

Jakob Christensen, 7 November DSK2024

PAT in a new large pharma facility

– Implementation experience
and challenges

The image shows a close-up, low-angle view of a modern building's facade. The building has a dark blue or grey metallic finish. The 'nne' logo is mounted on the upper part of the facade, above a large glass window. The logo is white and consists of the lowercase letters 'nne' with a registered trademark symbol (®) to the upper right. The sky in the background is a clear, light blue.The 'nne' logo is positioned vertically on the right side of the slide. It consists of the lowercase letters 'nne' in a white, sans-serif font, with a registered trademark symbol (®) to the upper right of the 'e'.

Agenda

INTENTION

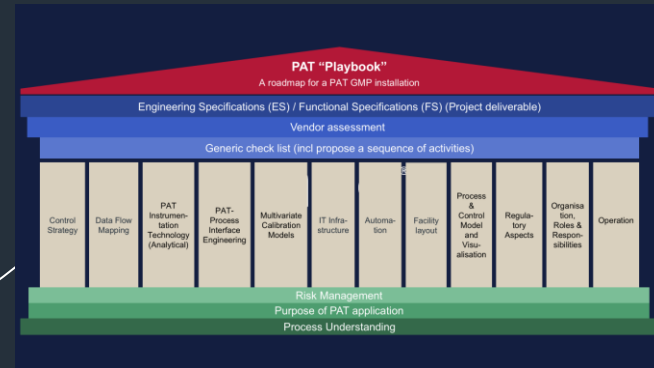
Share some experiences from implementing PAT in large scale

The case - The manufacturing facility

**Disclaimer :
No modelling**

Some background. How did we get there?

The PAT house to highlight some experience and challenges from the engineering perspective



PPV

The Factory of the Future



**Flexible
modular
design**



**Closed
process**



**Flow
process**

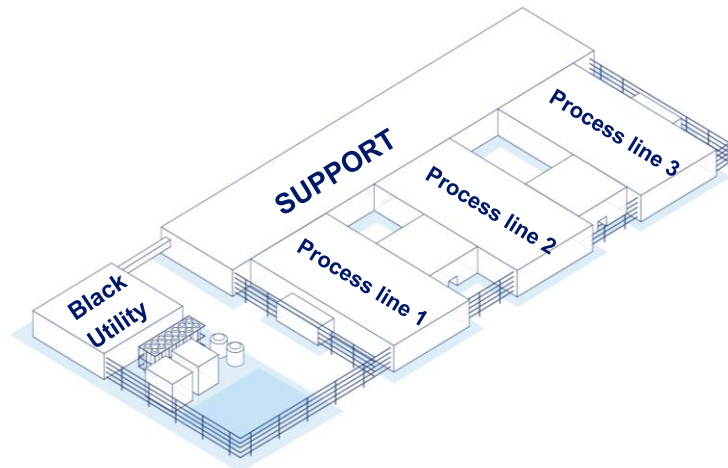


**Highly
Automated**

PPV Facility

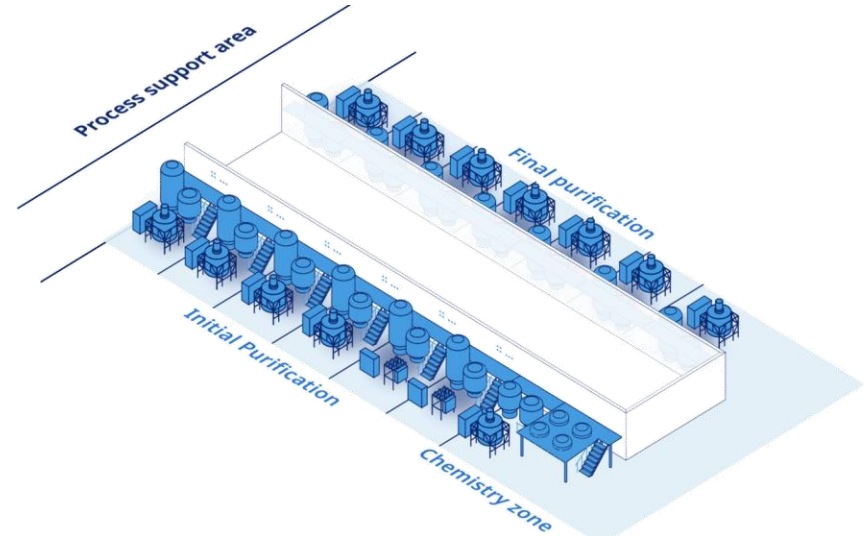
Site divided into sections of:


- Utility building
- Identical process lines 1-3
- Support building



Each process line built up of:

- Starting dissolution step
- Number of multipurpose process bays
- Fixed chemistry zone
- Final drying step






Some background
How did we get started?

The driver: Control Strategy

7 June 2022 A case study for full scale implementation Novo Nordisk®

The vision for the control strategy

Based on no off-line in-process analysis during routine production




API specification analysis kept as off line analysis

8 June 2022 A case study for full scale implementation Novo Nordisk®

The why

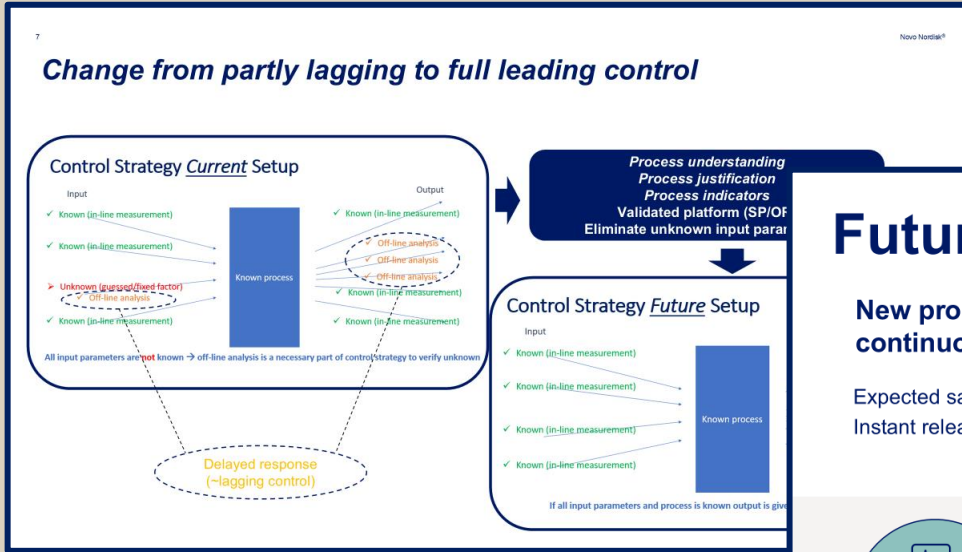
No off-line in-process analysis during routine production

- **Reduce manual operations incl. related cost and variations**
- **Improve process control by having all relevant measurements in real time**
- **Support flow production**
- **Support optimal capacity utilisation**
- **Prepare for instant release**



Credit to Anne Mette Gregersen @NN

Towards the goal

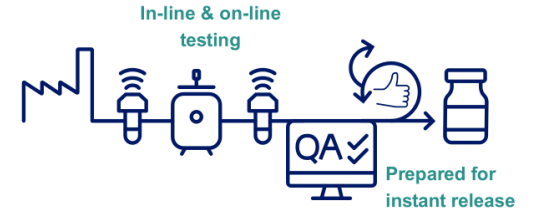


Future control strategy



New process supporting continuous process flow

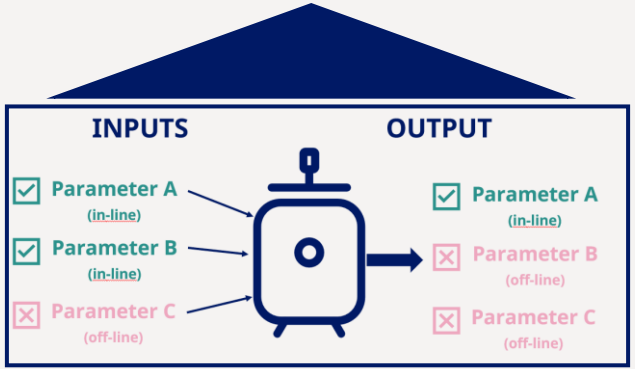
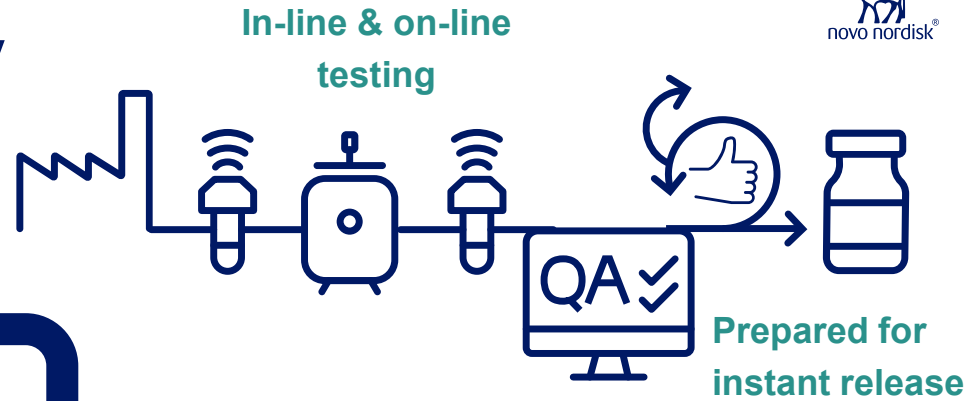
Expected sample reduction: ~70%
Instant release readiness



- Leading real-time results
- Improved product quality
- Increased equipment utilization
- Reduced manual handling
- Lower unit cost

Control strategy

- *Elimination of unknown input parameters*
- *Validated platform*
- *Process understanding*
- *Process justification*

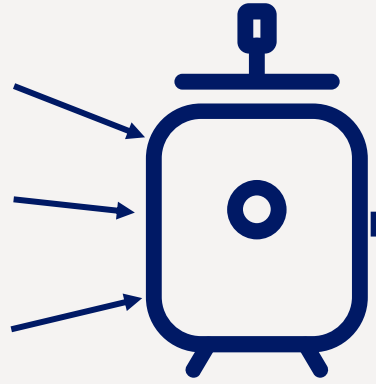


INPUT

- ✓ Parameter A (in-line)
- ✓ Parameter B (in-line)
- ✓ Parameter C (in-line)

OUTPUT

- ✓ Parameter A (in-line)
- ✓ Parameter B (predicted/calculated)
- ✓ Parameter C (predicted/calculated)

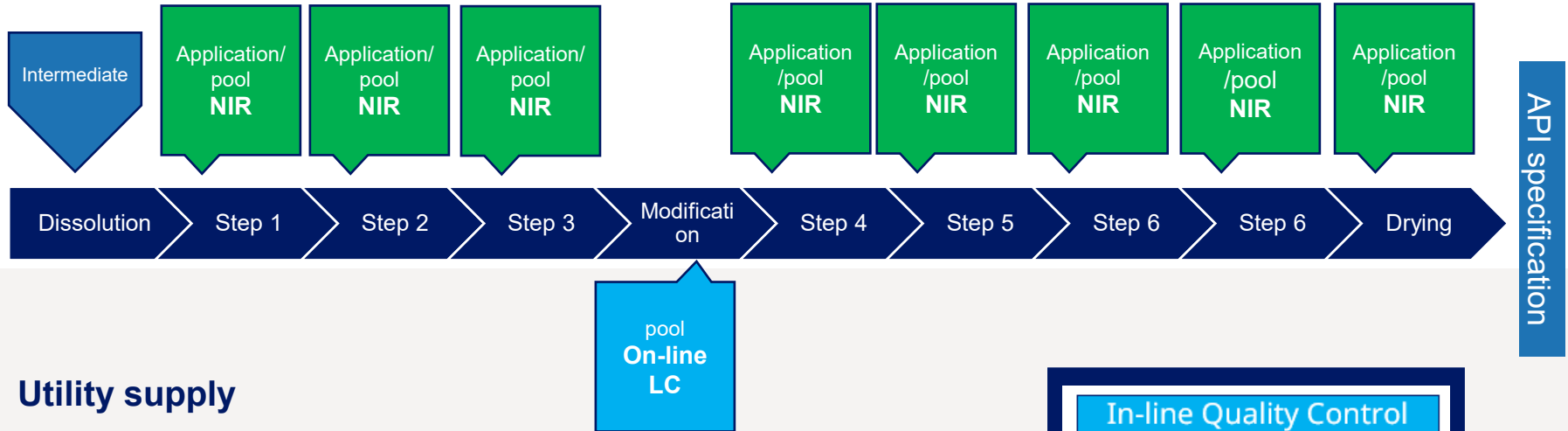


The PAT scope

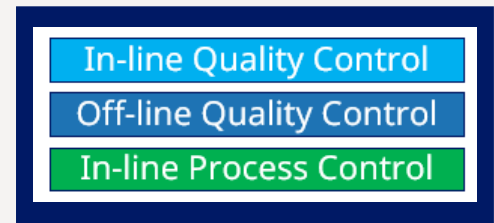


Process analytical technology

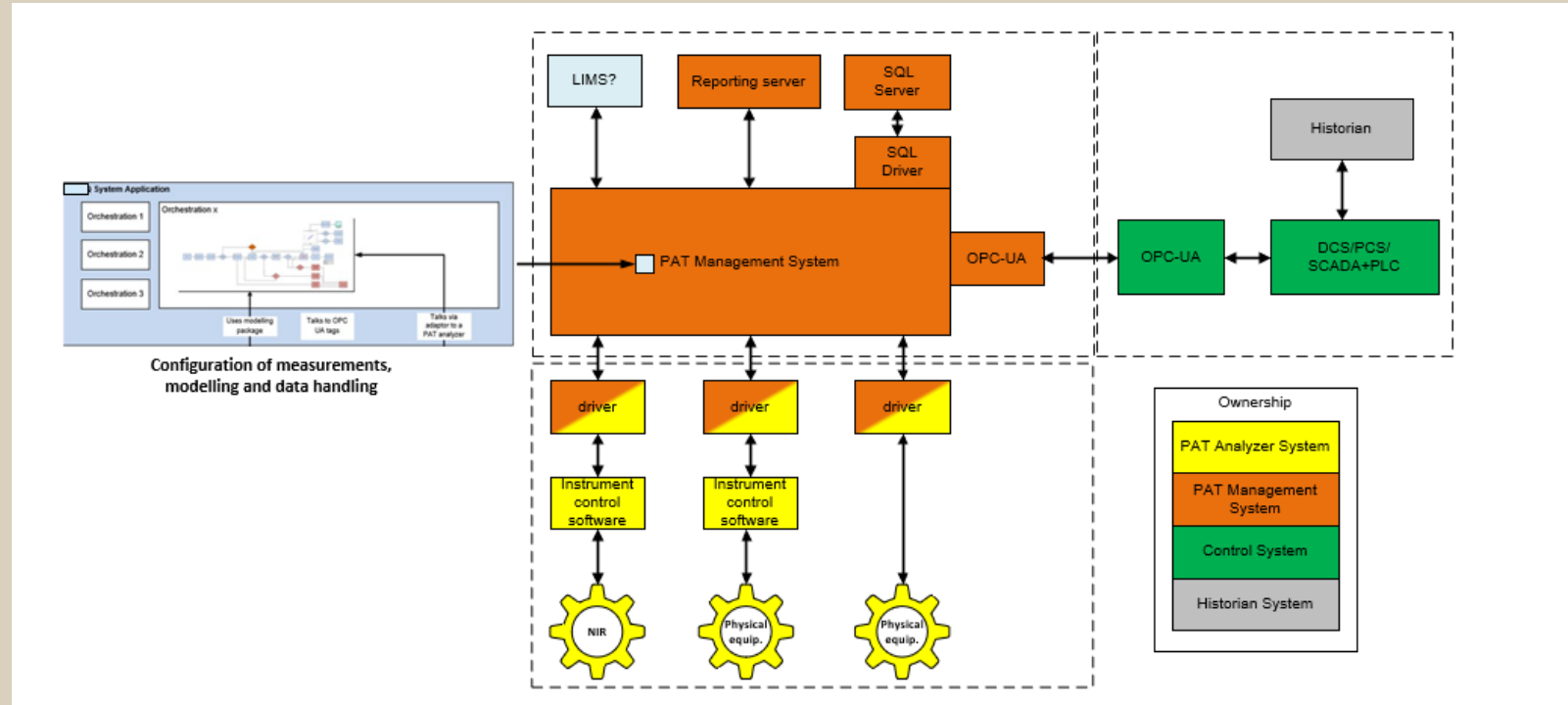
Core process



Utility supply



Integration with Process



Implementation experience
and challenges so far
– from the engineering
partner



PAT "Playbook"

A roadmap for a PAT GMP installation

Engineering Specifications (ES) / Functional Specifications (FS) (Project deliverable)

Vendor assessment

Generic check list (incl propose a sequence of activities)

Control Strategy

Data Flow Mapping

PAT Instrumentation Technology (Analytical)

PAT-Process Interface Engineering

Multivariate Calibration Models

IT Infrastructure

Automation

Facility layout

Process & Control Model and Visualisation

Regulatory Aspects

Organisation, Roles & Responsibilities

Operation

Risk Management

Purpose of PAT application

Process Understanding

Thank you for the attention

