Metrology's Digital Transformation in Industry – Perspectives from Novo Nordisk

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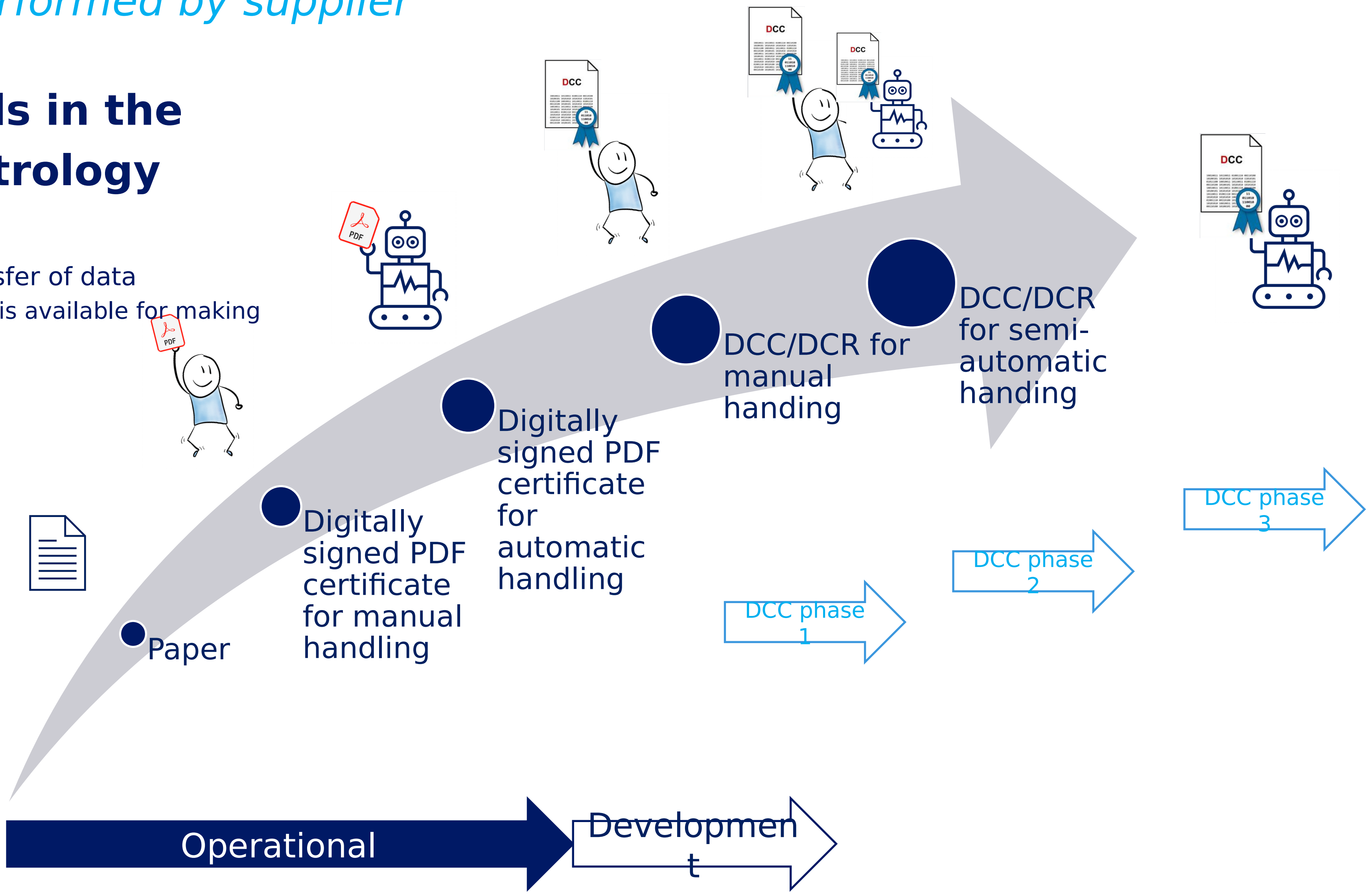
Digitalisation and Automation Journey

- Calibration performed by supplier

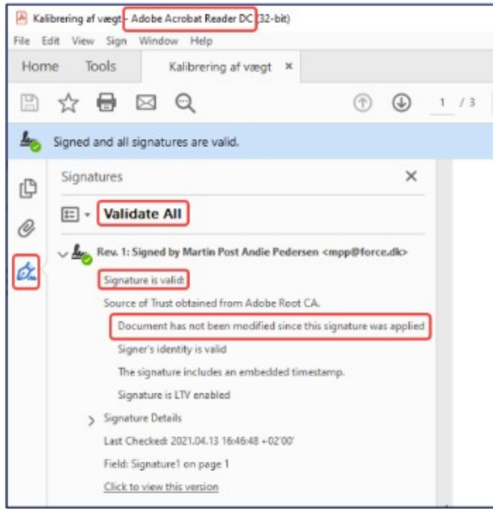
Strategic goals in the corporate metrology process:

- Remove manual transfer of data
- FAIR and relevant data is available for making decisions



Digitalisation and Automation Journey

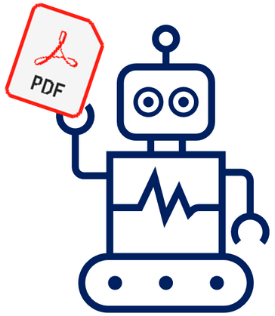
Operational – digitally signed PDF calibration certificates



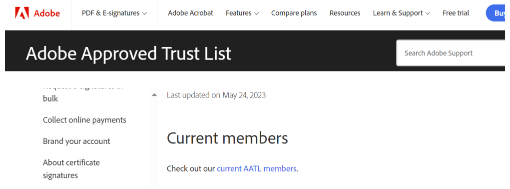
- In 2020, a process was established for receiving digitally signed PDF calibration certificates.
- The data integrity of the certificate is manually verified, and these certificates are subsequently manually uploaded to a database.

Digitalisation and Automation Journey

Development – RPA solution for digitally signed PDF calibration certificates



- In May of this year, an RPA solution was implemented with the following automated functions:
  - Verification of data integrity for calibration certificates
  - Upload of calibration certificates to the IT system for archiving
  - End-user notification



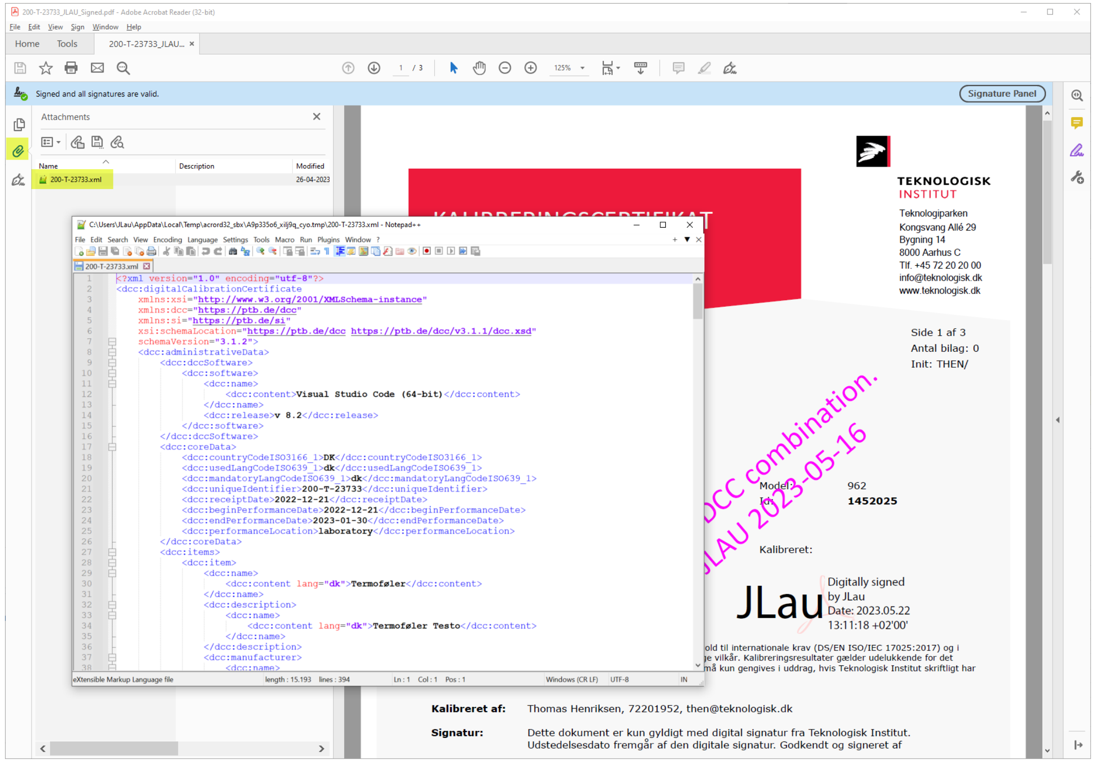
- Preconditions:
  - Agreement with supplier
  - Mail body requirements –metadata for process
  - Signature root certificate is available in AATL (Adobe Approved Trust List)

Digitalisation and Automation Journey

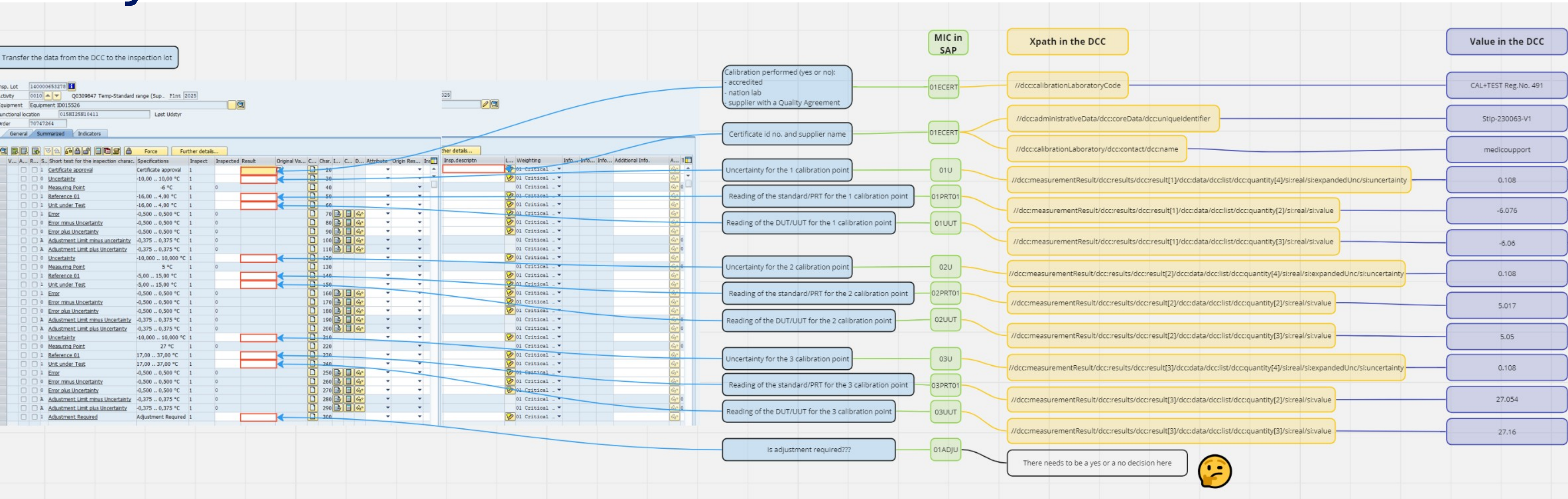
Development – Phase 1 DCC/DCR for manual handling (pilot phase)

Future direction:

- Leverage past experiences
- Incorporate XML files as attachments within the PDF



Mapping of Dataflow from DCC to NN IT System



ALCOA principles

A

Attributable to the person generating the data

Who performed an action and when?

If a records is changed, who did it and why? Link to the source data

L

Legible & permanent

Data must be recorded permanently in a durable medium and be readable

permanent ink, we archive documents, we save electronic records and have back up systems

C

Contemporaneous

The data should be recorded at the time the work is performed, and data-and-time stamps should follow in order

we document the activity at the time of performance – no matter if paper or IT system – it system has secure date/time stamps that cannot be altered

O

Original record or "true copy"

Is the information the original record or a certified true copy?

We keep the first data "the raw data" - we must be able to reconstruct the entire sequence of events

A

Accurate

No errors or editing performed without documented amendments

data are correct and trustworthy and verified by 2nd person review

ALCOA + & ALCOA ++ principles

C+

Complete

All data including any repeat or reanalysis performed on the sample.

C+

Consistent

All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence.

E+

Enduring

Not recorded on the back of envelopes, cigarette packets, sticky notes, or the sleeves of a coat but in notebooks or electronic media in the data systems of instruments.

A+

Available

Can be accessed for review and audit or inspection over the lifetime of the record.

ALCOA + +

Traceable

Data should be traceable throughout the data life cycle, and changes should be recorded as part of the metadata (i.e., audit trails)

WHY

- 20.000 supplier calibrations a year

- Remove manual transfer of data to the database
- Trending on calibration data
  - Transparent data insight via dashboard
  - Machine Learning under development to trend on data including metadata, and classify between equipment exhibiting systematic drift or not

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