

LIFE SCIENCES

Manufacturing

Lean manufacturing
Product compliance
Process benchmarking
Quality
Change control
Capacity management
Supply chain design

the science of regulated manufacturing

why

wci

**“we deliver
lean compliant
processes for
life science
companies”**

Why this is important

Making fundamental change in a regulated manufacturing environment requires a holistic approach. Understanding where to begin is key, as is the capability to make sustainable implementation happen. Increasingly, it is becoming apparent that compliance and performance are not mutually exclusive. In fact, compliance and performance have a single solution.

Simple manufacturing has morphed into a monster

Isolating the small number of fundamental issues that ultimately dictate manufacturing performance and compliance is not easy. Years have been spent coping with the effects of such issues and often the mechanisms put in place to cope have, themselves, become problematic. Furthermore, the management mechanisms put in place to ensure the fix is effective become expensive and wrap the real issue in so much cotton wool that it may never be seen again.

A little like covering a leaking roof with a tarpaulin, and then subsequently sewing the tarpaulin when it later rips; In a regulated environment, the tarpaulin specification, its repair and composition of the thread used to sew it become part of standard operating procedures. Then the ‘appropriate’ quality mechanisms are put in place. In time, it is easy to understand how the simple loose tile that originated the problem becomes forgotten and the organisation grows around the fixes. Fixes that started as short term measures to keep the line running and become accepted as part of the fabric as other, more pressing, matters take attention.

In the real world of pharma and biotech manufacturing, the manifestation of this syndrome is apparent to the experienced eye.

Manufacturing performance is below what it was designed to be; work-arounds deflect attention from unfixed problems, there is an exponential growth in QA activity and a lack of confidence in output dictates excessive QC, you still can’t inspect quality in – you must build it in; that’s old news. To compound the matter, with such layering of additional activity it becomes increasingly difficult to isolate the real problem, let alone to properly and permanently resolve it.

Begin by understanding the context

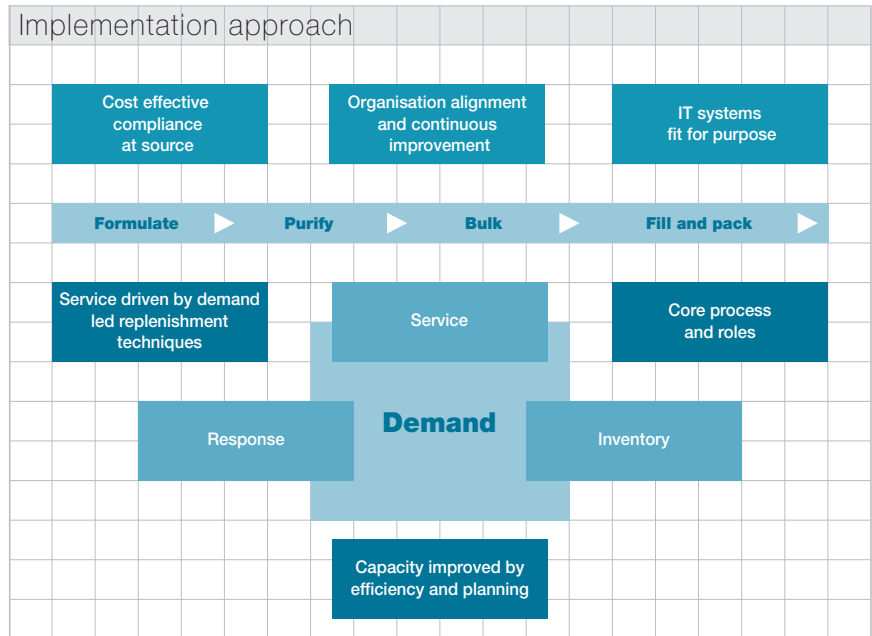
Firstly, it is a question of understanding the business and its relationship with customers, regulators and competitors, and

where it is regarding the lifecycle of its products. What needs to be done will not change based on the business context, however, the context dictates the priorities.

There is no blockbuster solution. There is no need for one. The correct approach involves decomposing the known problems to their constituent elements, understanding the interaction between these elements and knowing what proven solution or approach to apply to each.

The order of events is clear; establish what to do, prioritise based on business need and dedicate the appropriate resources to the task. As you might expect, the patient is key to success; in diagnosis and in applying the remedy.

Model for Success



“we assure performance and compliance through simplification of core processes”

Focus on the drivers of success

- isolation of root causes
- the right solutions and approaches for each
- the right priorities for the business
- the right resources
- the right plan
- management commitment to the plan
- management commitment to the delivery
- management commitment to the results

This is, perhaps, best explained by way of examples.

Quality

Quality must shift focus to permanent resolution of problems, which result in a quality problem. True, a good response to a problem is to up inspection levels. True, this will protect the customer and the business. True, this is a cost which must be borne. The new truth; this is a cost which should continue to draw management attention to the fundamentals of the problem and drive their resolution. It is all too easy for an inspection regime to become the ‘norm’. Quality should be measured based on permanent resolution, non-repeats, improvements in manufacturing performance and compliance. Apply the principles of lean manufacturing to the laboratory.

Change control

To resolve the underlying problems described in manufacturing, changes are inevitable. In a regulated business there is an appropriate burden to ensure such changes are appropriate. This is a prime area of the business to enjoy the benefits of effective processes. Typically, this activity is unnecessarily cumbersome; too many and

“we have delivered significant operational benefits to life science companies”

irrelevant approvals, backlogs, unclear priorities and over reliance on individuals not aligned with the need. If ever process re-engineering could help with a business constraint, this is the place.

This approach is proven in Big Pharma...

2000 people, two geographically disparate sites, a long list of 483 observations, a warning letter. Demand outstripping supply, products not being shipped, almost a thousand projects, initiatives and activities to resolve. An urgent situation, you could say.

This business had a strong management resolve to fix the problem, but diverse views on what needed to be fixed and how. Management alignment was key, and the way to get it was objectivity. Using data to inform opinions, making the subjective objective and creating a single view of the opportunity to enable decisions to be made with full awareness of their implications.

A twenty one month programme ensued. Three months were needed to identify the main issues and agree priorities, then a programme of twelve projects was set, in two waves of seven and five. Resource was dedicated to the projects, each team clearly having all the capabilities required to address its focus. Management discipline was key to decision making and to resolving resource conflicts; this was driven through a rigorous programme management structure and CEO commitment.

It is interesting to note the build up of the twelve projects; less than half were in the factory itself, highlighting the need to fix all that enables, supports and governs manufacturing.

“we understand cross industry best practices and apply to a life science context”

The results for this business were clear: in order, warning letter lifted, supply re-established, throughput doubled.

...and can be applied to smaller, developing organisations

As the Biotechnology industry became subject to the same stringent regulations as the Pharmaceutical industry, businesses became non-compliant over night. It was observed in many such businesses that manufacturing activity resembled overgrown laboratories, with unproven processes and quality regimes of little relevance in volume production. Indeed, the quality regimes were well suited to experimentation and headcounts were an order of magnitude more than was really needed. But the submission included the over bearing regime, and irrelevance of this had to be progressively proven.

Some of the best examples in recent times of transforming manufacturing performance and compliance come from this sector. Maybe there is something that pharmaceutical manufacturing can learn from their younger cousins?

Set up for future success

In many instances, compliance challenges in manufacturing are a direct consequence of the way in which new products are introduced to commercial manufacture. The urgency to get new products to market doesn't help in the drive to ensure the robustness of new production, but it is imperative to give full consideration to the challenges of commercial volume manufacturing before the new product is handed over. Handed over? Many in manufacturing will tell you that is a generous description of an incoming missile!



Simplify what you do

to assure compliance and boost performance

The good news is that the development teams in many businesses have an improving understanding of the consequences of their decisions on others. The better news is that there are proven ways to harness this understanding to protect the business from itself, for example, putting new products into production because they are ready and safe to produce. This is not in conflict with the urgent need to get to market; rather, it de-risks getting to market quickly by ensuring that the known pitfalls are avoided. It is not difficult to get universal agreement to the principles of good product introduction to manufacturing. It is, however, easy to take things for granted, to rely on out-of-date knowledge and to under-estimate the significance to the business of not taking timely and appropriate account of the needs and constraints of manufacturing, the other customer of development.

It's obvious, isn't it?

On reflection, it often is obvious. It is important, however, to be clear as to why some succeed in transforming manufacturing while others fail.

Try to do it all yourself, you will fail. Try to make it happen without the support of the business, you will fail. Take on more than you can resource, you will fail. Assuming the management of such a programme is an extra task for you, or can be done by an up and coming manager, you will fail.

Experience is everything with such programmes. Experience in isolating the root causes, creating the programme, aligning the business, selecting and applying the best techniques for the job, driving the changes into the business. All those individuals who you think can do this will be great team

members. But this is not a time for a bit of personal development, this is a time for results, and results come from having all the required capabilities available and leveraging the strengths of all. Don't fear asking for qualified help – just make sure the help has the track record you need to become part of.

Good news – transforming regulated manufacturing is a science. Better news, it is an applied science. But, this is not a time for experimentation; it is a time to consult the experts.



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