

**CIPM-ILAC Joint Webinar:
Digital Transformation in the context of Accreditation**



Digitalisation of metrology process at Novo Nordisk

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- I. Introduction: Novo Nordisk, Metrology, digitalization
- II. Digital calibration certificate
- III. Measuring equipment specification
- IV. Smart use of calibration history
- V. Future perspectives

Agenda

Novo Nordisk at a glance

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark.

Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders.

We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease.

1. <https://companiesmarketcap.com/pharmaceuticals/largest-pharmaceutical-companies-by-market-cap/>
(As of 4 April 2022).



The Metrology Footprint



+400,000

Calibrations pr. year

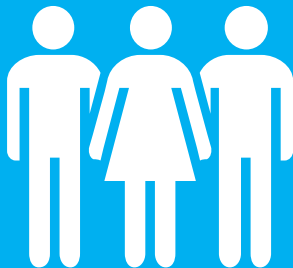
**A global process applied
through the value chain**

**Ensures reliable measuring
results and thereby correct
decision-making**



+60

Inspections / year
All addressing metrology



+7,000

Users have 1 or more SOPs assigned

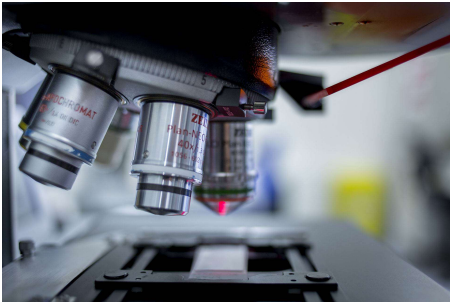


+6100

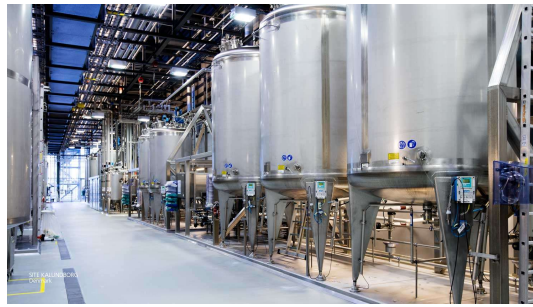
QMS docs mapped to Metrology

Metrology is applied in the whole value chain

R&D



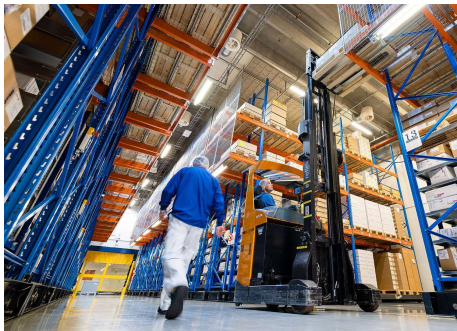
Manufacture



Fermentation, purification, aseptic filling, assembly, packaging, tableting



Quality control



Storage & Distribution

Parameters:

- Temperature
- PH
- Mass
- Flow
- Pressure
- Humidity
- TOC
- Conductivity
- Particle
- Geometry
- Spectroscopy
- ...

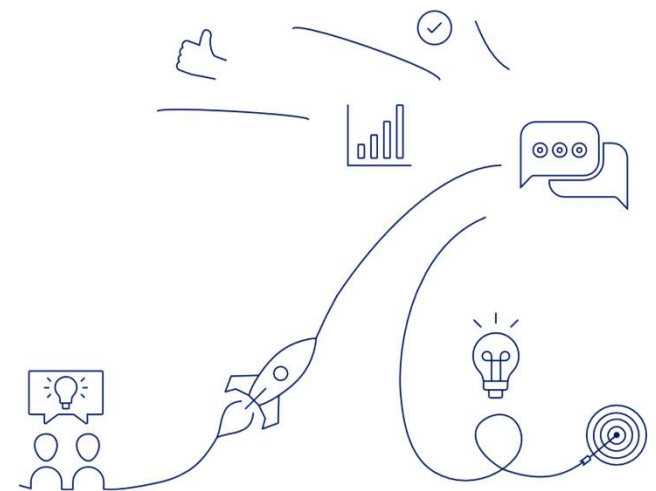
Ambition for the metrology process

In 2025 the metrology process is...

Only the necessary and sufficient and supported by intuitive solutions

Enabled by:

- Harmonisation
- **Paperless, digitalisation, and data availability**
- Interface to other processes are optimized and **digital**



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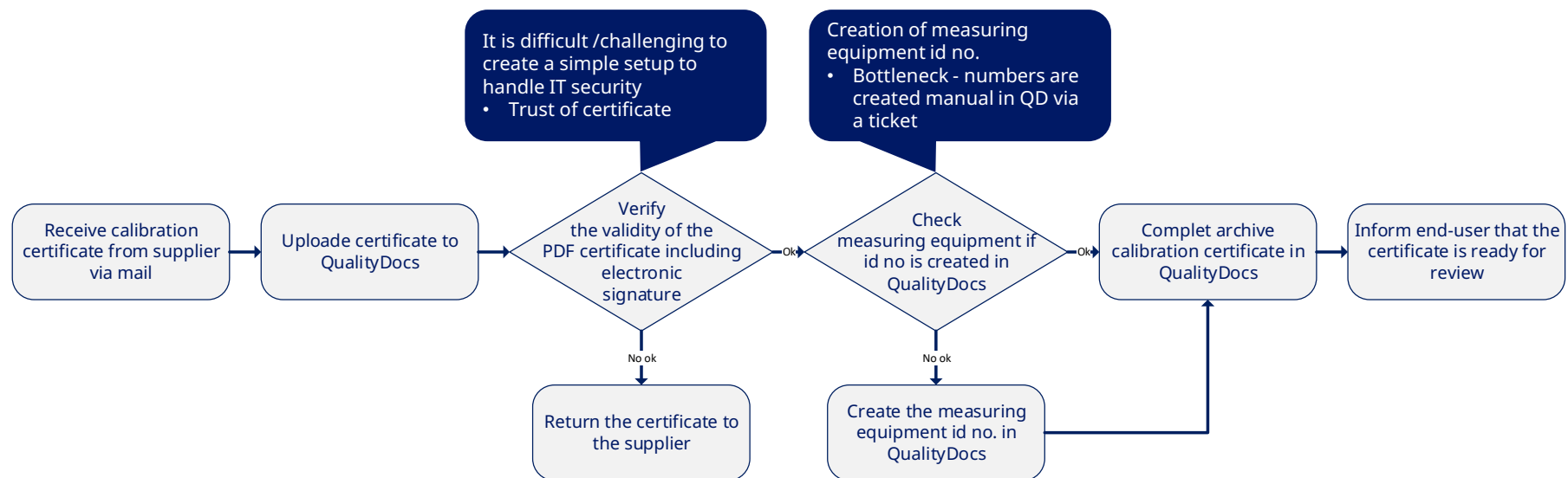
Digital solution for calibration certificates



Digitally signed PDF calibration certificates



RPA (robotic process automation) to archive digitally signed calibration certificates



E-mail

QMS

E-signature

Equipment ID

Archive

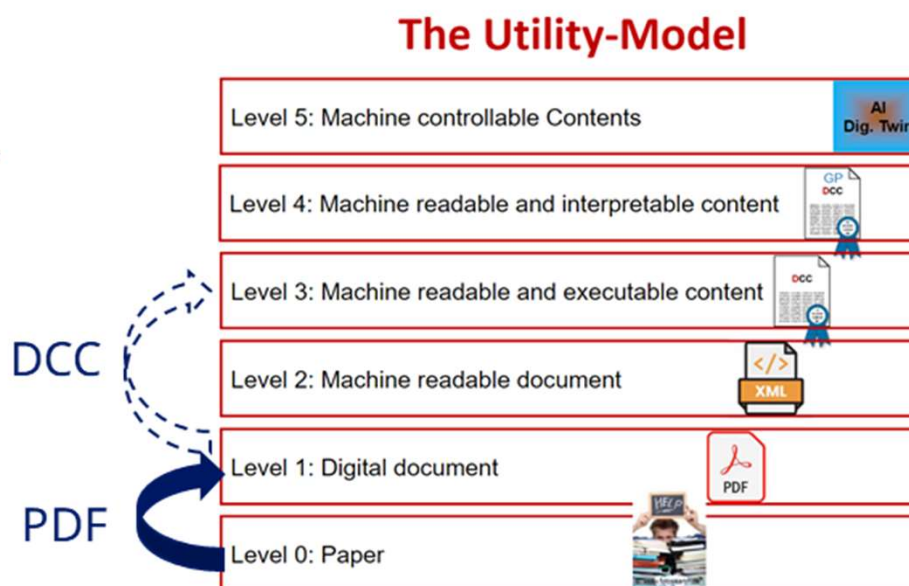
Notifcation

Full digital calibration certificates according to EU-standard

Pilot in SmartCom and follow-up project

Auto-transfer calibration results and metadata from suppliers into CMS (SAP) by DCC

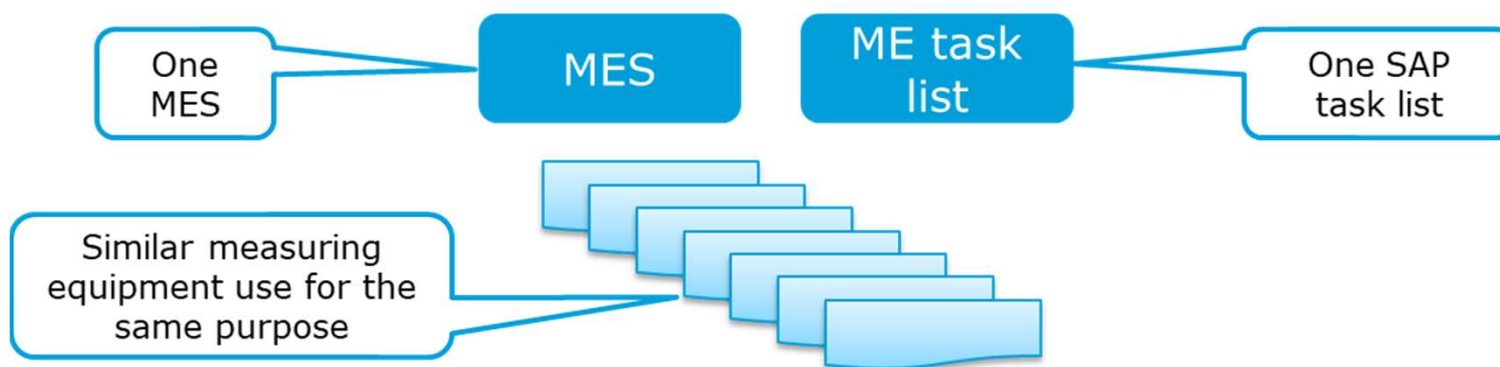
- Digital Calibration Certificate (DCC)
- Digital calibration request (DCR)
- Digital calibration answer (DCA)



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Measuring Equipment Specification (MES)



One-for-all:

- Create and maintain equipment specifications
- Change request
- QA approvals
- Create and maintain SAP task list

To be continued:

- Full digital solution in CMS (SAP)
- Specifications: not only what but also why

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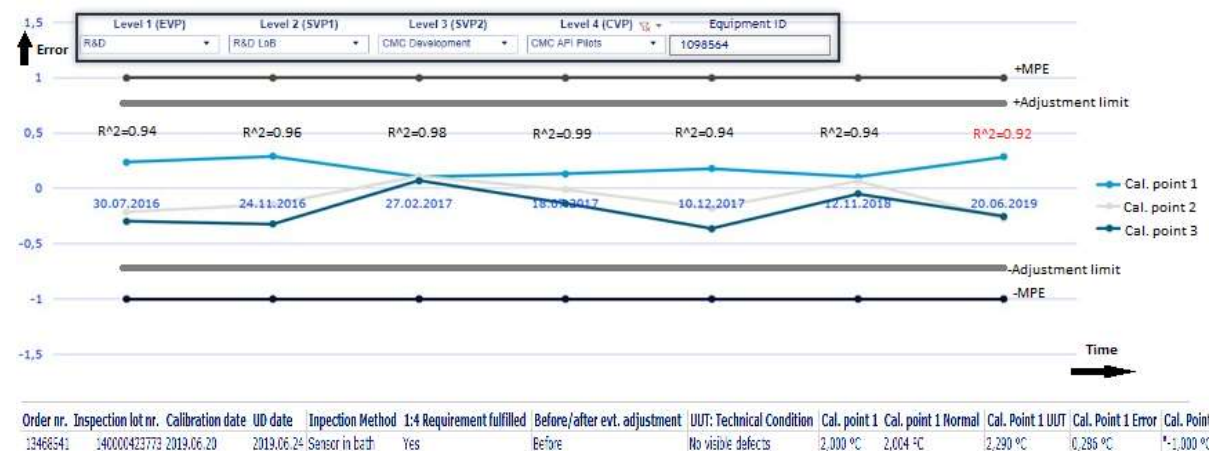
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Smart use of calibration history



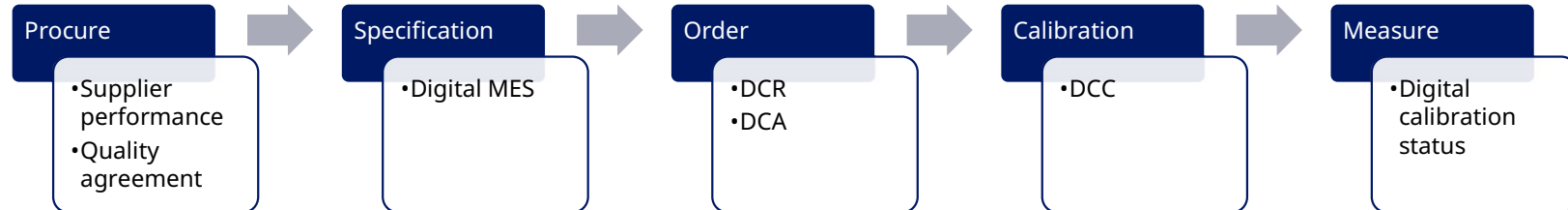
Potential benefits:

- Data-driven scheduling of calibration interval
- Optimization of interval and MPE
- Support risk assessment for postponement and deviation
- Performance driven procurement



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Business intelligence, big data, AI, digital twins

Training

Why is digitalisation so hard for pharma?





What do we need from you?

- **Accredited service:** always preferred
- **An intuitive CMS:** you cannot digitalise a process that is not harmonised
- **Early engagement:** we want to be at the forefront
- **Standardisation:** standard = compliance & efficiency, international standards, data interchangeability

