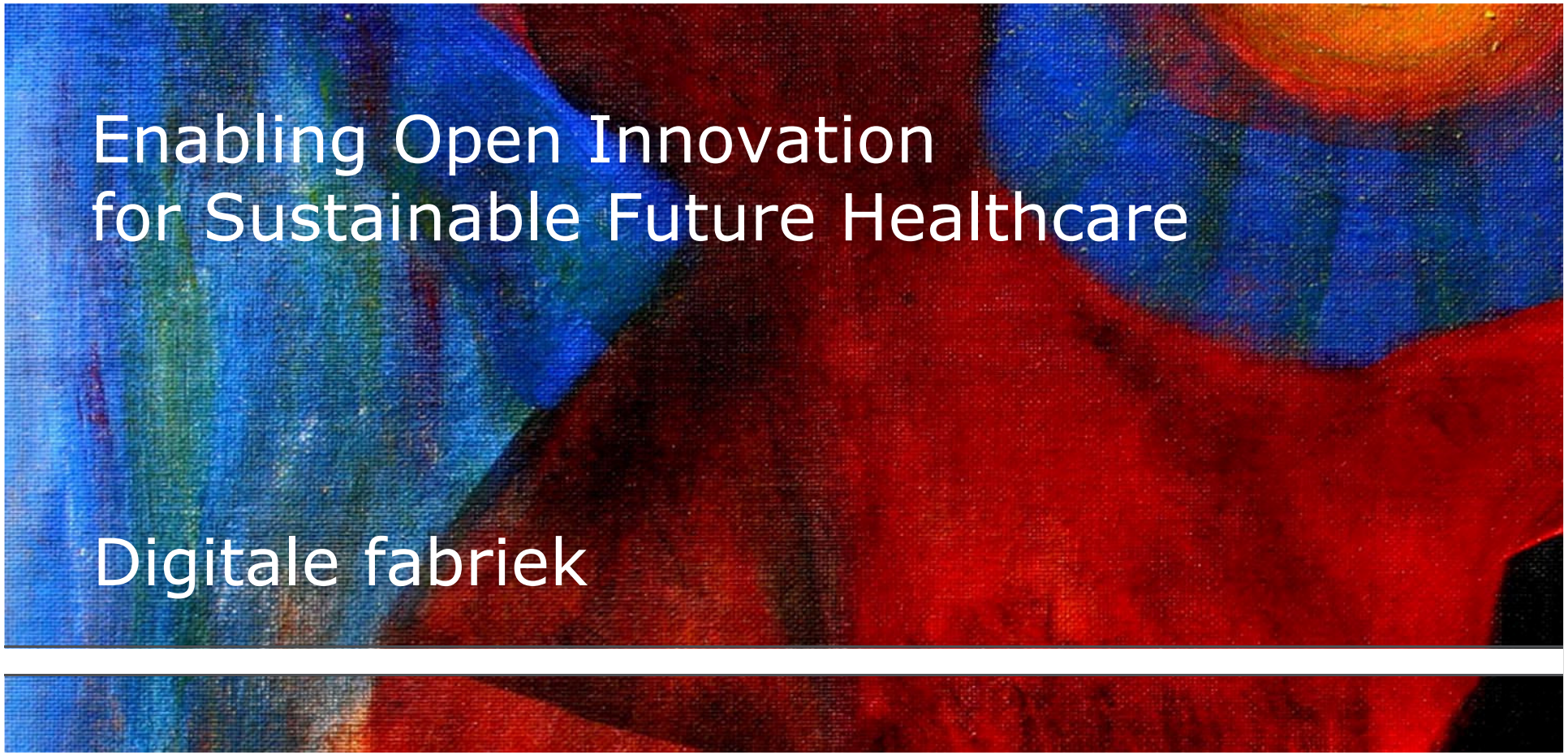


Janssen Pharmaceutica NV

Janssen Campus Belgium

ONE TEAM Making the Difference for Patients WORLDWIDE

janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

Historiek

"Pharmaceutical **manufacturing operations** are **inefficient** and **costly**. Compared to other industrial sectors, the rate of **introduction** of **modern engineering** process design principles, new measurement and control technologies, and knowledge management systems is **low**. Opportunities for improving efficiency and quality assurance . . . are not generally well recognized."

In a 2004 report, 1.*Innovation and Continuous Improvement in Pharmaceutical Manufacturing*, US Food and Drug Administration, 2004. the US Food and Drug Administration put the problem this way.
McKinsey - Pharma manufacturing for a new era

Historiek

- Released September 29, 2004
- Scientific principles and tools supporting innovation
  - Process Understanding
  - PAT Tools
  - Risk-Based Approach
  - Integrated Approach

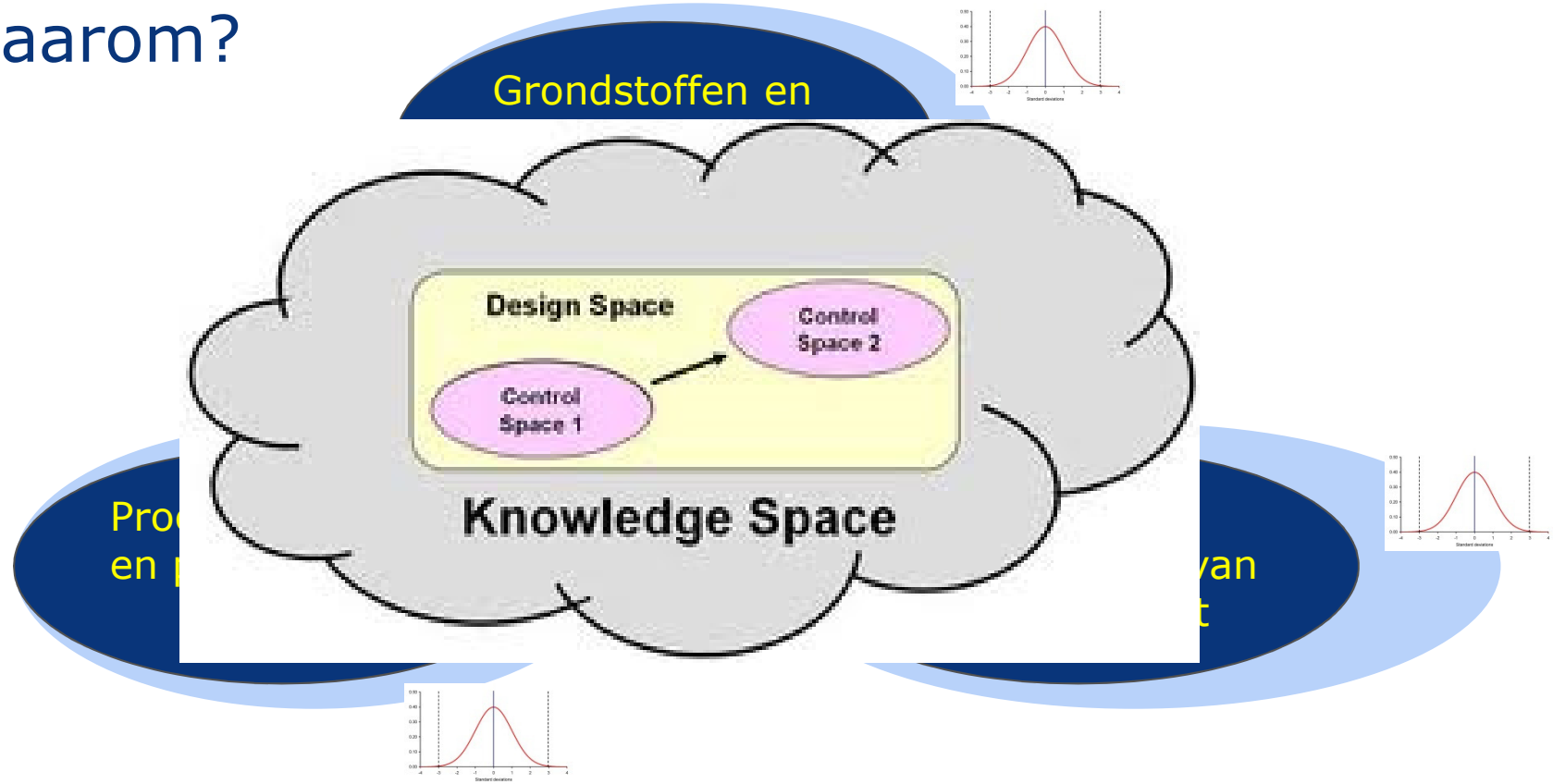
Guidance for Industry

PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)

Pharmaceutical CGMPs
September 2004

Waarom?



Waar ligt de grens van de variabiliteit van elk onderdeel?
Welke zaken moeten gemeten worden en welke niet?

Wat is Process Analytical Technology?

A system for:

- designing, analyzing, and controlling manufacturing
- timely measurements (i.e., during processing)
- critical quality and performance attributes
- raw and in-process materials
- processes

"*Analytical*" includes:

- integrated chemical, physical, microbiological, mathematical, and risk analysis

Focus of PAT is Understanding and Controlling the manufacturing Process

with the goal of ensuring final product quality

ISPE: International Society for Pharmaceutical Engineering

Waarom PAT?

Right First Time

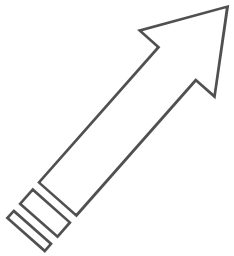
Well Controlled Process

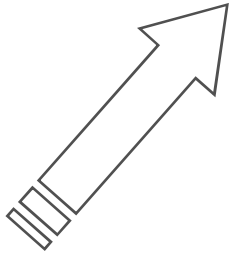
Fundamental Goals

Improved quality.

Improved safety.

Cost savings.





Process Control

Process Knowledge

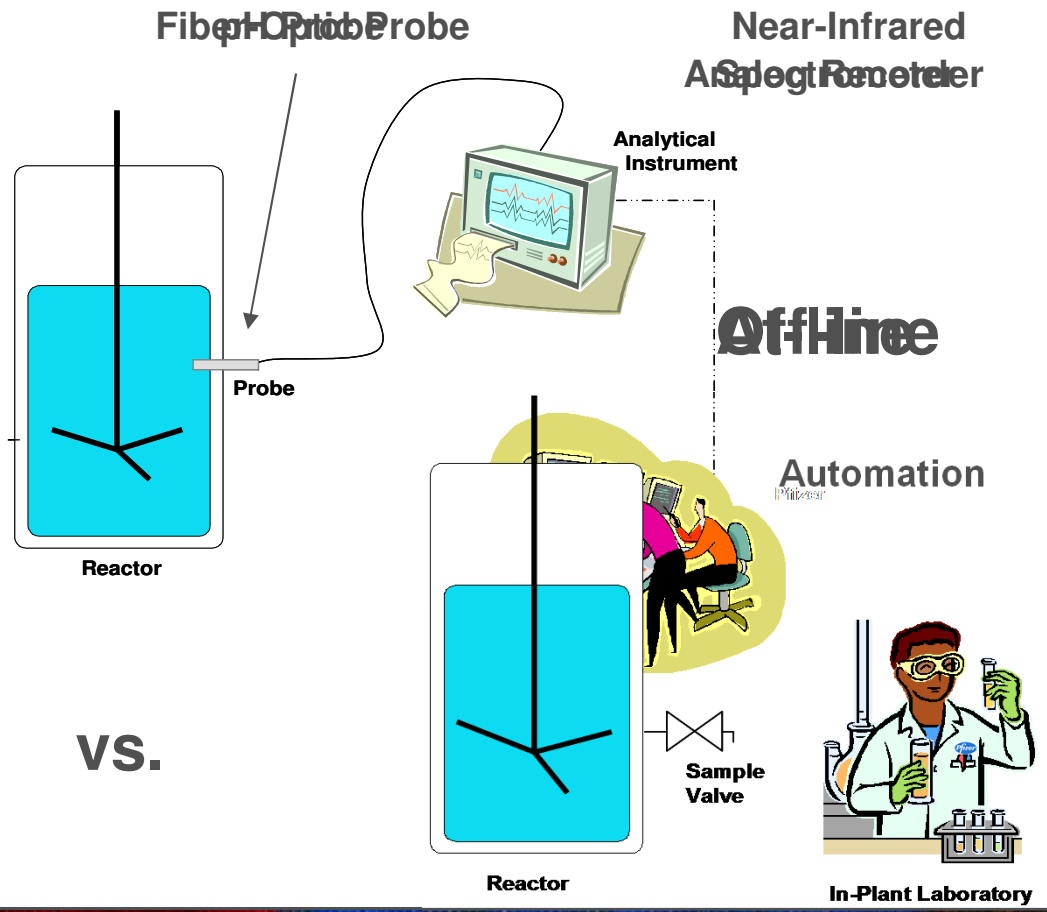
Use of PAT to Achieve Right First Time Benefits

- Reduce
  - deviations
  - cycle times (operational efficiency)
  - inventory levels
  - costs (reworks, resample, retesting, etc)

- Improve
  - customer service (product availability)
  - capacity utilization
  - compliance (reduce deviation reports)
  - assurance of quality

What is (a) PAT?

On-line



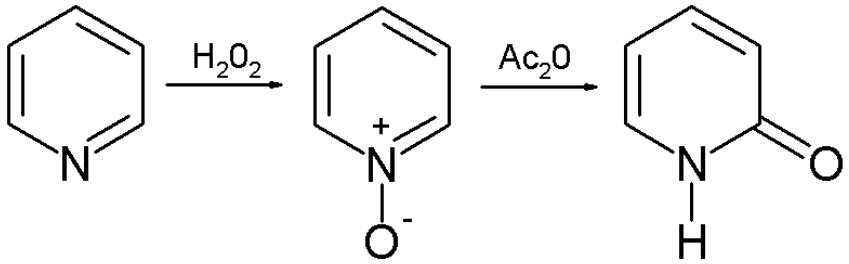
vs.

Off-line

Waar staan we?

Batchproces → Continu proces

- Chemische Synthese = stappen proces
  - Tussenproducten
  - Procesparameters
  - Volume en opbrengst
  - QC/QA per stap
  - Lange doorlooptijden



Naar een Continu proces

1. Batchproces: automatisatie van huidig proces

2. C e en
   n
   -
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-
-

eindproduct

Van informatie naar kennis

Informatiebronnen – R&D of Productie

- Materialen: Productie
- Procesparameters: Productie
- Eind-/tussenproducten: Productie (QA/QC)

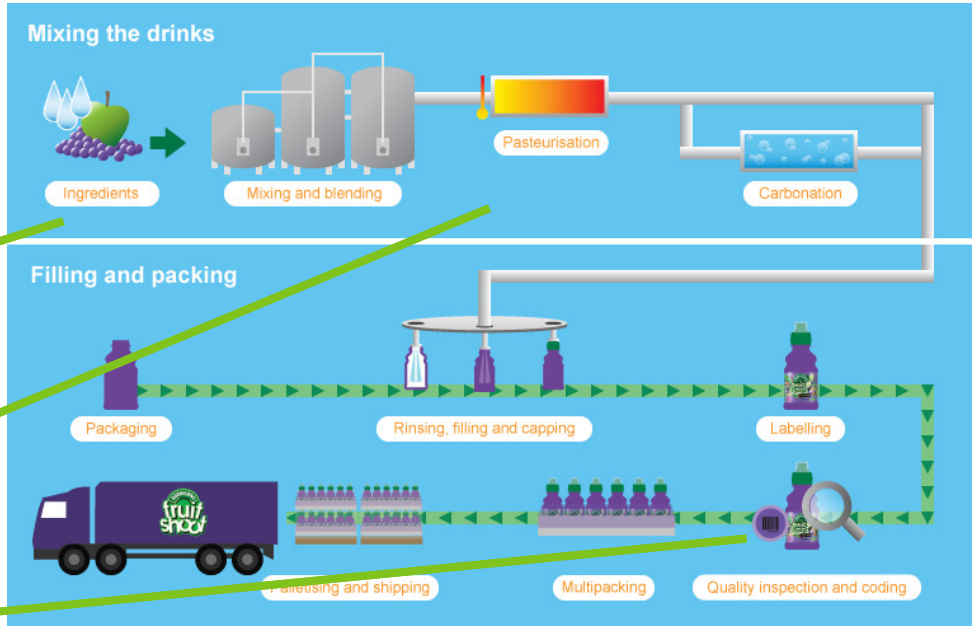
Informatie - Analyse

- Grote datasets
- Groot aantal variabelen
- Rekencapaciteit en software

Rekencapaciteit en software

- Inhouse
- Universiteiten
- Vlaams Supercomputer Centrum

Van informatie naar kennis



Materialen

Proces

Product

Analyse

Reken capaciteit

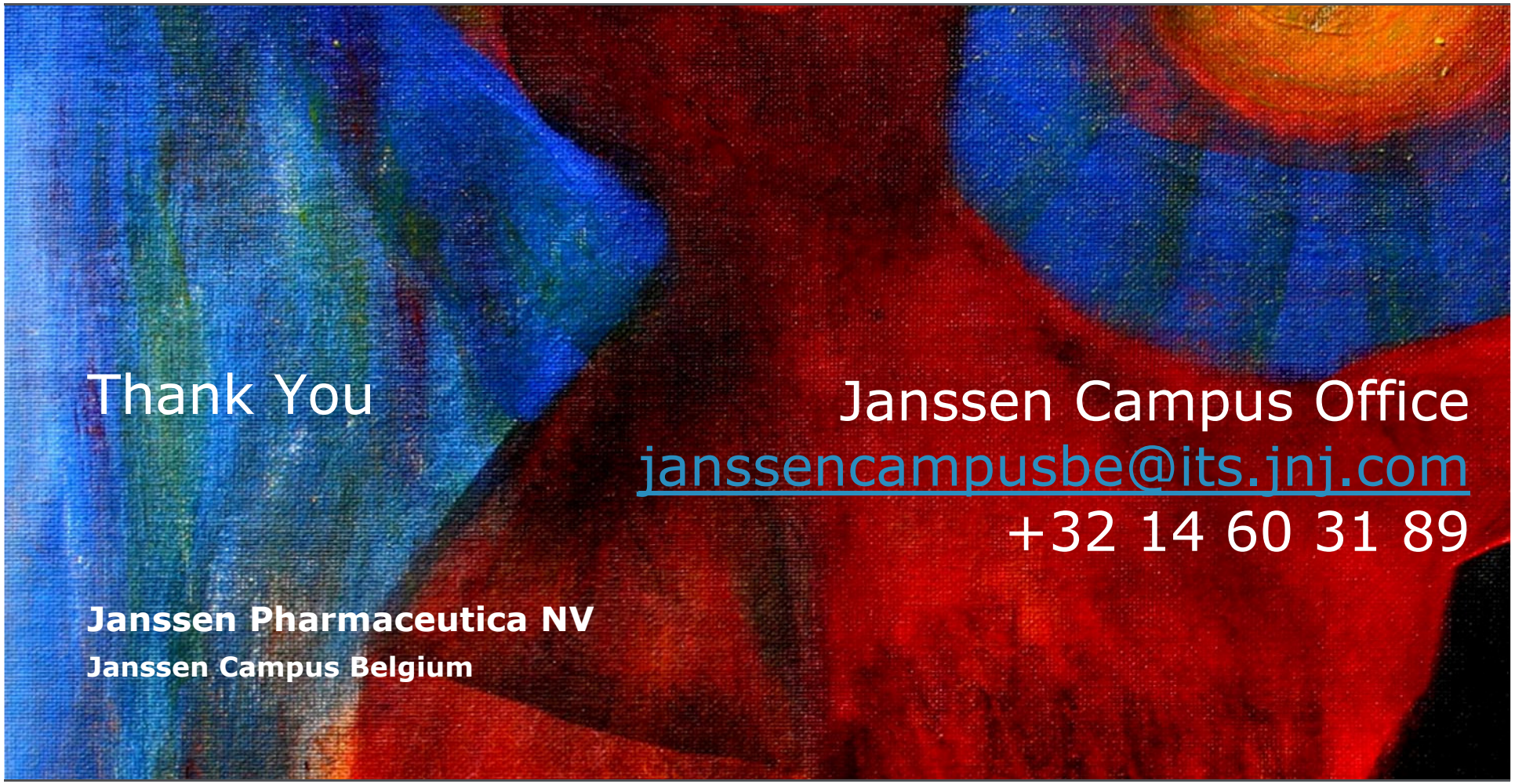
Software

Kennis

Fabriek van de Toekomst
- Controlled processing
- Optimalisaties

R&D
- Nieuwe producten en processen

Chemical Development Pilot Plant in Geel



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