Lean Six Sigma Implementation at BioReliance

Introduction - Implementing Lean Six Sigma

Colin Barr Associates are very experienced at delivering Lean Six Sigma programmes. This article walks through the various elements of such a programme and gives some top level summaries and advice on implementation. It does not go into detailed descriptions of each element.

About 18 months ago, Colin Barr Associates were selected as Lean Six Sigma partners for BioReliance in the UK and in our opinion this organisation has followed many good practices in adopting the methodology. In this article we have included the real life experiences of the BioReliance Process Improvement Group. Lynne McConnell and Brian McLennan head up that group and are the two key people responsible for leading the implementation of Lean Six Sigma across the BioReliance operation in the UK.

Hence this article combines our own advice with the experiences of a medium sized company which have recently adopted Lean Six Sigma as their improvement methodology.

Introduction to BioReliance

BioReliance is the world's largest provider of contract services for the biopharmaceutical industry. The company provides testing, development, and manufacturing services for pharmaceutical products from pre-clinical development through to licensed production. Formed in 1947, the company now supports over 600 clients annually including some of the biggest pharmaceutical companies in the world. BioReliance is based in Rockville, Maryland, USA. There are three major facilities in the UK at Glasgow, Stirling, and Edinburgh which employ roughly 300 people.

A Background of Continuous Improvement at BioReliance

BioReliance has been engaged in continuous improvement for many years. The emphasis since 2004 in the UK operation was on systems implementation aimed at creating robust processes. However, 18 months ago it was decided to rapidly build on what had gone before.

Lynne McConnell: "We really wanted to re-invigorate process improvement by deploying Lean Six Sigma more widely within the organisation. Only a few local people had been trained in the methodology prior to this and of those, only one had gone through a certification process. The Six

Sigma methodology existed in the US operation but it was at a very high organisational level and included very few people."

Brian McLennan: "One of the key drivers for improvement was that the systems implementation had, for the first time, made metrics like our assay (test) performance much more visible. It was clear that we had work to do and everyone began to get measured against these new metrics. For example, improving on-time-delivery became a big focus."

Structured Approach

There are many ways to structure a Lean Six Sigma programme. Consideration has to be given to elements such as :

- Leadership of the programme
- Objectives
- Alignment and Choice of Projects
- Participant Selection
- Training Modules
- Review Process
- Recognition and Certification

These elements are discussed in the following sections.

Leadership Of The Programme

It's generally accepted that Lean Six Sigma programmes will only succeed when the senior team is fully on-board with it. This means more than just saying the right words in team forums. The senior team has to be involved in communicating the vision in a compelling manner, setting top level goals and objectives, agreeing the projects and participants, maintaining a sense of urgency, reviewing progress, continuously selling the message, supporting the training, recognising the successes, and re-grouping the efforts when things go wrong. Sounds easy...right ? The tough reality is that the drive for improvement will not work without this level of involvement and commitment.

In addition to the above, it is likely that in a medium or large organisation an "Implementation Leader" will be required to drive the programme forward. Depending on the size of the business this may be a full or part time role. At BioReliance this implementation role was assigned to Lynne McConnell of the Process Improvement group.

Lynne McConnell: "We have had superb support from senior management not just locally, but on a Global basis. All of the senior team have shown commitment to the effort. We have heard (from you Colin) that this is not always the case, so it's an obstacle that we have not had to overcome. We do feel well supported."

Objectives

Any business wishing to adopt Lean Six Sigma first needs to figure out what it's trying to achieve by utilising the methodology. We have a view that says when initiatives of this sort fail, it's because of a

lack of understanding, not of what can be achieved, but of what ***cannot*** be achieved. For example - Can I use Six Sigma to develop a strategy ? No ! Can I use Six Sigma to create disruptive innovation ? No ! These are but two examples from a list of many. It's a question of engaging the right techniques into the appropriate opportunities.

Often Lean Six Sigma programmes have financial objectives as their target and this makes sense. However there are often important improvements required where measuring a purely financial gain is not necessarily easy. Lean Six Sigma is not confined to financial-only improvement.

Think of a ***process*** in your business where ...
- Things repeatedly go wrong, or
- Performance is not up to scratch, or
- Measurement of performance is inadequate or non-existent, or
- Customers keep complaining about it, or
- We fixed the problems before but "it's back", or
- The process is inefficient, wastes time or materials, takes too long, or
- The competitions version is much better

This is not meant to be an exhaustive list, but if you recognise any of these situations, then Lean Six Sigma is probably the right methodology to apply. With the right methodology you can set meaningful objectives, financial and non-financial.

Lynne McConnell: "At BioReliance the business has overall cost reduction targets for the year. Our aim was to use Lean Six Sigma to achieve a proportion of those targets. Each Laboratory Director has his own financial objectives split down from the total business picture. Together with the Process Improvement Group and the Finance Department, the Laboratory Directors review progress towards these objectives on a monthly / quarterly basis."

Selecting Projects That Matter

With the correct overall objectives established, specific projects can then be identified.

We always advise our clients that careful project selection is a critical success factor in a Lean Six Sigma programme. A major pitfall is biting off more than the organisation can reasonably chew. It is also important that the projects are aligned with current strategies and the core objectives discussed above. This is no place for nice-to-haves. In our experience, non-core projects don't get resourced and are likely to fail.

The Process Improvement Group at BioReliance maintains a "Data Sheet" of potential improvement projects. The Group oversees a quarterly process where the Data Sheet is used as a funnel for projects to pursue, and ones to keep on hold for the future. The analysis includes estimating the financial benefits to identify the high value areas of opportunity. These are the projects which will give the Laboratory Directors success.

Potential projects get into the funnel as a result of internal operational issues or customer feedback. The Process Improvement group look for common themes suggesting systemic areas for improvement. Monthly performance metrics are reviewed regularly to "smoke out" potential improvement areas.

Brian McLennan: "We also run an "AIM Campaign" where AIM stands for "All Ideas Matter". This is a general invitation for any employee to submit a potential improvement topic. All ideas are reviewed as part of the funnel process."

Selecting the Right Participants

People who are trained as expert practitioners in Lean Six Sigma normally take on the title "Green Belt" or "Black Belt". It's just a title that reflects a high degree of expertise in process improvement and problem solving. Our usual advice to clients regarding Green Belt and Black Belt candidates is that there are no formal educational qualifications required. However, given the investment you are making in these people, you would expect them to come from your high performer, high potential population. They should be numerate and reasonably comfortable at using Excel. Above all they should be seen as the change agents in your organisation, be willing to learn, and be motivated to work on process improvement.

Brian McLennan: "As leaders of this improvement drive, Lynne and myself decided it was important for ourselves to embark on Green Belt and then Black Belt training. We took the opportunity to bring as many others as we could, up to these levels as well. We will exit this first year with 15 trained Green Belts and 4 trained Black Belts."

Lynne McConnell: "We decided that our set of criteria for people to participate in the programme would be, first, that any candidate should have a minimum of two years service. Second, they should be identified as a high performer, and third, that they should already have shown some initiative to implement improvements within their own group."

Lynne McConnell: "We wanted to get a spread of people from the three UK sites so that it wasn't seen as a "Glasgow programme" which is our biggest location. We also endeavoured to get a good mix of people from both the operational areas and our support groups."

Training and Certification

The training programme for Six Sigma Black Belts has gradually standardised on about 20 days in class. These sessions are broken up into various modules with gaps in between, hence completion of the training takes several months. Across industry, Green Belt training is much more varied in duration, but roughly it should sit as a half-way-house between zero and Black Belt level. It's not our intention to go into the details of the training structure and content in this article, but more details can be found within www.colinbarr.com . Whilst the many tools and techniques have become standardised, it is normal to partially customise the training to client requirements - running a mortgage business is a somewhat different environment from building warships !

Often the training and projects run simultaneously within a programme. Training and Projects are usually based on the Six Sigma DMAIC structure. This is where you first ***Define*** the problem, ensure

you have the right ***Measures*** in place, fully ***Analyse*** the situation, before moving onto the ***Improve***ment stage, and then finally establish ***Control***s for the new process.

BioReliance decided to start their Lean Six Sigma training with a relatively short Green Belt development programme. After successful completion of this, selected participants move onto a full set of Black Belt level sessions.

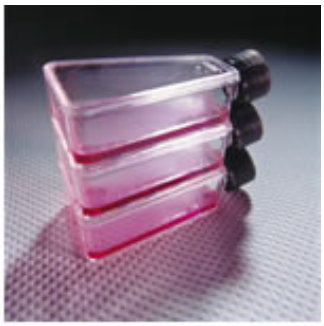
At BioReliance, every Green Belt is required to deliver a project as part of their involvement. The Six Sigma DMAIC approach is used to progress projects. The last phase of DMAIC i.e. "Control" must last for 3 months - no Green Belt at BioReliance gets away with a "flash-in-the-pan" improvement ! The new measured performance must be sustained for at least one quarter before the project is deemed to be concluded.

So do BioReliance people gain a Green Belt certificate after that ? Well, not quite. There is also an "exam". This is based on the material from the Colin Barr training programme. It's an open book event, however pretty much all of the material has to be reviewed in order to successfully complete the paper. This mechanism is as much to do with re-enforcing the learning of tools and techniques, as it is with assessment.

Some organisations prefer not to have "exams" and certification is designed in accordance with specific business requirements.

Current Benefits At BioReliance

At the start of their Six Sigma programme the senior management team set cost reduction targets for the organisation. After the first wave of completed Green Belt projects these targets have been ***exceeded*** by a whopping 50% !



Part of the benefits have come from re-using new knowledge gained from some of the successful projects. One such project was aimed at improving the turn-around time at the front end of the bio-testing process for a key client. The turn-around time was reduced by a factor of three !

The methodology worked so well that the process re-design has been replicated in other parts of the business. This project started in Test and ended up being re-used in Manufacturing.

Of the nine projects which were initiated, seven have successfully delivered, one is ongoing, one has stopped. This is a great result. In our experience there is often a much higher percentage of "project fall-out" than this. We always start with 100% project delivery as the target, but in reality some of them just don't make it.

Review Process

A key to successful Six Sigma project delivery is frequent, regular, monitoring and review of progress. We cannot overstress the importance of this to maintain momentum, keep the communication going, see the milestones being met, and break through the inevitable difficult patches. This is where senior managers can be visibly involved in the programme.

BioReliance decided to implement weekly Project Reviews with all of their nine first wave Green Belts. The outcomes of these weekly meetings are updated and displayed in the Process Improvement office. Anyone can walk in and immediately get a detailed view of what's going on.

Recognition and Communication

Whilst we normally advise our clients to start small, for example with a core team of Green / Black Belts, and build on that foundation of success, it is a good idea to keep the wider organisation informed of what is going on. This also gives the business a chance to recognise the good work of the Lean Six Sigma practitioners.

Whenever you walk into the front door of the main BioReliance Building in Glasgow, you are greeted with a notice board which shows a top level summary all of the Green Belt projects. Work areas and objectives are displayed for all to see. Green Belt photos accompany each project sheet. This is good practice.

Spreading The Word - Engaging The Wider Organisation

Every organisation needs to decide for itself how and when to engage the wider "community" in Lean Six Sigma. This is where cultural change can begin to happen. Of course, it would be inappropriate to train everyone to Black Belt level. However, it is certainly appropriate for the wider organisation to understand the intent, the language, and some of the basic tools and techniques of improvement and change.

Many businesses which adopt the methodology embark on "Yellow Belt" training. This is normally a one or two day training session which gives a wide audience an appreciation of the approach. It is a useful investment as most improvement projects will be cross-functional in nature and Yellow Belt training can prevent some "blank looks" when someone from the organisation joins a team but knows nothing of Lean Six Sigma.

Another popular way to engage a wide variety of people is to use the "5-S" system. This is the route BioReliance chose. More than just a "method of housekeeping", 5-S can be a great way to get people thinking about improvement and physically making change happen in a way that's visually apparent. Brian McLennan is a keen advocate of 5-S and at the time of writing, had personally trained 94% of the BioReliance population.

Lynne McConnell: "As well as our AIM campaign, and our 5-S initiative we also tried to spread the word via various promotions. We have 'Process Improvement Mugs' in the offices and cafeteria, and various very visible 'Quote Posters' e.g. 'Take Away the Cause and the Effect Ceases'. "

Process Improvement Is Not An Easy Life !!

Colin Barr and Associates have worked in process improvement for many years. Whilst we love working in this field, it is never a particularly easy path to walk. Problems can be complex. Motivation for change varies across groups. Organisations often have conflicts somewhere. Beliefs can become entrenched positions. Teams go through periods of elation and depression. Support can wax and wane. Priorities can swing away from the original goals. This is reality. No point in making it sound like "a breeze". So what has BioReliance found difficult...

Lynne McConnell: "Although we've had seven projects deliver, there were times when we thought some of these would stall. You just have to try to keep it all going. However our eighth project did fail. It was probably due to a general lapse in focus. Also, we based our projects on the DMAIC structure. In some areas we had difficulty getting across an understanding of the whole DMAIC concept and how important it is. We had people who just wanted to do jump to "i" for "improve" without letting the project teams do a proper job of the first three vital elements of DMAIC. At times we had to put the reins on some managers in this regard."

Developing Customer : Supplier Relationships

Much of the activity of improvement is about gaining a better understanding of customer : supplier interfaces. This applies to both internal and external relationships. It is often the case that, once established internally, Lean Six Sigma programmes extend forward and backwards in the supply/service chain.

Lynne McConnell: "We have now developed a really good Process Improvement relationship with our biggest client. We share information about our process improvement initiatives e.g. we have improved our 5-S process based on that exchange. We have also helped one another on specific issues. One example was where we had a problem with the manual changeover of carbon dioxide gas cylinders. We tied in with our client and gained practical benefits through sharing best practice. It's now a very open forum that we have with them. They are very honest with us - and (to be frank) sometimes we have to find the best ways of communicating this "honesty" to the rest of the organisation."

Lessons Learned

In all Lean Six Sigma programmes there will be lessons to be learned through experience. The nature of these will be different for each organisation and implementation. So what did BioReliance learn so far ...

Brian McLennan: "You have to introduce a bit of fun here and there."

We couldn't agree more ! For example, our training is designed with this very much in mind - a bit of a challenge when it comes to the Statistics modules.

Lynne McConnell: "I'd just emphasise again that one of the key elements of the programme was the weekly project meetings. It helped us maintain the pace and work through problems. It gave the Process Improvement group an understanding of the difficulties that the teams faced and we were able to escalate these issues and get them resolved."

Next Phase Of The Programme

Brian McLennan: "We will at least double the size our small core team of Green and Black Belts next year. We also have to make sure that our trained people maintain their certification. We will do that by making sure they are involved in the next round of projects. We'll also try to arrange to have a Black Belt available for each project team. We also intend to open the participation further by including more of the support groups like sales and finance."

Lynne McConnell: "We will also build on the 5-S work that we've done by extending the Lean training to more people in the organisation. Hopefully we will get more people thinking about and improving process efficiencies."

Lynne McConnell: "Probably the work of the Process Improvement team will gradually change from helping to deliver projects to managing the whole activity as the amount of improvement activity increases. We've been doing this work for over a year now, however there are still lots of potential areas for improvement....I think we'll be busy !"

Lynne McConnell and Brian McLennan