

# Future Pharmaceutical Manufacturing

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New high-performance manufacturing technologies in terms of efficiency  
(volumes, speed, process capability etc), robustness and accuracy

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FACULTEIT FARMACEUTISCHE WETENSCHAPPEN



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FACULTY OF PHARMACEUTICAL SCIENCES  
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# BACKGROUND

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health sector is facing major challenges in Europe: **population ageing** creates need for

- new type of medicines
- more medication per capita
- more personalized and targeted medicinal products

# CHALLENGES

- increasing financial pressure to keep up the standards of the European public health system
- competition from generic pharmaceutical companies (public health care system will benefit from efficient and low-cost medication)
- Increasing interest to outsource activities into low-cost countries + more and more R&D activities to Asian countries



# CHALLENGES

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- number of new molecules reaching the market ↓
- not enough new blockbuster molecules in pipelines of European pharma
- ➔ optimize the few new molecules + maximize value of already existing ones + streamline related dosage form design and manufacturing
- new molecules are larger and more challenging from processing point of view

European pharmaceutical sector with long and successful history  
is close to a most severe crisis during its existence

Europe must focus on building up the future technologies

**“The pharmaceutical industry has a little secret: Even as it invents futuristic new drugs, its manufacturing techniques lag far behind those of potato-chip and laundry-soap makers.”**

**Wall Street Journal (Sep 3, 2003)**

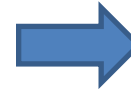


- still partly applicable today
- manufacturing of pharmaceuticals is conservative and old-fashioned field of engineering
- heavy documentation based regulatory structure ensuring the quality of the final product

# FUTURE PHARMACEUTICAL MANUFACTURING

## CURRENT WAY OF MANUFACTURING

### BATCH PROCESSING

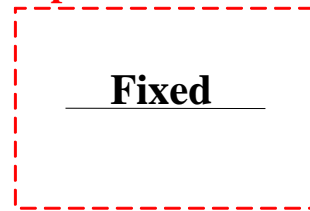


### off-line quality control in QC lab

- specific quantity of materials processed
- if quality is not met → batch rejection

- sampling during each unit operation
- limited number of samples
- no real-time information
- no process understanding
- no real-time release

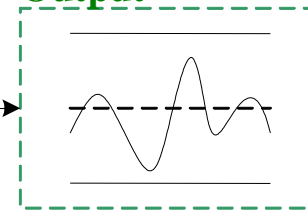
### Input Variable



### Process



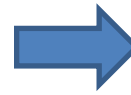
### Output



**ALTERNATIVE: CONTINUOUS PROCESSING**  
*a radically different system*

## ALTERNATIVE

**CONTINUOUS PROCESSING**  
*a radically different system*



**Process Analytical Technology (PAT)**

- 'one in, one out'- principle
- less scale-up issues
- lower cycle time
- faster release of manufactured goods

- in-line / real-time quality control
- risk-based manufacturing
- improved process understanding
- increase of process efficiency
- real-time release possible

**CURRENT WAY OF MANUFACTURING**

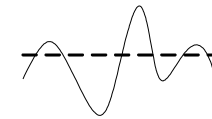
**Input Variable**

Fixed

**Process**

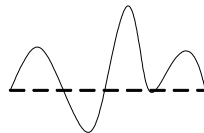
Black -Box

**Output**

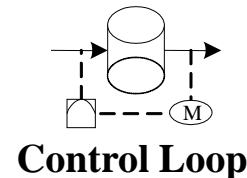


**ALTERNATIVE**

**Input Space**



**Processing**



**Product Space**



**continuous manufacturing** would provide a **new processing philosophy (Factories of the Future)** for the pharmaceutical field and, both remarkable **cost savings** and increased level of **safety** for the final medicinal product

# AIM OF PROJECT

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*pharmaceutical industry has a responsibility to deliver medicinal products with sufficient quality and price*

➔ project aims to strengthen the European pharmaceutical industry by

- 1.** creating the conceptual framework for continuous manufacturing of pharmaceuticals
- 2.** developing and demonstrating continuous manufacturing lines for selected advanced drug delivery systems
- 3.** providing an independent forum for developing a regulatory framework for advanced manufacturing concepts, such as continuous operations.

**This project requires the presence of three main elements:**

**1. Academic partners**

- a) applied material sciences
- b) engineering/manufacturing sciences
- c) measurement/sensor technologies, related process monitoring/control solutions and knowledge management
- d) physical/mechanistic modeling of material properties and manufacturing

**2. Industrial partners**

- a) end-users, both large innovator companies (“big pharma”) and generic companies
- b) measuring/process control/knowledge management technologies
- c) engineering/manufacturing technologies

**3. Regulatory partners** ensuring the implementation of new approaches

***Possible related sectors: food, machinery, sensor/control/IT industries***