills and energy of people within the organisation. Waste in these areas may have a number of causes, including delays in decision-making caused by poor information availability and communication, and the inefficient use of the resources (both people and equipment) available. Such waste is unacceptable, particularly with the growing pressure on R&D departments to improve their pipeline and bring products to market as quickly as possible. These pressures...
are being fuelled, of course, by the large and ever-increasing cost involved with bringing a product to market, coupled with the limited protection – in terms of exclusivity – provided by patent protection.

In the manufacturing process, there are likely to be many sources of waste that can be identified. In the manufacturing laboratory environment, waste will be anything that the laboratory does unnecessarily and which costs money, makes the lab run inefficiently or – perhaps most importantly – holds up the manufacturing process. Delays in the manufacturing process may be brought about by inefficient laboratory processes, lack of trained staff to do the testing required at any particular time, inefficient use of scientific equipment and poor management of the work backlog. All of these can lead to delays in the manufacturing supply chain that can cause many knock-on effects within the organisation as a whole. A symptom of this type of problem is often the inability of the laboratory to adapt easily to the changing requirements of its customers (that is, the manufacturing operations) when a new product or new formulation is being introduced, or when a change in the manufacturing process takes place.

Within the manufacturing sector, the QC laboratory may be the last great unimproved area, and may be the cause of significant delays in batch and lot release, thereby significantly delaying the manufacturing supply chain. With increasing competition from manufacturing plants around the world, many of which may have significantly reduced labour costs, inefficiencies of this sort will not be tolerated in tomorrow’s manufacturing and business environment.

**THE VALUE OF THE LAB**

In all the cases outlined above, the laboratory and laboratory function must not be seen as a source of waste within the organisation; these laboratories must be looking at ways of improving their performance. The pressure on laboratories to prove their worth and value to the organisation they are part of is increasing all the time, and laboratories are under constant pressure to improve their efficiency and effectiveness. This pressure means that there is also a constant risk of more and more outsourcing within all laboratory areas. This risk applies as much to research and development as to manufacturing QC laboratories. This can be illustrated by looking at the number of pharmaceutical companies that use third parties to run and manage their drug development and clinical trials projects, how many enter into or fund joint research projects, and how many license products from other organisations.

Whether we like to admit it or not, this is outsourcing of research and development.

Laboratories that face this type of pressure should not be afraid of embracing improvement techniques such as Lean, and indeed in many ways are ideally suited to the adoption of these types of techniques. Key to the successful implementation of Lean is the concept of observation and measurement. Observation and measurement help you understand the present position; if this is understood, then what needs to be done to improve that position can be identified and implemented. Further measurement of the outcome then helps you to understand if the improvement has been successful. Clearly, in the laboratory environment, observation and measurement are key activities, and scientists are trained in these areas and techniques. In addition to this, laboratories are data-rich environments – especially if the laboratory has implemented a Laboratory Information Management Systems (LIMS) or other scientific data management system – and this data and information should be readily available and accessible. It is, however, unusual to find laboratories and organisations that actually use this available information as an aid to process improvement.

**RESOURCE PLANNING AND SCHEDULING**

There may be a number of reasons why the data and information available within laboratories may not be used as a resource to help process improvement. These include a lack of acceptance of the need to improve performance, a lack of understanding of the principles

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All business is constantly undergoing change at a rapid rate and nowhere is this more true, or the rate of change more rapid, than in the biopharmaceutical industry. Here, change is fuelled by scientific advances, technological advances (both in scientific equipment and in information technology and informatics) and changing business needs in terms of the types of products required. Involved and a lack of tools to manage and interpret the data. The need for the adoption of improvement techniques such as Lean within the biopharmaceutical industry has already been outlined above. However, techniques that can help improve processes are also becoming available, and once again have been adapted from the manufacturing industry. One of the key techniques available is resource planning and scheduling (RPS). RPS is concerned with looking at all aspects of resource availability, utilisation and workload to help organisations manage their operations. When applied together with Lean, or as part of a continuous improvement process, RPS can help eliminate waste by identifying where time is spent and how that time is split between value-adding and non-value-adding activities. In the same way, RPS can identify bottlenecks within processes and help to optimise process flow. In addition, ‘what if’ scenarios can be run to model the effect of changes to the process or system, for example, the introduction of new products or the introduction of new equipment or machinery. Within the laboratory-based environment, these techniques can be used just as effectively to identify bottlenecks and model the effect of such things as changing resources in terms of equipment and people, and the ability of the laboratory operation to deal with changing needs and demands from its customers.

All business is constantly undergoing change at a rapid rate and nowhere is this more true, or the rate of change more rapid, than in the biopharmaceutical industry. Here, change is fuelled by scientific advances, technological advances (both in scientific equipment and in information technology and informatics) and changing business needs in terms of the types of products required. Laboratories must be able to respond to these changes rapidly and effectively. It is not acceptable for laboratories to run sub-optimally, either in terms of cost or in terms of the service or product they supply. For example, laboratories must be able to identify the minimum number of samples that make running an auto-analyser cost-effective and manage their back-log accordingly; they must understand what the needs of their customers are in terms of the service they supply as defined in Service Level Agreements (SLAs), and they must be able to measure their performance against these SLAs. In addition, they must be able to respond rapidly to changing needs, including the ability to quickly and effectively change the set-up of the lab and instruments, as well as having multi-skilled and cross-trained staff capable of taking on a variety of roles.

Pressure to Perform and Improve

In summary, laboratories in the biopharmaceutical industry are under increasing pressure to perform and improve. One approach to addressing these issues is the implementation of continuous improvement techniques that have proved their worth in other areas of business that may, at first, seem unconnected with the biopharmaceutical industry. One such technique is the implementation of Lean as a continuous improvement process. Biopharmaceutical laboratories are ideally suited to the adoption of techniques such as this because they are data-rich environments where the information required to help in the continuous improvement process should be readily available. This is particularly true for laboratories that already have a LIMS in place. By adopting continuous improvement techniques, laboratories will be better able to meet the needs of their customers, provide a value-adding service to their customers (where the business itself is seen as a customer of the laboratory) and therefore prove their value to the organisation or business as a whole.

However, one vital point to emphasise is that the laboratory cannot undertake initiatives like this in isolation; they must ensure that they understand what their customers and/or the business actually requires from them, and that there is a common understanding of the overall aims of the business. In other words, the laboratory and the business need to be aligned, and this requires close communication between all interested parties.

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