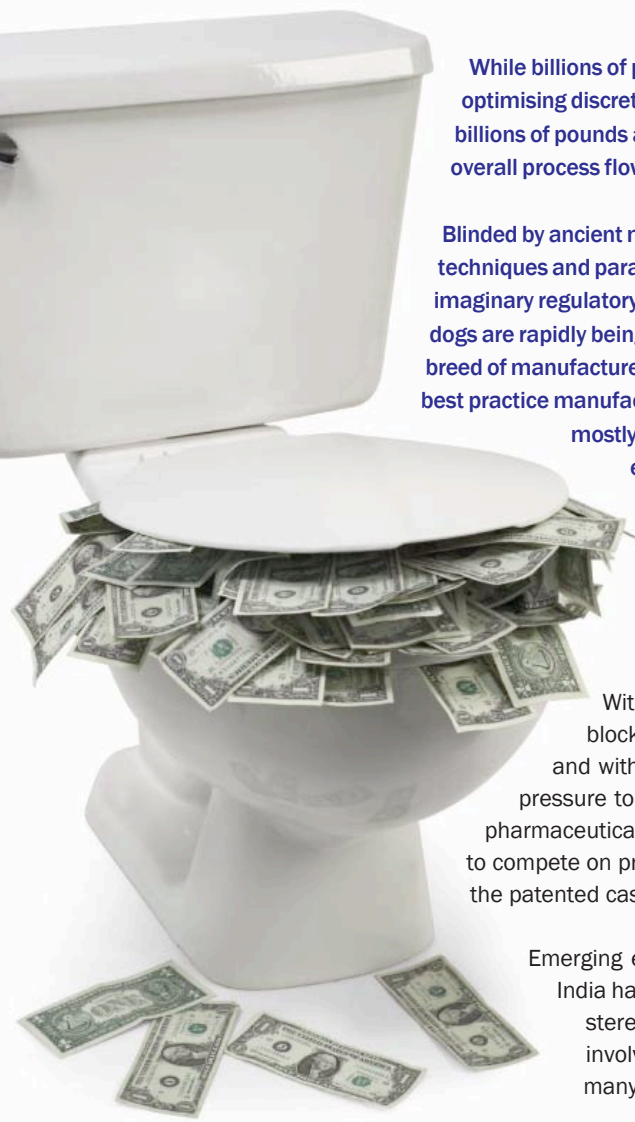


Pharmaceuticals —



While billions of pounds are invested in optimising discrete process operations, billions of pounds are wasted in poor overall process flow.

Blinded by ancient manufacturing techniques and paralysed by real or imaginary regulatory constraints, the old dogs are rapidly being overtaken by the new breed of manufacturers embracing current best practice manufacturing techniques – mostly generic and many from emerging markets.

A new game

With the pipeline of blockbuster drugs drying-up and with the socioeconomic pressure to reduce prices, pharmaceutical companies are forced to compete on price rather than rely on the patented cash cows of the past.

Emerging economies such as India have moved away from stereotypical models involving cheap labour and many have embraced the

lean manufacturing principles as being the way forward in modern Active Pharmaceutical Ingredients and 'solid dosage' plant design.

The trends

Western industry's response is to focus on improvement of unit processes, which in many cases means a shift from batch to continuous - wet granulation is a prime target for such a transformation.

This tendency to go continuous is mainly driven to improve the adjustability of a plant to changes in demand (PULL) and shorter response times resulting in reduction of inventory, one of the biggest wastes according to the lean manufacturing philosophy. The traditional batch processes, such as wet granulation and coating of tablets, usually require additional equipment when an increase of capacity is needed.

Overlooking the solids flow issues

While unit processes are looked at in great detail and improved as isolated problems, amazingly little or no attention is given to the huge challenges that the industry always has been confronted with: how do we get product from one unit to the next?

Cont'd...

Marketing View

By Simon Strothers, ITCM

The situation in pharma markets is a classic example of market forces at work. In the good old days of blockbuster pharma it was patent protection, regulation and high entry costs which gave pharma giants control of the market. They enjoyed relative freedom in pricing; pressures were from governments with restricted choices rather than competitors; they also controlled the volumes of products released onto the market. This all meant that big pharma companies could operate as the equivalent of 'supertankers'; a direction is set and don't try to stop us!

Comparisons can perhaps be drawn with good old Henry Ford and the Model T; you can have it in black!

The automotive industry went through similar turmoil over 30 years ago, when the Toyota production system of lean manufacturing principles and a shift in corporate culture rocketed Japanese competitors ahead of their Western counterparts.

If we continue to draw the parallels you might conclude that the pharma market will become a mixture of two types of company: those which are service-focused i.e. specialist, niche, high-value products and services to a select population (equivalent to high-end car manufacturers; Rolls Royce, Range Rover etc.), and those which are product-focused i.e. mainstream manufacturers of functional, mass market, low cost, product (equivalent to the Ford Focus).

In reality, companies will sit on a continuum between the two types, and depending on their brands, may service both markets. What is important however, is that companies associate their brands with one or the other, or they risk confusing consumers.

With research and development of cutting edge technologies, formulations, devices and customised treatments for patients, companies will require the ability to generate ideas from far wider reaches than just the pharma population. Embracing the principles of open innovation is one way of making this happen -



penny wise or pound foolish?

“The pennies saved by major investment in unit process optimisation sometimes appear trivial compared to the pounds wasted in non-lean overall process flow.”

Cont'd... Huge sums of money are wasted directly or indirectly related to ongoing solids handling problems. Powders stuck in hoppers and pipes, segregation issues, uncontrollable flows, flushing, bridging, rat-holing to name a few; all result in inconsistent feed or even straight forward 'wrong' product arriving at the inlet of the unit process that has been subject to the expensive make-over. A continuous system is only as good as the quality of the system that feeds it.

All these problems have led to a manufacturing world that is used to large quantities of inventory and 'buffering'; just-in-case! In lean terms, safety inventory is the biggest waste of all, covering flaws, poor plant design, and long changeover times.

Continuous batch

Continuous steady state pharma-processes are often still sequences of unit operations that need to be linked discontinuously. A well designed multipurpose Intermediate

Bulk Container (IBC) system can provide the solution for this seemingly contradictory challenge.

By decoupling the various processes, whether in classic batch type plants or in modern continuous plants, a striking set of benefits appear:-

- It is no longer necessary for unit processes to work 'in sync' to reach the steady state (i.e. bottleneck problem).
- There can be parallel flows (e.g. two tablet presses fed by one mixer).
- Now you can start producing the next formulae at the beginning of the line in the back of the previous one - there is no waiting.
- The plant will be much more flexible to cope with changes in demand (PULL) removing the need to take the interfaces apart for cleaning.

The pharmaceutical industry could certainly be served by not just investing in improvement of isolated operations but by looking at the plant concept as a whole and the interface system to be used. This results in significant reduction of waste and consequently a much fitter manufacturing facility.

Technical View
By Wim Spook, Matcon Benelux

where the Intellectual Property (IP) for a new product or service does not necessarily have to be developed by the pharma company itself, but where innovative partnering and licence agreements can enable new business models and revenue streams to be established.

In addition, the ability to 'fail fast' and 'fail cheap' will give a competitive edge: companies which can rapidly test and assess several new technologies in parallel and at low cost, will be best placed to hit on the few successful ones for commercialisation. In addition, re-conceptualising production processes on lean manufacturing principles is essential for existing big brand pharmas to reinvent themselves and compete with generics. These are core focus areas for ITCM's services - helping customers to develop new products and innovative new processes and machines for their manufacture in an increasingly complex and competitive market.

For the UK, perhaps our destiny is in the Formula 1 of pharma?

