
What can Pharma manufacturing learn from Lean Thinking?

by Hedley Rees

Where is Lean Thinking in Pharma?

It is hard to deny the reality that Pharma has not been able to properly convert Lean Thinking into the quality, cost and delivery performance advances that other sectors have achieved.

In a recent article¹, G.K. Raju, Executive Director of the Pharmaceutical Manufacturing Initiative at MIT, is quoted as saying "Although some companies have implemented processes that run at 6 Sigma, the industry overall still operates at the same Sigma level of 2.5 to 3 that it did last decade". A sad indictment of typical quality levels within Pharma. When viewed in tandem with the shortages, recalls, and instances of product adulteration that are reported all too frequently these days, the overall impact of Lean Thinking is at best undetectable, and at worst, retrograde.

So why is it that other sectors, such as semiconductor and automotives, have been using Lean Thinking to drive quality and service levels up, while taking cost out, when Pharma is still scratching its metaphorical head?

The truth behind Lean Thinking

To get at the truth, we need to go back to the roots of Lean Thinking. As Japan struggled to re-build after the Second World War, with money and resources tight, the foundations of Lean Thinking were laid in many Japanese companies, the most notable being Toyota. The Toyota Production System (TPS), as it was christened by the west, was a completely new approach to producing goods for customer markets. Driven by necessity, Toyota focused on turning customer orders into cash in as short a time as possible. Taiichi Ohno, who is credited with leading Toyota through much of the company's resurgence, is quoted as saying, in Jeff Liker's excellent text 'The Toyota Way'² "All we were doing is looking at the time line from when the customer gives us an order to the point when we collect the cash. And we are reducing that time line by removing non-valued wastes".

Along with his new found, necessity driven approach to production, Ohno also made what was then a revolutionary insight; the market dynamic in the automobile industry was rapidly changing.

Customer markets change in a fundamental way

In his book³, The Toyota Production System, Ohno lists the drivers of emerging change:

1. Instalment payment plans
2. Used car trade-ins
3. Sedan-type body
4. Changing models yearly
5. Improved roads

There is a vast diversity of opinion on the relevance and applicability of Lean Thinking in the Pharma industry. Some have been totally disillusioned, as Lean has become a euphemism for cost cutting and headcount reduction. Others are nervous that it could lead to 'corner cutting', with the associated exposure to regulatory non-compliance and quality failures. Still more are travelling down the Lean path, experiencing various levels of success.

From that, he concluded that customer markets were moving way past the one size fits all paradigm of the Model 'T' Ford. In effect, he had predicted the end of the 'Blockbuster' auto era. Customer markets were becoming more segmented, increasingly seeking variety and customisation. The days of producing huge volumes to drive down unit cost, often at the expense of quality, were numbered. Customer was becoming King.

What of Pharma markets?

There is little doubt that the market for Pharma products is going through fundamental change and almost every other article on the industry recounts a permutation of patent cliff, generic competition, disappointing R&D productivity, growth of biologics, aging populations, stratified medicine, orphan drugs, personalised medicines, Government cost containment etc, etc.

However you wish to put the list together, the conclusion has to be that this industry is, and has been for some years, at the point where the old ways of mass production are not adequate to service this industry. However, unlike the auto industry, the 'Toyota' of Pharma has not yet emerged. Who knows if it ever will, but for the purposes of this article, we consider what such a company would need to do in moving to a production system paradigm.

The production system (PS) concept

There is much written about production systems, but for simplicity sake we will focus here on the principles, which are outlined in the now famous text "The Machine that Changed the World". Many readers in Pharma manufacturing will be familiar with them, but hopefully we will discover a perspective here to get at the essence of what the principles mean in practice.

Principle 1: Specify value from the standpoint of the end customer by product family

The important point here is that focus must be on delivering

value to the prospective users of the product, according to their frame of reference. So often, companies carry out operations in a plant that do not impact the value-for-money proposition for the customer.

The last three words are also very important – by product family. That means equipment must be arranged specific to that family, not spread around various locations in a production facility.

Principle 2: Identify all the steps in the value stream for each product family, eliminating whenever possible those steps that do not create value

There are two critical aspects to this principle. Firstly, each stage should be assessed for validity. Can it be eliminated or combined with another step? The second is that the entire, end to end value stream should be considered, because very often downstream activities are driven from upstream (and vice versa).

Principle 3: Make the value-creating steps occur in tight sequence so that the product will flow smoothly toward the customer

Moving towards a tighter sequence means the production system cannot tolerate defects or delays. So problems occurring anywhere in the process need to be solved and defects eliminated; also, machine cycle times need to be reduced so that flow can take place without excessive losses through changeovers.

Principle 4: As flow is introduced, let customers pull value from the next upstream activity

This principle is closely linked with Ohno’s desire to conserve cash until customer orders were received, rather than making to a forecast demand that may not materialise. He actually found a way of doing this by visiting supermarkets in the US and noticing they did not replenish the shelves until the stackers could see stock was being depleted, and then they refilled. This was converted in the Kanban (trigger or signal) and supermarket concept.

Principle 5: As value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced. Continue until a state of perfection is reached in which value is created with no waste

This final principle is about doing all the above continuously, with passion. Note however that the merits of a prospective improvement should always be judged on the value stream impact.

Maybe we should illustrate the concept by considering a practical example. Figure 1 shows a solid dose facility working to the traditional mass production functional approach. Each stage is separately planned to make batches of product based on a forecast (educated guess). Because forecasts are always wrong, the plant soon finds itself making products the customer does not need and not making the ones it does. So the schedules change to reflect the new reality – and yes, that

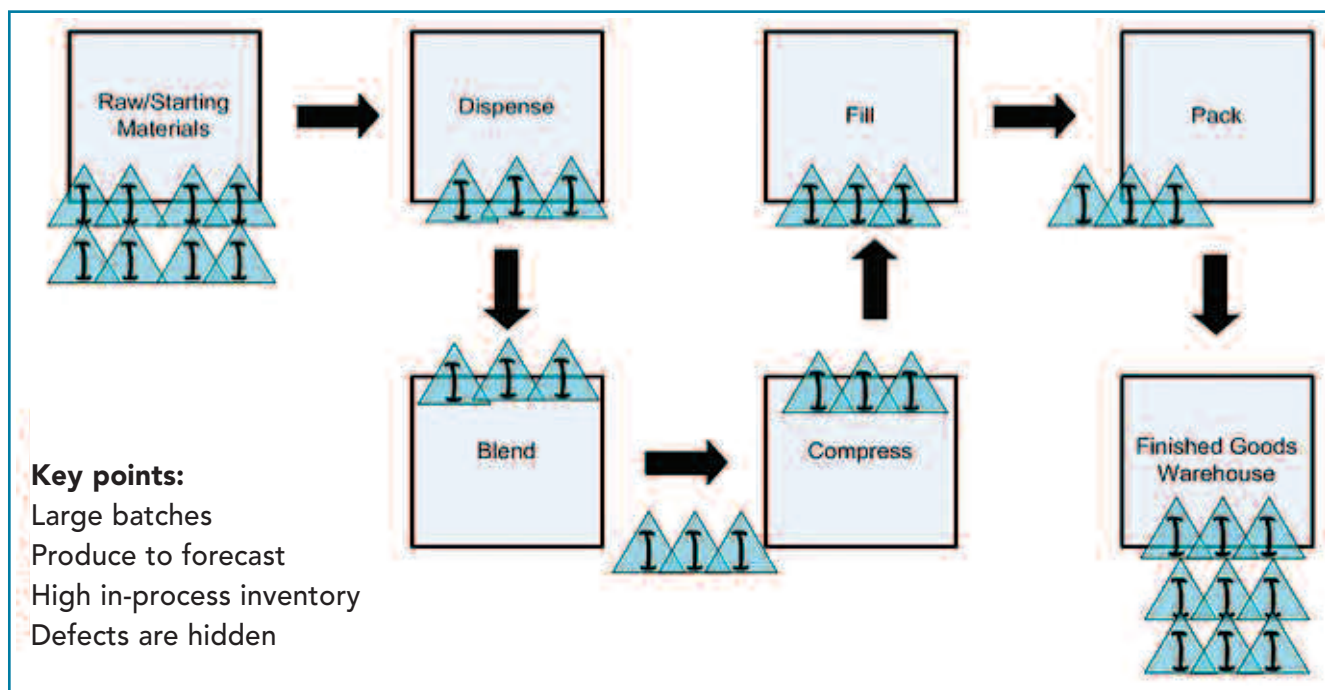


Figure 1: Traditional functional layout– solid dose

is soon out of date. The net result is inventory builds at all the stages and defects are very hard to find and eradicate.

Figure 2 shows the value stream alignment. Here each stage is joined to the next so that product flows. If there is a problem of machine malfunction, for example, the entire value stream stops until it is fixed. This means that in-process inventory does not build above set levels; and problems causing defects are fixed immediately.

The arrangement by product family means that variants within the family can be accommodated with minor set-up changes or machine adjustments, so that the flow is never interrupted. The value stream then is set to run at a rate equal to consumption in the market (TAKT – measured by the length of time allowed to produce one unit).

In terms of production planning, only one stage in the value stream is scheduled, termed the pace maker. The line is normally balanced so that the pace maker operation is at the customer end.

When we hear the term continuous improvement, it is important to remember that relates to the value stream, and is primarily about solving problems that impede proper functioning of the value stream, rather than random waste removal that may not impact the value stream.

Old habits die hard – are the barriers too great?

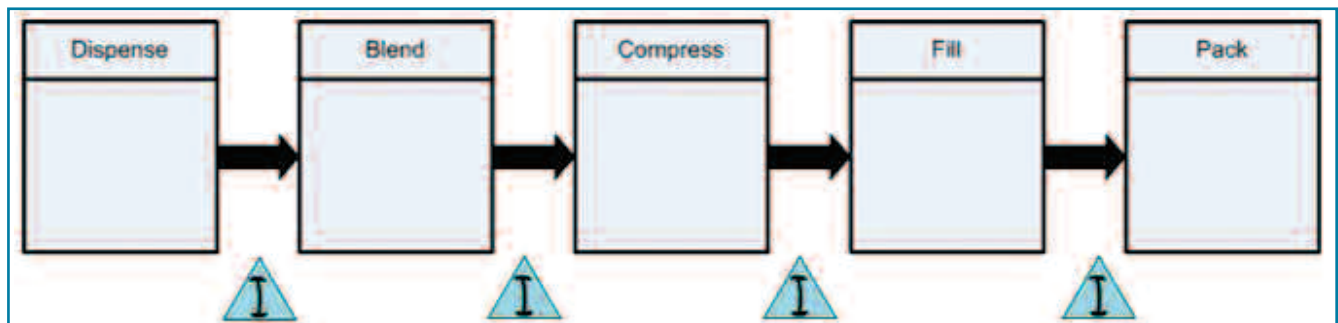
In the West, where this eastern challenge threatened the very existence of long established sectors, the extent of the cultural and behavioural barriers that had to change was enormous.

The old ways of working, based on driving through volumes and inspecting-out the defects were hard coded into the industry psyche; but eventually, given the competitive pressures, the new approach took hold.

In Pharma, we have not seen similar competitive pressures and still witness many of the manufacturing failings associated with mass production; but if, however, we believe Ohno’s message above on the impact of changing market dynamics, the writing is on the wall.

So what could stand in the way of change? Firstly, those hard coded assumptions are rife – a few examples below:

- Big is beautiful: Invest millions in high speed, long changeover equipment to produce massive batches. Extended lead-times and inflexible response to change.
- Campaign scheduling: run the same product, in all its variants, in long campaigns to reduce the impact of complex changeovers. The customer waits.
- Scheduling to 12 – 24 month rolling forecasts: Plan production to sales forecast and change the plan with every monthly update (or daily/weekly!). Belies the reality the most products can be produced at a reasonably steady rate and still satisfy market demand in the market.
- Run to bulk: gives the option to keep running a machine, even if the next stage malfunctions or is not available. Defects produced potentially undetected and unwanted inventory produced.



Key points:

- Schedule pacemaker only
- Set rate at TAKT (Production rate required to match rate of consumption in the market place)
- Pull from the pacemaker (Kanbans and supermarkets)
- Solve production problems (A3 Management)
- Take out variation (SPC)
- Reduce defect rates on incoming materials
- Use Single Minute Exchange of Dies (SMED) to reduce cycle time

Figure 2: Value stream alignment – solid dose

- QC testing is the measure of quality: reliance on testing to prove quality conformity. Excessive rework and remediation activities when issues found.
- Don't worry, the QP is in control of it all: Physically impossible and gives a false sense of security. Those doing the work are likely to take less ownership.
- Arms length relationship supplier relationships: little involvement of supplier in product development and improvement activities.

These then are some of the outmoded, ingrained assumptions that pervade manufacturing in the Pharma industry. Until these underlying and often unspoken assumptions are replaced, Pharma will continue to underperform in the world of manufacturing and supply.

Be assured though, these are only a sub-set of higher level assumptions held dear by the industry for many decades. These relate to the discovery, development and commercialisation assumptions that are a legacy of the blockbuster era. These assumptions emanate from early successes based on serendipity, whereby the manufacturing supply chain was lowest on the pole until regulatory approval.

No-one wanted to rock the boat until then, and if the vessel had not already sunk before launch, there were enough holes in it to ensure keeping afloat was a full time occupation.

In Conclusion

If we learn only one thing from Lean Thinking, it is that a fundamental change of attitude to the consumer of products is required. This starts with the most senior person in the organisation (in the case of Toyota it was Taiichi Ohni and his predecessors) maintaining a steely determination to carefully identify those needs in great depth; and then align the production system to deliver on those needs – so that fit-for-purpose products, when measured on quality, cost and delivery performance, reach the customer every time.

Let us hope there is a Taiichi Ohno waiting in the wings of Pharma, ready to show the world the way.

References

- ¹ Liker, Jeffery K, *"The Toyota Way"*, McGraw-Hill, New York 2004, P7
- ² Ohno, Taiichi *"Toyota Production System: Beyond Large-Scale Production"*, Productivity Press ,1998 PP103, 104
- ³ Womack J, Jones, D, Roos D, *"The Machine That Changed the World"* Simon & Schuster UK Ltd, London, 2007.