



CMC - Registering a Drug of Building a Value Stream?

Historically in pharmaceuticals, performance of the supply chain has been a low priority. Blockbuster drugs with secure markets and 'silly' margins meant that the focus was always on the scientific and technical aspect of registration and supply. So long as the drug was approved and patients received the drug manufactured to the regulators satisfaction, then job done. However, vitally important though the science is, it is the supply-chain that delivers the value - and there are signs that key stakeholders are demanding more.

The global pressure to contain healthcare budgets is focussing on prescription medicine, which in turn spotlights the cost, efficiency and effectiveness of drug manufacture. The current FDA initiative to introduce Process Analytical Technology (PAT) is evidence of regulators responding. This is a positive start to facilitating improved ways of working in the supply-chain to favourably impact quality, cost and lead-time. At a recent conference in the Netherlands, Jon E Clark, Associate Director of Policy Development, CDER, FDA, is quoted as saying "There should be a way to protect the public without slowing CMC innovation and continuous improvement."

The question now is how will the industry approach the opportunity, and any further opportunities to modernise in the supply-chain? The plain fact is that, welcome as PAT is, the concept that quality cannot be inspected into a product has been applied in other industries for many years. Industry sectors such as aerospace, electronics and automotives have been attacking process variability and raising process understanding and capability for several decades. Quality has increased and costs have reduced dramatically. This has taken place as an industry driven imperative - working within the bounds of safety standards and regulation - but pushing the boundaries of modernisation. This has not been the case in pharmaceuticals.

'Batch and queue' manufacture, campaign scheduling, multi-sourcing procurement policies, large, capital-intensive, inflexible machinery and maximisation of batch sizes. These are just some examples of 'cultural' practices within pharmaceuticals that impede the adoption of world class methods. It will take more than just the regulators to modernise - the entire industry must attack the inertia built up over many, many years.

The starting point however, as demonstrated by the exemplar sectors above, is not in currently established supply-chains. It must be at the design, development and registration stage of the supply-chain. It is estimated by leading researchers at Cardiff Business School that over eighty percent of cost is locked-in to a product at the design and development stage. In pharmaceuticals, because of the historical change inertia, it is probably significantly higher.

The message then is clear - for meaningful improvement, scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until the drug has been registered, but should start as early as possible in the CMC development process and definitely before registration oriented or pivotal clinical trials. This will be particularly the case as the more virtual business models of drug development

present huge opportunities to harness the increasingly high calibre third party contract supply base, but at potentially increased risk, complexity and cost if not carefully managed.

So to the topic of this article - 'registering a drug or building a value stream?' The author suggests that CMC development must reset the line of sight - from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.

To use the words of Jon E Clark once again, from the same conference - "The pharmaceutical industry has one of the most technically advanced discovery organisations, but remains more conservative when it comes to using 'cutting edge' technology in manufacturing"

Hopefully, the wind of change is upon us!

About This Article

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