

## Digitale arkiver - Vedligeholdelse, tilgængelighed og forskning

13. maj 2014 på Rigsarkivet

## Archive strategy for electronic records

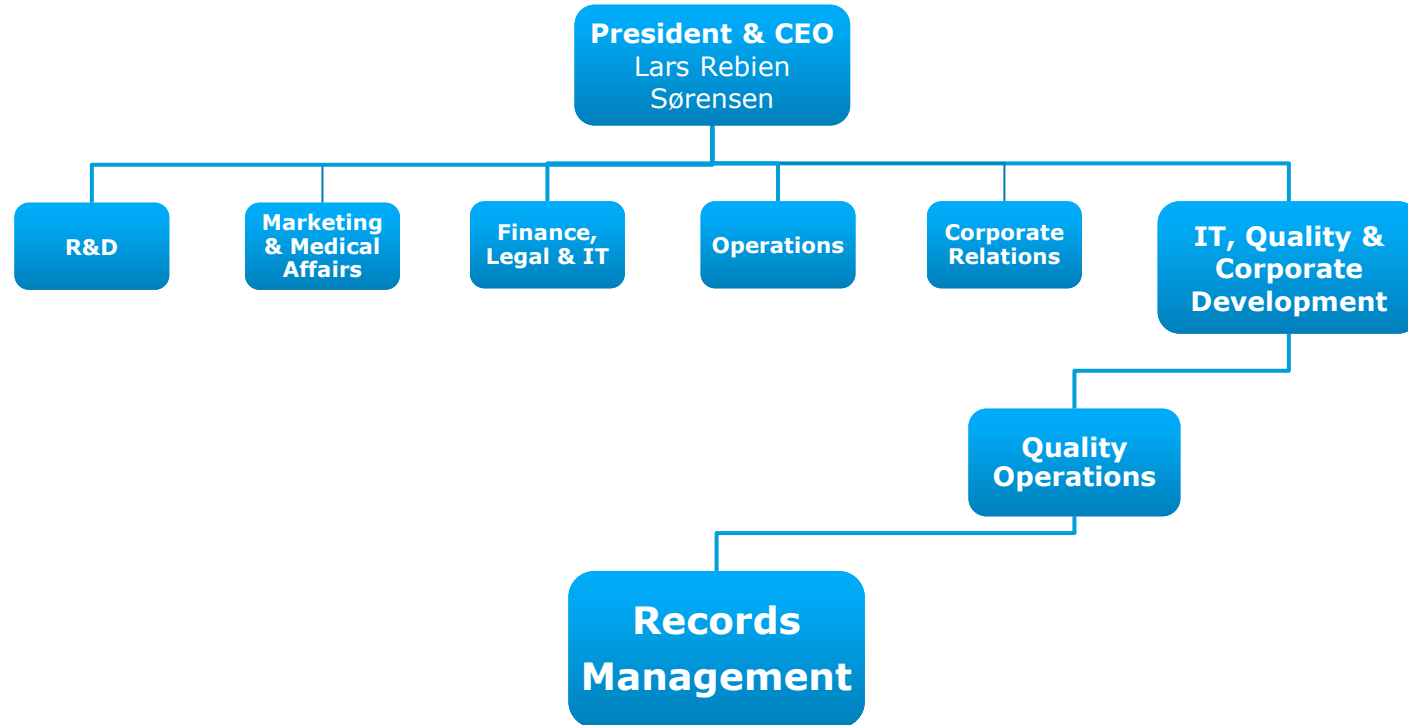
Peter Fæster Nielsen, Novo Nordisk  
13. May 2014

# Novo Nordisk at a glance



- Approximately 40,000 employees in 75 countries
- Products marketed in 180 countries
- A world leader in diabetes care since 1923
- Also leading positions in:
  - Haemostasis management
  - Growth hormone therapy
  - Hormone replacement therapy

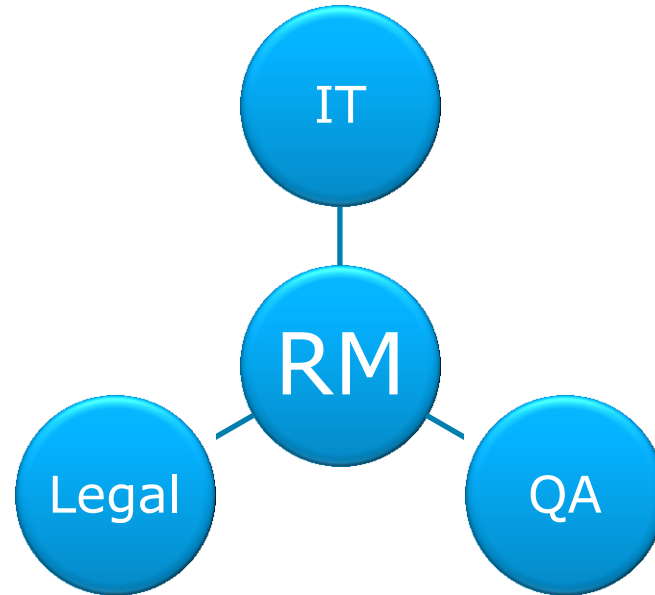
# Organisation



# Archiving electronic records - why?



# The way to a successful records management (RM) programme



# Landscape for physical Business Critical Records

Multiple physical archives

One RM system



Procedures:

- File plans  
(business process catalogues)



Governance:

- Global Retention Group



Scope: ER and  
physical records

# Archive System - definition



ENV/JM/MONO(2007)10  
OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE  
MONITORING  
Number 15

Advisory Document of the Working Group on Good Laboratory Practice

Establishment and Control of Archives that Operate in Compliance with the Principles of GLP



U.S. Food and Drug Administration  
Protecting and Promoting Your Health

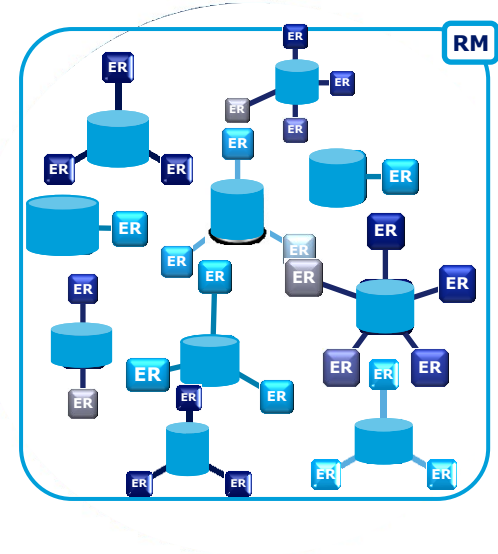
21 CFR Part 11  
Electronic Records; Electronic Signatures

# WHAT



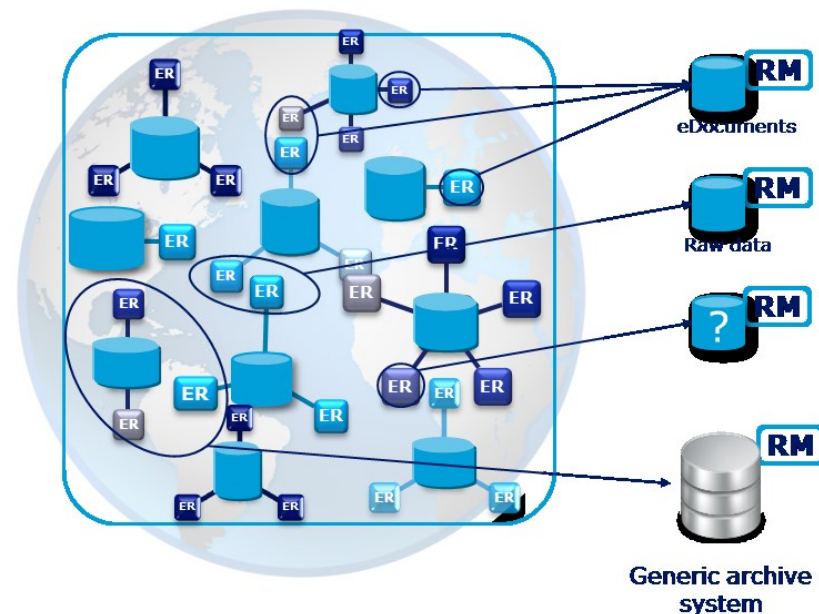
# Strategy Vision; the to-be situation

- Leverage record management for ER to the same level as records management for physical documentation

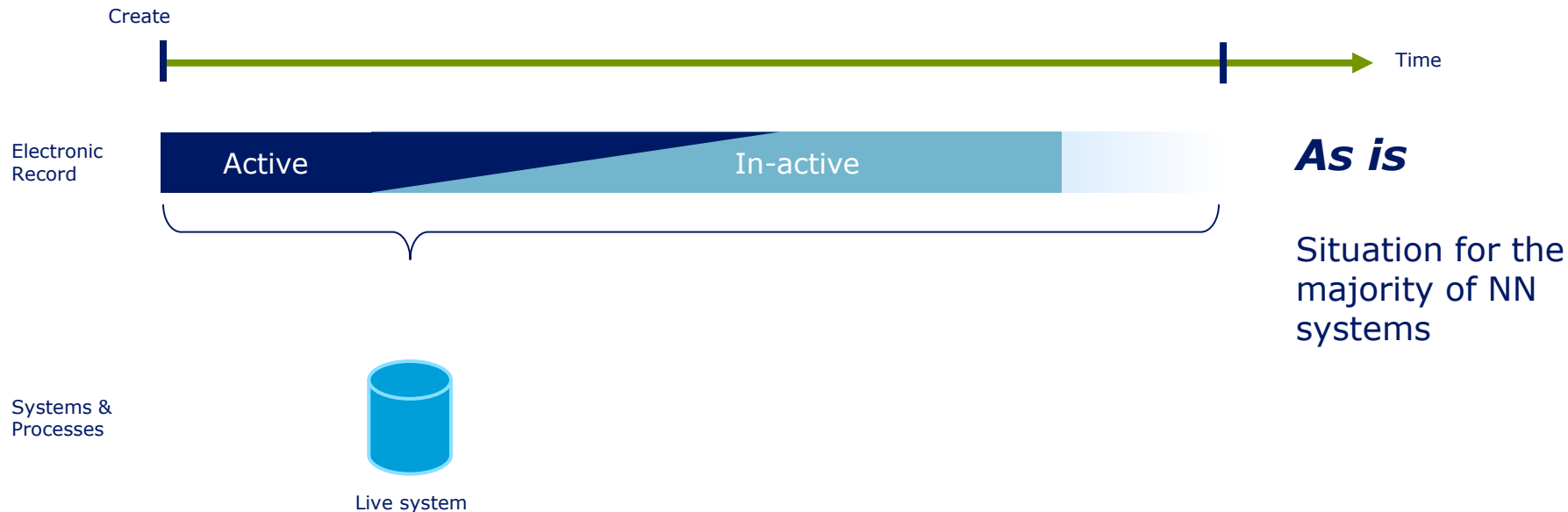


# Strategy elements

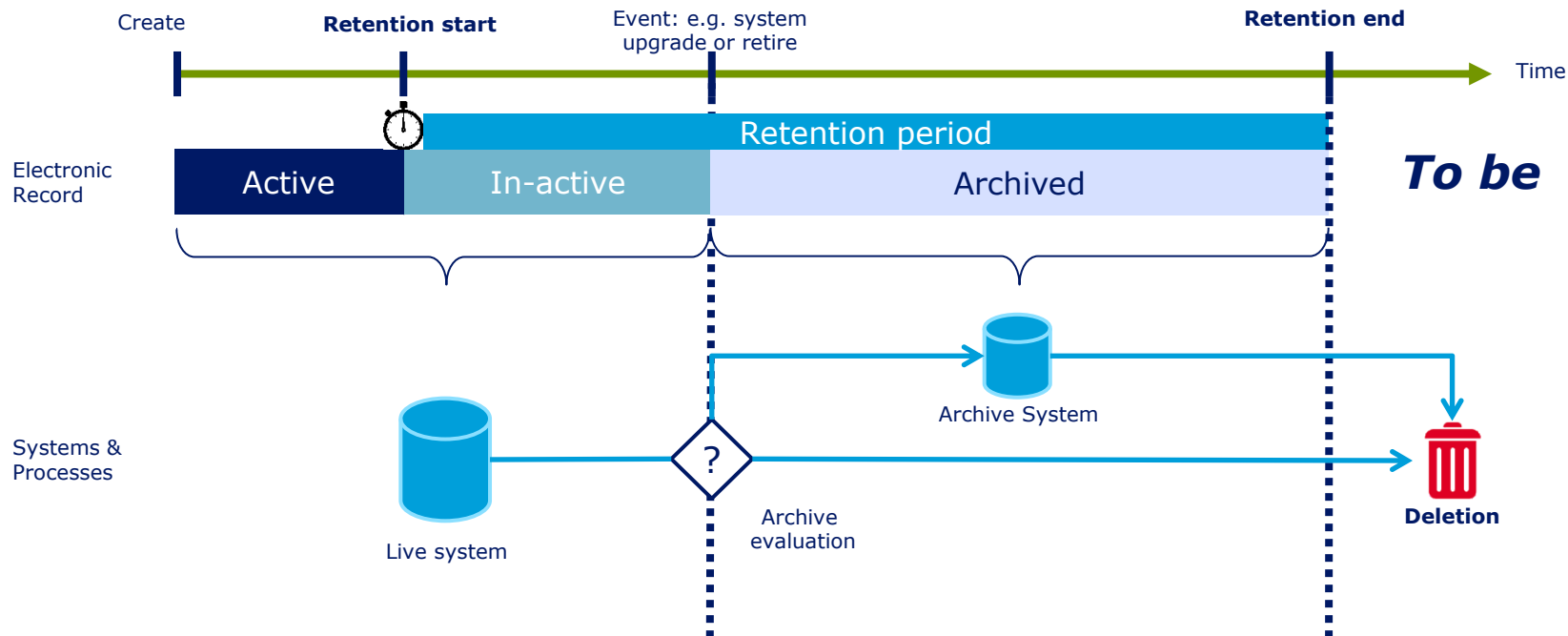
- Data/document type dedicated archives for ER
- One generic archive system for various file types
- Possible to initiate retention in live systems



# Strategy for archiving of electronic records (ER)



# Strategy for archiving of electronic records (ER)



# Strategy elements - readability

## Long term readability – decisions

- Long term readability are not secured through archiving of hardware and software
- Data is preferred to be viewed in the original format through the software used to create the data
- Prior to decommissioning of a system - future readability are secured through:
  - Migration of data to a new system or
  - Converting data to a human readable version (e.g. PDF)  
(only if the conversion preserves the accuracy, completeness, content and meaning of the original data)

# How

# Implementation of archive strategy

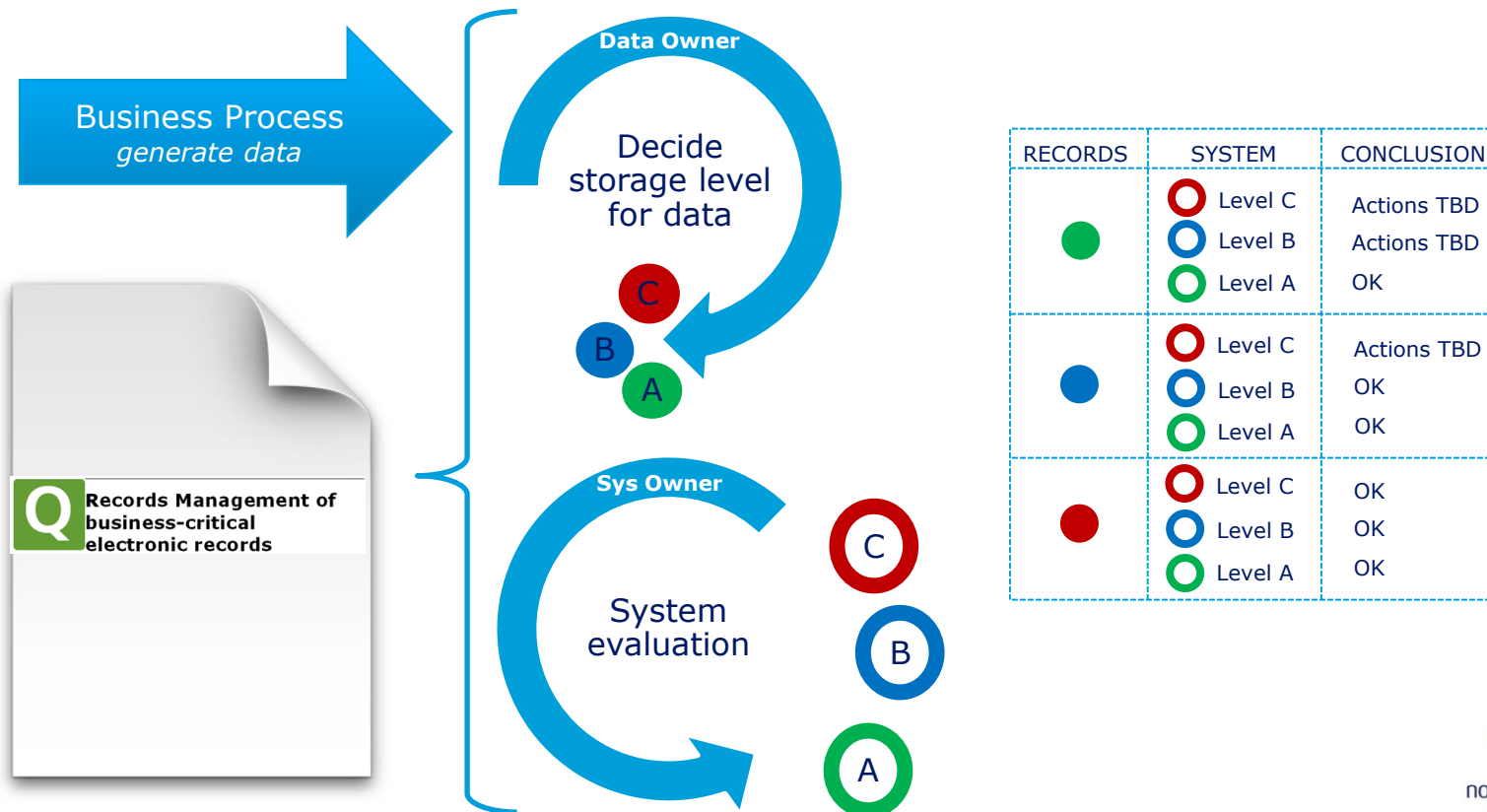
eg. SOP: Records Management of Business Critical Electronic Records

Workflow/process description for System Owners and Data Owners:

- Define 3 different storage levels  
(incl. Definition of an "Archive System")
- Describe the process for evaluating records in order to decide suitable storage level
- Describe method to evaluate an IT system in order to determine on which storage level the IT system can store or archive records

# Implementation of archive strategy

eg. SOP: Records Management of Business Critical Electronic Records





# Case

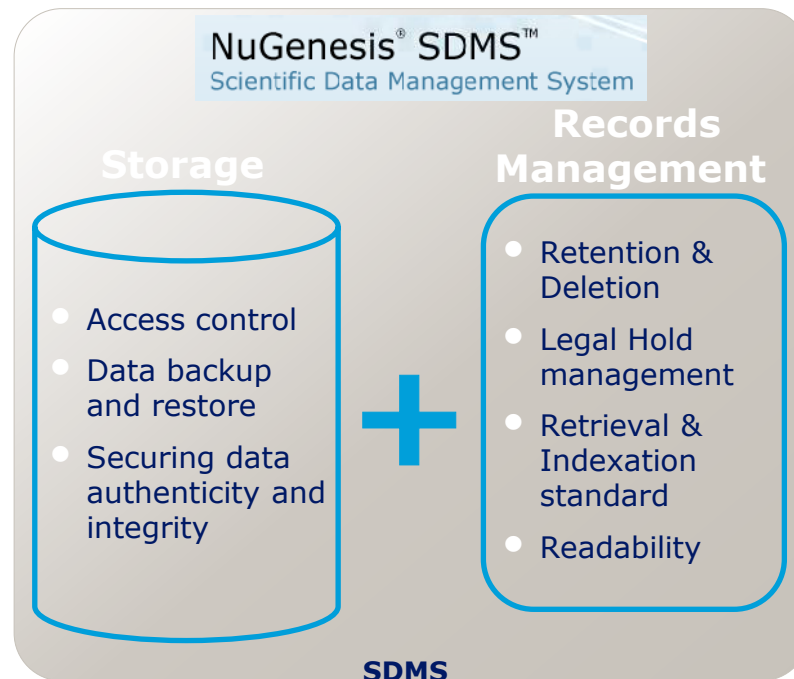
# Case example - Archive system for GLP raw data

## File Capture

### Instruments



GLP ER



## Print Capture

### Data Management Systems



Archive Reports



### Contract Research Organisations

# Initiatives related to archiving of ER

- 2007-2008: The Document Retention Programme:
  - Development of a global process based file plan
  - Establishment of a Global Retention Schedule
- 2009-2013: Global roll out of the OmniRIM system for physical records
- 2011: Guidelines for:
  - Differentiation of storage levels defined for IT systems
  - Deletion of non critical emails before they pass 3 yrs.
  - Deletion of Backup tapes after 3 yrs.
- 2011-2012: Pre analysis of GLP archive solutions for electronic records
- 2013-2014: GLP programme (GLP electronic records)
  - Implementing an archive system for electronic GLP data (SDMS)
  - Upgrade of global Document Management system to an archive system
  - Definition of roles, responsibilities and requirements
- 2013: Pilot for compliance scanning established



# Readability strategy for instruments

