

LEAN THINKING

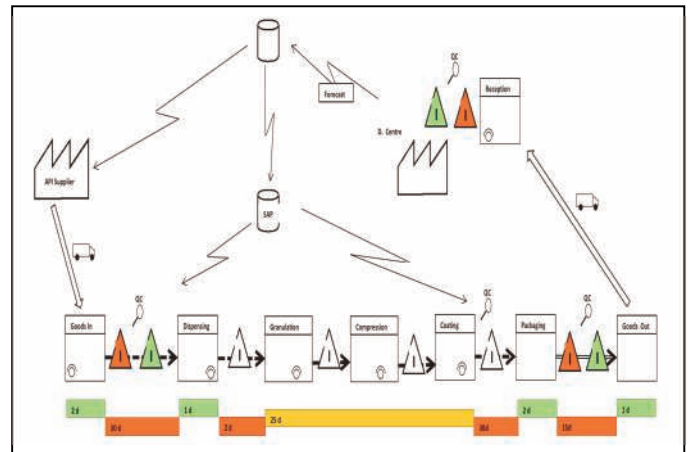
SOLID DOSAGE MANUFACTURING

Lean & Pharma. Driven by the competitive need for World Class performance, Lean Theory has now become a generally accepted improvement tool for the Healthcare industry.

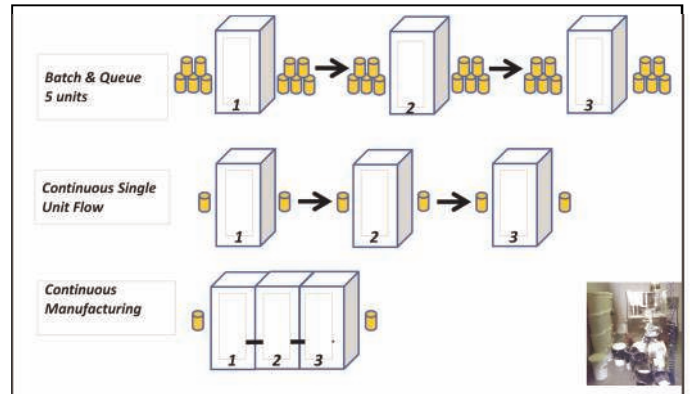
The gradual and consistent elimination of *Waste* has already led to a significant reduction in inventory and cycle times, improving cash flow, customer satisfaction and therefore bottom line profit.

To the right is a typical *Value Stream Map* of a Secondary facility. It makes the huge improvement potential very visible. *Waiting, Movements, Inventory and Defects* are the focus areas and often contain 'low hanging fruit' in pharmaceutical manufacturing.

For *multi-product* plants, a continuous set-up is less favoured for reasons of very high set-up times and consequent push to inventory. Individual *processes* may very well be continuous (for example milling, roller compacting or tablet pressing) and can appear to be very efficient in a multi-purpose pharmaceutical plant.



Creating Flow. The continuous reduction of *Waste* makes it possible to create true *Flow*. The second drawing demonstrates the difference when reducing the number of 'units' per run. Assume equal times for processes 1, 2 and 3 and the striking reductions in lead time and inventory (WIP) are evident. Even if the movements between processes are not ignored (they are a *waste* to be reduced), the inventory decrease is still significant. A 'Single Unit' is to be based on the minimal average quantity as ordered by the customers. This translates directly to Batch Size. If batches are bigger than ordered, you are producing to stock and increasing the inventory.



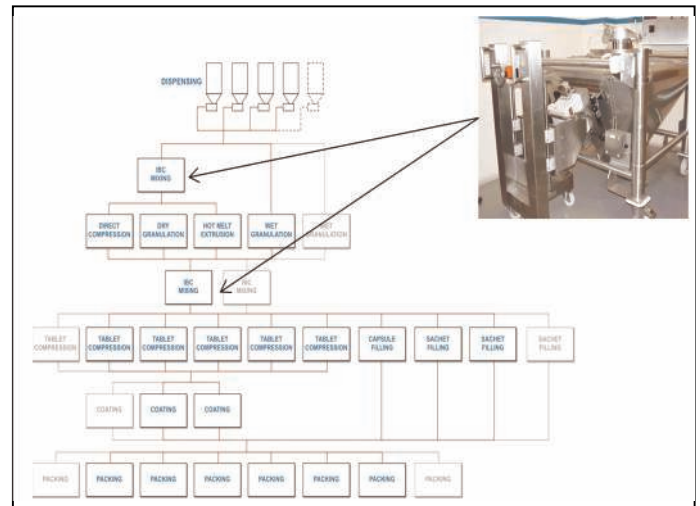
Continuous Processing and Continuous Manufacturing

Economical batch sizes are also influenced by other criteria such as the cost of re-validation, limitations of existing equipment and time consuming cleaning and QC activities. *Kaizen* events are a great tool to gradually reduce these influences. One major factor however is the manufacturing method and consequent scale up limitations, already laid down in the R&D phase. This problem can be overcome by using continuous processes (for example dry granulation) rather than the batch based traditions. Such processes do not need to be scaled up and compliance to a Lean Batch Size is simply a matter of run time. For single product facilities, it is interesting to link the processes permanently together and achieve continuous *manufacturing*, however the additional cleaning and set-up times, as well as synchronization issues, make such a set-up less beneficial for multi-product, flexible facilities using parallel processing techniques to maximize OEE.

Quality By Design

Unjustly often linked to continuous manufacturing, QbD can also make a huge difference in making a batch-wise operation *Lean*. Traditional Quality Control 'by sampling' lines up batches in quarantine, thus creating large amounts of WIP inventory. It also has a very negative impact on *flow* and cycle times and moves the organisation away from *Pull*. QbD solves this problem as batches can be released 'straightaway'.

The flow diagram on the right is a good example. A Matcon IBC Blender is much faster than many of the other downstream process steps, so one machine could 'serve' many, provided the cycle time is not increased by traditional Quality Control. Using **PAT** (in this case on-line NIR spectroscopy), this problem is solved and the OEE of the blender maximized.



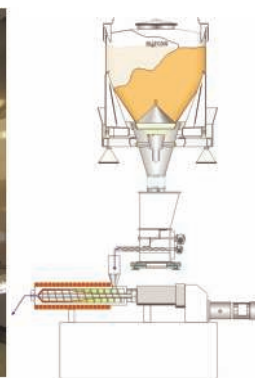
The Lean benefits of continuous process modules

Linking continuous (and batch) processes using a batch IBC System has significant benefits for reducing changeover times (off-line cleaning), as well as relieving bottlenecks using 'parallel processing', as shown in diagram above. Maintaining a steady state flow and full quality throughout the batch is very demanding on the IBC System itself. The **Matcon Cone Valve IBC System** guards this quality compared with other container systems by creating mass flow and control of feed. The Matcon system removes the risk of segregation, blockages and inconsistencies. Keeping a constant (and not flood-fed) head load on the inlet of the process, narrows variation at the output (for example a roller compactor). Avoiding segregation of often *blended product* is the most significant *Lean* contribution of a Matcon system to reduction of *defects*. Below are some typical Matcon applications feeding continuous processes.



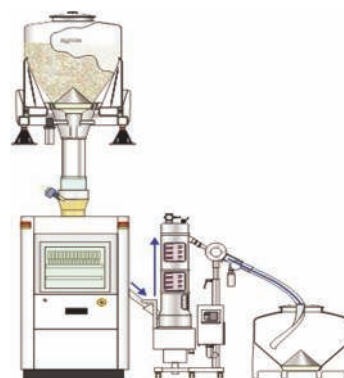
Roller Compactor Feed

Without segregation and minimized variation (6σ)



Extrusion

Accurate refill, steady process



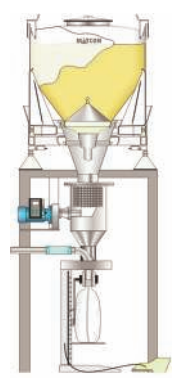
Tablet Press Feed

Without segregation, handling tablets in bulk



Sieving and Milling

Accurate feed, steady process



In Bin Blending - a Lean Solution

Often overlooked or assumed a fact of life, the immediate danger of serious segregation when discharging a stationary blender (Figures 1 and 2 below) is often a root cause of defects. Furthermore, when changing products, such blenders are very time consuming to clean. This results in a low Overall Equipment Effectiveness (OEE). A **Matcon IBC Blender** eliminates these problems as the blend is not *transferred* to the IBC but remains intact. The Matcon IBC Blender itself is not in contact with product and requires no cleaning.

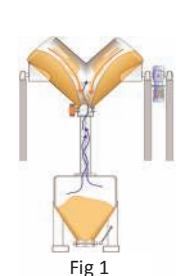


Fig 1

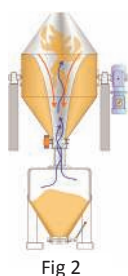


Fig 2



Matcon IBC Blending

Very high Overall Equipment Effectiveness and no segregation

