



White Paper

Lean Manufacturing – reduction of duplication

What is Lean Manufacturing?

Lean Manufacturing is determining an efficient manufacturing process through the removal of waste, and implementing a flow, as opposed to batch and queue. It is not a stand alone or singular process rather a philosophy that applies techniques to improve areas of the business. Some of the world's most successful companies, including Toyota, are pioneers of lean manufacturing. Their approach to lean manufacture is the reduction of waste human errors.

Lean manufacturing elements can be implemented into any business stream from manufacturing to laboratory operations, from warehouse to distribution centers. Lean manufacturing is very powerful in that it can be designed and utilised to meet the Pharmaceutical regulator's requirements and reduce overall business costs. Lean manufacturing and regulatory compliance are not mutually exclusive but can be combined to deliver simple but excellent performance improvements.

For example, in manufacturing operations we may ask:

Why does the operator on A shift always take longer than the operator on B shift to set up the filling machine?

Why is it that A shift yields are always slightly better than yields from B shift?

There are many tools in the lean manufacturing kit that can harness your best results and make the best results the standard. These include:

- value stream mapping (VSM)
- poke yoke
- standard work
- kaizen
- the seven wastes
- 5S.

These elements can also form the basis for 'visual factories'. How many times have you walked into your factory and not known whether the work place was in or out of control? Do you know where that urgent certificate of analysis is or where the testing is up to? Lean manufacturing can overcome all of these questions very simply.

How many times have you walked into your factory and not sure whether the work place was in or out of control?

Our experience is if it looks out of control, it usually is!

Value Stream Mapping (VSM)

Value stream maps are used to 'map' your current operations from procurement of materials to delivered goods, and identifying the non-value adding steps.

What is a non-value added step? Ask yourself, at any part of any process, would my customers be willing to pay for this step to be completed?

For example, would my customers pay for the labeling of product? The answer is yes because each customer wants to know what they are consuming. Would my customers pay for 14 days delivery lead time that is part of the current process? The answer is no as value is not being added to the product at the delivery step.

VSMs can be applied to even the smallest part of your process. When a process is mapped you can then decide how to navigate your map and improve the journey from one end to the other.

Poke yoke

Poke yoke is to 'mistake proof' or 'fail safe' your process. Poke yoke is a process that prevents errors from happening and allows easy detection of errors if they happen. Poke yoke must be built into a process so the costs of re-work are minimized, if not eliminated.

Standard work

The real value in standard work is that a process is monitored, measured and then rebuilt so that **all** operators perform the task correctly, in the most efficient way, and in the same way.

Kaizen

Kai means 'change' and **zen** means 'good'. Kaizen is similar to standard work in that a process is taken apart and rebuilt - both techniques focus their energy on the factory floor where the processes actually happen.

A kaizen activity, or 'blitz', takes a nominal 3-4 days and involves a number of key personnel. The process is dissected and all actions to improve the process must be realised and implemented within those days of activity. All other interested parties must be kept informed of progress by using tools such as kaizen newspapers.

The Seven Wastes

The identification and value stream mapping of processes is generally used to eliminate the seven wastes. The reduction of the seven wastes in any organisation will reduce process costs and help to develop a strong culture where processes are continuously improved.

What are the seven wastes?

- Overproduction; a customer will only pay for what they want
- Transportation; adds no value to the customer's product
- Waiting; a customer will not pay for your waiting time
- Motion; adds no value to the customer's product
- Processing; a customer will not pay for your administration time

- Inventory; a customer will not pay for you to store product, but will be dissatisfied if they cannot obtain what they want when they want it.
- Defects; no customer will pay for defective products, and the potential risk to customer's well being must be mitigated.

5S

The 5S process has a range of applications. Chemical industries use 5S to reduce the number of workplace accidents while other industries use 5S as a visual factory tool. With an implemented 5S system you can recognize whether a work place is in control or out of control with a glance. It can be a very powerful tool in any office area.

What are the 5Ss?

- **Sort**; an aggressive process that uses a tag and release mechanism to discard unused items in a workplace
- **Set in order**; where does equipment belong so that is accessible to operators and is conducive to smart work flow
- **Shine**; a clean workplace will instill pride and assist in creating a strong workplace culture
- **Standardise**; so that what you have achieved is 'standard procedure'
- **Sustain**; so that what you have achieved is maintained always.

Challenges

Resistance to change and the attitude of '*we've always done it this way*' is the absolute opposite to continuous improvement. Overcoming this attitude is possibly the most challenging part of the lean manufacturing journey.

Integrating lean principles with regulatory compliance is not a challenge to overcome. By introducing lean manufacturing the life sciences industry can in fact improve their compliance. If process 'A' is a validated process, then the implementation of lean techniques will ensure that process 'A' is followed each and every time it is performed.

About PharmOut

PharmOut is a consultancy to the Pharmaceutical, Medical Device, and Veterinary drug industries.

PharmOut specialises in GMP compliance, validation, continuous improvement consulting, and training.

Some of PharmOut's customers include –

Abbott Australasia (Healthcare), AC Immune SA, Acrux Limited, Agronico Research Pty Ltd, Amcor Limited, APHS Pty Ltd, AstraZeneca, Ausonex Pty Ltd, Austin Nuclear Medicine and Centre for PET, Australasian Lubricant Manufacturing Co., Avexa Limited, BD - Australia / New Zealand, Bernafon Pty Ltd, BioMerieux Australia Pty Ltd, CathRx Ltd, Chemeq Limited, ClearStep Australia Pty Ltd, CSL Bioplasma, CSL Parkville, Emerson Process Management, Ensign Laboratories, Enterix Pty Ltd, Faulding FH & Co Limited, Fonterra Co-operative Group, GCL Ltd, Go Medical, GSK, Hospira Pty Ltd, House With No Steps, IDT - Institute of Drug Technology, IG Science Pty Ltd, Intellidesign, Invetech Pty Ltd, Mayne Pharma Ltd, MDI - Medical Developments International, Pall Australia, Peplin Operations Pty Ltd, Pharmatel Fresenius Kabi Pty Limited, Probe Analytical - Intertek Caleb Brett, PT. Sanbe Farma, Royal Brisbane Women's Hospital, Siemens Ltd, Supercare Pty Ltd.

How PharmOut can help

We offer a range of services including experts in lean manufacturing and the implementation of lean manufacturing systems.



Visit: www.pharmout.com.au