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Enablers and Barriers for Continuous Manufacturing in the Pharmaceutical Industry

Aylin Ates, Rajan Talati and Umit Bititci
University of Strathclyde, Dept. of Design, Manufacturing and Engineering Management, T: 0141 548 2588, E: aylin.ates@strath.ac.uk

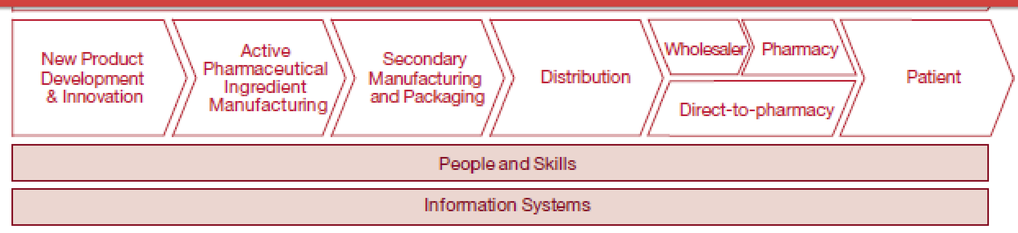
Vision

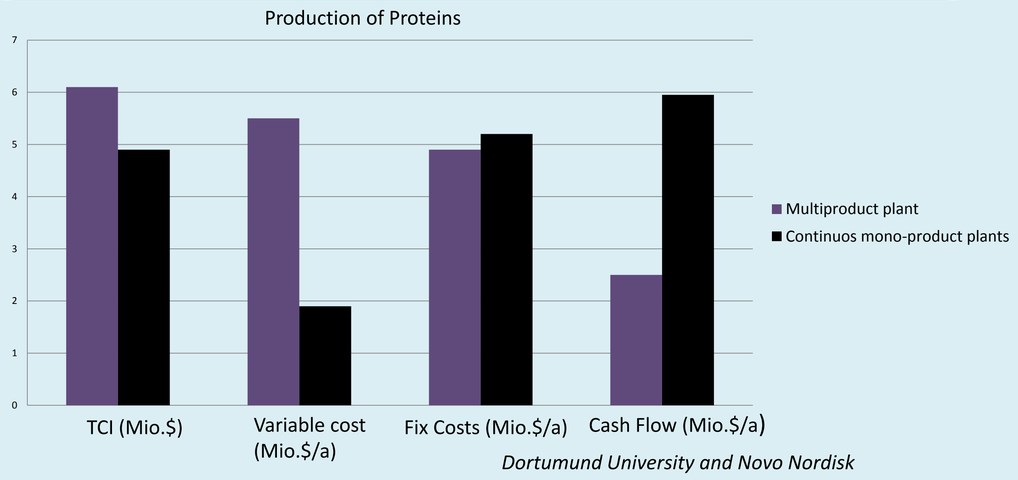
Developing a robust business case for converting Pharmaceutical industry from batch to continuous process with a vision to accelerate the adoption of continuous manufacturing processes, systems and plants for the production of high-value products to higher quality and variety, lower cost, more quickly and sustainably.

OBJECTIVES

- Identifying barriers and enablers for Continuous Manufacturing (CM)
- Developing current and future supply chain and manufacturing process configurations
- Learning from experiences of other industries that have successfully transformed from batch to flow based continuous production.
- Value chain road mapping

END-TO-END CROSS SECTOR VIEW
The supply chain is the backbone of a Pharma company





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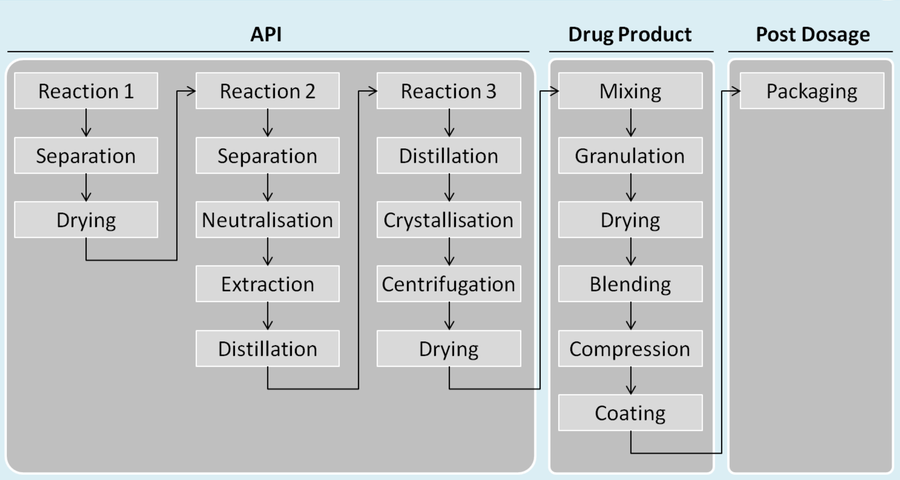

ENABLERS OF CONTINUOUS MANUFACTURING

Key Enablers	Description	Benefits
PLANT FOOTPRINT	CM allows the use of smaller production facilities with a reduced overall plant footprint.	>50% ↓
CAPEX	CM is highly capable to reduce the overall capital and operational cost of the facility.	50% ↓
CYCLE TIME	CM is capable of reducing overall cycle time of the process.	1 week to 1 day ↓
YIELD	Product yield will be higher in CM. Throughput will be significantly increase in CM.	20% ↑
SOLVENT USE	Solvent can be recycled more effectively in CM. Energy cost will be reduced by 50%.	70% ↓
TIME TO MARKET	CM accelerates the introduction of new drugs through efficient production processes.	50% ↑
INVENTORY	CM has potential for reducing the inventory cost due to less WIP, reduced material handling and continuous flow of material while increasing visibility.	12 to 3 months ↓

BARRIERS OF CONTINUOUS MANUFACTURING

ECONOMIC
- Investment risks, sunk costs
- High capital required for continuous mode
- Specialised personnel required

PROCESS
- Process control and safety
- Lack of process understanding
- Integration between PAT and the control software

TECHNOLOGICAL
- Losses during start up and shut down period
- Long reaction times of solid
- Continuous crystallisation, isolation and drying technology

SOCIAL
- Perception of that only suitable for large volume
- Lack of experience and fear of unknown
- Varying customer demand, uncertain market and shorter product life-cycle

REGULATORY
- Perception of that current regulatory system is rigid
- Change in the current batch process that has been already validated

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