

Lean Compliant Operations in Life Science

Increasingly beleaguered, pharma in general and biopharma in particular still shiver at the edge of the pool of lean operations, watching wistfully as the top performers from other sectors splash happily about. Lean principles have transformed operational and compliance performance wherever they have been fully applied.



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There is general recognition in the Life Sciences sector of the need to change and of the nature of the obstacles to overcome, but not much action. The lean principles are by now well proven and, with effective adaptation to the specific requirements of the pharmaceutical industry, they can be applied with the same successes. Nothing should stop pharma and biopharma from jumping into the pool. Now, the regulators themselves are applying the very principles that underlie 'lean' to their own regulatory approach. The options are rapidly closing!

In this paper, WCI's Marty Boom reviews the background and looks at some of the practical ways of achieving and entrenching that essential breakthrough to world-class performance that the life science industry so patently needs.

Why not pharma?

Pharma in general has been a late and slow adopter of lean technology – and biopharma is also well behind other sectors in improving operational performance. Automotive is just one example in which the 'lean' approach goes back decades. In this sector, current best practice is used everywhere and improvement nevertheless continues. So why are pharma and biopharma such late entrants? It is no revelation to say that the traditional and rigid 'silo' structure of pharma poses a significant practical barrier to progress. Changes, inherent both to achieving competitive performance and compliance, require the full co-operation and involvement of all those silos. That is difficult, even when the problem is recognised.

The late start can be explained by the fact that pharmacos were focused on research & development on the one side and sales & marketing on the other. They saw manufacturing and the supply chain as a cost, not as a source of competitive advantage.

Organised for the good times, they have taken a while to wake up to the realities of global competition and slow to change their classic structures in response. But pressure is mounting: new



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blockbusters are thin on the ground, patents are running out and competition from generics and 'me-too's' is rising. In response to these trends and to regain competitive advantage, products and manufacturing processes are becoming more complex. Complexity and the risk of non-compliance go hand in hand and could ultimately threaten the capability to supply. Operations has, at last, been put on the Board's agenda.

At the same time, a different approach is emerging from the regulators. This systems approach to compliance looks across the whole operation. It focuses on integration and effectiveness rather than on administrative precision. This really ought to be good news, because it couples real compliance with flexibility.

It *should* mean less hassle, provided you keep getting things right. However, it is a way of working that sits ill with those silos. It is no longer practicable to have a 'compliance silo' in which compliance is a separate, specialised activity aimed at getting the right ticks in the boxes. Your own compliance brief will now have to run like a bright thread through the entire cloth of your operation, because it ensures that what you do is the right thing. It is, therefore, part of any and every activity, improvement and change.

What is happening is rather like the breaking up of the ice-sheet over the Arctic Ocean. Making it start requires huge amounts of energy. But once it is under way, the process is unstoppable, inexorable, and frighteningly fast. That turning point is where the life science industry now is. What can be done to ride the flow?

Lean Operations + Compliant Operations = Lean Compliance

Compliance is not an end in itself, nor is it a business goal. But neither is compliance activity wasted work, aimed solely at passing an audit. Instead, it is a means of demonstrating control, so that processes are secure and reflect best practice. That makes compliance itself a value-adding *business* process. Take resolving non-conformities or performing investigations. These are cross-functional business processes. As a business begins to think of its entire operation as a matrix – business processes along one axis, functions or systems along the other – it begins to shrug off that silo straightjacket. From there it is a small step to combining lean operations and compliance into **lean compliance**.

Is efficiency enough?

The focus of the push to lean compliance is **making pharma and biopharma operations work to their capabilities**. The very reasonable assumption being that the current baseline on any business or performance metric is well short of the potential!

Traditionally, the way to get more out has been to squeeze assets, to get the highest efficiency. Efficiency is good, but is it enough? Bigger benefits are there for the taking if we adopt a more global, integrated view. Cleaning up bits of the operation, even by significant percentages, may not transform the performance of the whole supply chain.



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For example: overall batch cycle time in packaging is often measured in weeks to months. But total processing time (on the assets) is, typically, just days. Brilliant work might reduce reaction times but still only have a marginal impact on overall cycle times! To lean up the operation, you need to shake out the truth about where and why so much time is being lost – and fix it!

A shorter cycle brings benefits whether you have insufficient capacity at peak loads **or** enough capacity to cope with peak loads. With *over-capacity*, you gain the headroom to shed resources yet still meet the peaks. When you have *capacity constraint*, shorter cycle times mean higher throughput, higher productivity and better delivery.

Lean Compliance

With the global viewpoint, the foundation of the approach is retained – to make operations both efficient and effective. The traditional lean principles and practices – *Blitz Kaizen* on equipment, making the machine sweat, improving the Overall Equipment Effectiveness (OEE) - can still be applied.

The Japanese concept of '*kaizen*' is the art of continuous, gradual improvement. A '*blitz*' is a rapid change programme in a small area that forms a constraint (bottleneck) in the supply chain. Clearing it will produce a disproportionately large improvement in the performance of the total operation. Quick, big wins, in other words are what are needed: wins that stick, wins that aid the development of a mindset that makes 'looking for more' part of daily routine.

With the assets running optimally, the focus moves to the supply chain environment – quality assurance and control procedures offer great opportunity for streamlining and thereby reducing the constraint that they put on the supply chain overall.

Sweet, embraceable change – an example!

Once the performance of the granulators, blister lines and other manufacturing equipment has been cranked up why does it still take weeks or even months, to push an order through the whole process and into the market?

Batch release times can be excessive because of Non Conformities (NCs) or deviations that have not been closed off. Production has finished making the product and everybody is now chasing around the factory, the QC labs and the QA offices to get a resolution on every NC so that the product can finally be released.

The process of dealing with an NC can be transformed through established Business Process Redesign (BPR) techniques. BPR will make the process for dealing with an NC more efficient. But will it make the supply chain more compliant? Will it ensure that the NC will never occur again? The answer is a blunt '*No!*'

Only when quality systems are embraced and looked at in a cross-silo, holistic way can real performance improvement be achieved. The root cause of many a deviation or NC is the degree of complexity, accuracy and currency of the documentation – standard operating procedures, batch



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records and so on. To transform it into something helpful WCI bring together shop-floor people, QA and other experts. With our facilitation, they simplify these documents and produce, for example, 'one point' lesson sheets or simple visual work instructions. Because their expertise is recognised, their input visible, the people who produced these solutions will use them. Training them in these documents then becomes straightforward. More important; executing the process in the prescribed way is a no-brainer and as a result the number of deviations and non-conformities falls sharply.

Simplified procedures, work instructions and batch records do mean fewer deviations and NCs. And because supervisors and operators feel ownership for the documents, they will use, and *keep on using* them. The documents will embody best practice – permanently. The documentation structure is simplified and fully connected, one update reaches all relevant documents at the same time, small improvements that operators make are incorporated and disseminated wherever necessary throughout the system.

Isn't this starting to sound like real compliance? It can be done – and it has.

Lean compliance really works

Let's come back to our starting point – breaking up the traditional silo structure is desperately overdue for both pharma and biopharma. It is a pre-requisite if you are to gain the big benefits available through lean operations. The trigger is **the need to get value out of compliance**. Accept that principle and you begin to look at everything from the point of view of added value, getting more with less. The silo structure cannot be sustained in the face of that sort of pressure for change.

The integration of regulatory compliance with operational improvement is the key to WCI's success in generating major, not marginal, improvements in pharma and biopharma operations.

The message is clear. Only by embracing change across the board, by including all the silos and having everybody focussed on lean compliant operations, will we achieve true performance change and at the same time embed quality and compliance in everything that is done.

Compliance has to be of practical value to the business, not an end in itself or a way of avoiding regulatory wrath. When we achieve this, we enhance both lean operations and lean compliance. That is a real difference. And for pharma and biopharma, where results have already, in our own experience, exceeded expectation, the opportunity is unprecedented!



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