

# LIFE SCIENCE INDUSTRY VIEW ON AUTOMATION

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# Industry Segments

- Pharmaceutical companies (chemistry)
- Biotech companies (molecular biology)
- Devices and delivery systems
- Diagnostics and laboratory services

Common feature across segments is the very high degree of regulation which has previously placed significant barriers to implementing change and adopting new process technologies

# Key Industry Trends

- Concern over R&D productivity : high cost and long gestation
- Bandwagon effect in major disease segments
- Fewer approvals of new molecular entities
- Patent expiry of blockbuster drugs : greater generics competition
- Focus on collaborations, licensing deals, mergers, etc.
- Investor value for “monetisable products” rather than promise of “platform technology”
- Strong pressure to respond to demands for affordable healthcare

# Personalised medicine

Relentless scientific pursuit towards targeted medicine based on functional screens

Advances in genomics and proteomics combined with data mining tools from bio-informatics

Poses significant manufacturing and regulatory challenges

- small, individualised lots
- quick and frequent product changeover
- can lead to high costs due to lack of economy of scale
- opportunity for use of disposable equipment

# Challenge posed by biological processes

Poor understanding of complex synthesis pathways within the micro-organisms or animal cells

Poor understanding of all the factors controlling growth and product formation

Productivity gains focussed on strain improvements and nutrient optimisation rather than external process variables

Direct contrast to chemical processes where stoichiometry determines maximum productivity

# Regulatory Initiatives

21st century GMPs : A risk based approach

FDA initiative on Process Analytical Technology

Harmonisation of international regulations

Focus on “affordable medicines” through policy initiatives

- abbreviated regulatory pathway for chemical entities
- initiating debate on “similar” biological entities
- orphan drug status for rare diseases

# Automation in the Indian context

Big pharma with patent protected drugs has never had the incentive to focus on cost of goods

Typically, cost of active pharmaceutical ingredient (API) is less than 10% of branded price in US/EU.

Significant price erosion upon launch of generics : Cost of API becomes crucial to profitability

India has a strong presence in API supplies and generics (presently in chemical entities)

Automation can be successfully deployed to address issues of productivity, cost reductions and capital effectiveness

# Impact of Automation

Fewer deviations : consistency, safety, regulatory compliance

Control on impurity profile through control of side-reactions

Some operations such as crystallisation (polymorphs) and micronisation (particle size distribution) have direct bearing on bio-availability of the drug in patients

Increasing use of complex control strategies in fermentation and cell culture (e.g. pH or temperature profiling, dosing of nutrients or inducers linked to metabolic state of organism)

Data mining and trending to improve process understanding



# Biocon: A fully integrated bio-pharma company

**Syngene**

**Clinigene**



## Drug Discovery

- Research & Development
- Molecular Biology
- Synthetic Chemistry

## Development

- Clinical Research
- Clinical Development
- Clinical Trials

## Commercialization

- Microbial Technologies
- Pharmaceutical Manufacturing
- Sales & Marketing

Library  
Screening

Lead  
Molecule  
Optimization

Pre-clinical  
Studies

Human  
Clinical  
Trials

Process  
Scale-up

Regulatory  
Approvals

Marketing  
& Sales

# Biocon strategy: Delivering on a long term vision

**New drug  
discovery &  
development**

**Co-development of new molecules  
In-licensing of novel drug delivery  
systems  
Line extension of molecules**

**Generic  
Biopharmaceuticals**

- Products with large global markets
- Near term patent expiry
- Fermentation derived molecules
- High technology barriers
- Few potential competitors

**Funding discovery-led research through a generic development strategy**

# Biocon's Market Focus :

**Cardiovascular  
(CVS)**

**Immuno-  
suppressants**

**Recombinant  
insulin**

**Monoclonal  
antibodies**

**Specialty  
Enzymes**

**THANK YOU**

**&**

**BEST WISHES TO THE A.I.A.**