

# Automation enabled global business integration

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# Vision

- Pharma companies are likely to take different steps forward as they reshape their strategies and infrastructure to prepare for future developments.
  - For example, a company may choose to implement relatively modest improvement investment in a plant that is manufacturing a product that is nearing the end of its patent life.
  - Elsewhere it may choose to plan for a rapid and full scale move to Process Analytical Technology (PAT) enabling realisation of FDA's vision of real time product control and release, based on continuous manufacturing operations.
- But the starting point has to be the vision of where the company wants to be in 10 to 15 years time and how this will impact manufacturing methods and practices.

# Success strategy of global leaders



- Reducing the time to market
  - Accelerating a product launch by 2 years could increase the revenue by \$600 million
  - An effective Clinical Trial Supply management can help to improve the product launch date
- Building product quality into the process
  - To maintain consistency in quality, invest to bring the process sigma to 4.5 or greater
  - FDA & GAMP compliances integrated in process
- Reducing manufacturing expenditure
  - Efficiency improvement & operational excellence

# Manufacturing Excellence

- First reason for Automation



# Enabling true integration

- Final reason for Automation



Connectivity to the business system through all the 3 stages:

From R&D, through Clinical trial to Commercial Manufacturing

Track and Trace to plug the holes & eliminate counterfeit

# Automation is needed Now!

- Profit pressures require manufacturing to contribute
- Operational effectiveness on top management radar
- Enables a compliant manufacturing environment that delivers product to plan with minimal cost and risk