

Creating a culture of continuous improvement

As pharmaceutical companies strive to minimise the cost of developing and manufacturing drug delivery devices, device manufacturers have a duty to ensure they offer their partners the best possible value. This requires them to apply a philosophy of continual improvement throughout their business so that products are manufactured in the most efficient, effective and value driven way possible.

It is often thought that cost savings can be achieved simply by reducing margin and for some, that may be the case. For device manufacturers who have built their business by creating close, value driven relationships with their partners this route is neither sustainable or indeed, realistic. Though it may provide a short term fix, longer term it simply creates a catalogue of other potential issues including lack of production capacity, loss of quality standards, poor R&D output and no realistic or achievable roadmap for future investment and success. When margins are tight, manufacturers must seek out efficiencies in other ways, primarily through process improvement and waste elimination. There may also be efficiencies in product development, though the level to which improvements can be made is entirely dependent on the regulatory constraints for that particular product.

This article will examine how a data led methodology such as Six Sigma can benefit device manufacturers, a methodology which demonstrably improves decision making, delivers better control and ultimately improves efficiency.

Creating a data led approach to improvement

Often in the past 'continuous improvement' meant the engineering department identifying a problem and through a combination of skill, experience and a certain degree of tweaking, the issue would sometimes be resolved but because this approach to problem solving was driven by engineering intuition rather than by fact based analysis of the whole process, it was sometimes the case that the "solution" caused problems elsewhere. Occasionally the 'fix' worsened the situation over the medium or long term and in addition, the learning gained from the improvement could not be readily shared with teams involved in similar tasks, permanently embedded into a process or still further enhanced.

In order to deliver consistent and meaningful continuous improvement it is necessary for device manufacturers to adopt a data led, fact based approach. Six Sigma is built upon this principle and is now a globally renowned methodology for ensuring continuous improvement. At its core, Six Sigma uses the manufacturer's own data to create better processes, deliver better products and remove unnecessary waste.

Fitness for purpose

Like every methodology, Six Sigma needs to be applied appropriately, indeed 'Lean Sigma' is a popular term now used by organisations that take the most relevant elements of a classic Six Sigma toolkit and apply them to their own tasks. An improvement project should also be timely and have a pre-agreed deliverable. 'Paralysis through analysis' is not an option for modern device developers and manufacturers. Indeed, current thinking suggests that if an improvement passes the 'blatantly obvious' real world test then in all probability the need for data (and the time taken to create that data) to support the decision is negligible.

Reinforcing and supporting a culture of continuous improvement

In order to avoid unnecessary 'paralysis through analysis', device manufacturers should look to harvest the real and valuable contribution towards improvement that can be made by employees. By applying a QCDSM (Quality, Cost, Delivery, Safety, Morale) control and brainstorming ideas; organisations can identify and qualify Six Sigma projects that will make a real and tangible contribution. Indeed, Bepak a leading specialty medical device manufacturer estimates that 98% of ideas generated through a QCDSM approach have true value and around 5% have exceptional value.

Organisations will often find that ideas fall broadly into three categories – just do it, which are quick, cheap and worthwhile; KAISEN projects (the Japanese term for continuous improvement), which need more robust data and resource planning; and Six Sigma projects which tend to be tasks of significance and therefore need substantial multi-disciplinary effort, resource and data.

An example of a 'just do it' project could be to reduce cost and gain a greater level of technical support simply by purchasing direct from a manufacturer rather than through a distribution channel.

In line with GMP (Good Manufacturing Practice) a batch changeover requires that manufacturing machines be shut down and thoroughly cleaned, lost manufacturing time that clearly impacts on productivity. Bepak, a leading exponent of the Six Sigma methodology, recently targeted a reduction in the time taken to changeover their

manufacturing machines and reduced the lost time by 50%. By using a KAISEN approach to improvement, Bepak have been able to improve that particular machines productivity by circa 5%, saving tens of thousands of pounds per year in lost time.

Elimination of waste

Cost reduction can often be one of the most obvious start points in the creation an ongoing programme of continuous improvement. The strategic target for all device manufacturers should be to minimise waste in the business and an overall reduction in operating costs. The commitment to waste reduction should run right throughout the business and whilst management focus is important, it is often “employee buy-in” that is the decisive factor.

Too often employees equate waste elimination with a reduction in headcount. Care should be taken to ensure that the continuous improvement programme does not fail because of this fundamental misunderstanding. Waste management is very much about making employees lives easier to ensure that best value is extracted from their time. Fundamental to a waste management strategy is the holistic implementation of a better way, one that the operator contributes to as well as benefits from. This well rounded approach contributes to greater consistency in people and process, ensuring an all round better service for the customer.

Device manufacturers should be mindful that whilst processes and procedures can be modified and improved, fundamentally, amendments should not be made to the design or specification of the finished product. Though the general ISO9000 (2000) standard provides for a measured element of continuous improvement, ISO13485 (the standard for medical delivery devices) rigidly states that standards should be maintained, not improved and certainly not compromised. Therefore a balanced approach to change must be maintained.

Elimination of bad days

‘Bad days’ can potentially have a long term impact on the viability of the device manufacturers business. Whether bad days are derived form unforeseen ‘glitches’ or more systemic process issues, without an appropriate resolution the ultimate sanction can be an expression of sufficient concern from the regulatory authorities resulting in product recall and substantial financial penalties.

The prevention of bad days is best served through a structured problem solving methodology that delivers the necessary improvements in business process. DMAIC (Define, Measure, Analyse, Improve, Control) are the five phases of Six Sigma process improvement that lead the task force logically from defining the problem through to

implementing a solution. By identifying the underlying cause and establishing best practice to ensure the solution remains in place, the number of bad days can be radically reduced and systemically erased.

Supplier control

Often smaller suppliers do not have the resource or expertise to employ a Six Sigma programme of their own. In such cases, device manufacturers can and should play a key role in helping them eliminate waste and eradicate their own bad days. After all, a continuously improving supplier will have a positive impact on the overall improvement strategy for the device manufacturer. It is important that suppliers recognise how the smallest defect in the apparently least important component can have an effect throughout the supply chain and if allowed unchecked into the product will ultimately affect the end user of the device.

The leading Six Sigma manufacturers are now creating Continuous Improvement Teams consisting of specialists from quality, R&D, purchasing and operations to enable suppliers to improve their processes and product performance.

Continuous improvement should complement not constrain other methodologies

Continuous improvement should be viewed as an enabler, a contributor to the realisation of the organisation's strategy. To that end, it cannot operate in isolation and neither can it be employed to the detriment of other business critical methodologies.

As an example, Bepak have created their own proprietary planning tool – the Bepak Product Introduction Process (BPIP) which guides and controls product through the manufacturing process from concept creation to industrialisation, manufacture and on throughout its life. Aligned entirely with Design for Six Sigma, this methodology enables new product introduction to be initiated in a consistent, repeatable and pragmatic way. Like Six Sigma it replaces reactionary decision making with fact based planning and provides a platform for continuous improvement throughout the life of the product. Most importantly of all, it enables an approach that like 'lean sigma' is tailored to the needs of individual projects and upon which improvements can be assessed and actioned appropriately.

Conclusion

Though Six Sigma was only conceived around 20 years ago, its evolutionary journey has been rapid and high profile. For manufacturers of medical devices it offers real benefits in

the quest toward reducing development and manufacturing costs. It also provides a critical control to ensure learning is retained and solutions are maintained.

Device manufacturers should recognise that any continuous improvement approach, including Six Sigma, needs to be tailored to match the strategy and objectives of the individual organisation. Though many of the initiatives and methodologies may be consistent with the benchmarks established by other organisations it is important that the approach is fit for purpose. Historically approaches such as Total Quality Management (TQM) have failed because they were not embedded sufficiently in the strategy of the organisation. Moreover, because there was no monitoring or control, it was almost impossible to assess whether or not the process had made any real impact – positive or negative.

A number of core cultural 'ingredients' are required to ensure that a continuous improvement programme delivers real benefits to the organisation. The first is a measurable integration of the methodology in line with business strategies, the objectives of which often fall into three broad categories: cost reduction, business process re-engineering and supply chain involvement. The second criterion is a tangible and long term commitment from both the organisations leadership and the employees. The impact of the programmes must be quantified if further improvements are to be made and the momentum towards continuous improvement maintained.