

VICTOR DA SILVA MELCUNAS and his father enjoy fishing together. Victor has Haemophilia A. Brazil



# Archiving challenges at Novo Nordisk

## - and the tools from DLM Forum

Presenter:

- Torben Juul, Senior Advisor, Records Management Centre, Novo Nordisk

## Content of presentation:

- Novo Nordisk at a glance
- How we organise and define our record classes
- Archiving challenge



JIM SHEEDER  
Jim has type 2 diabetes  
USA

# The business

Novo Nordisk is a global healthcare company with 90 years of innovation and leadership within:

- Diabetes care
- Insulin manufacturing
- Injection devices

Thanks to dedicated research into proteins, Novo Nordisk also holds leading positions within:

- Haemophilia management
- Growth hormone therapy
- Hormone replacement therapy



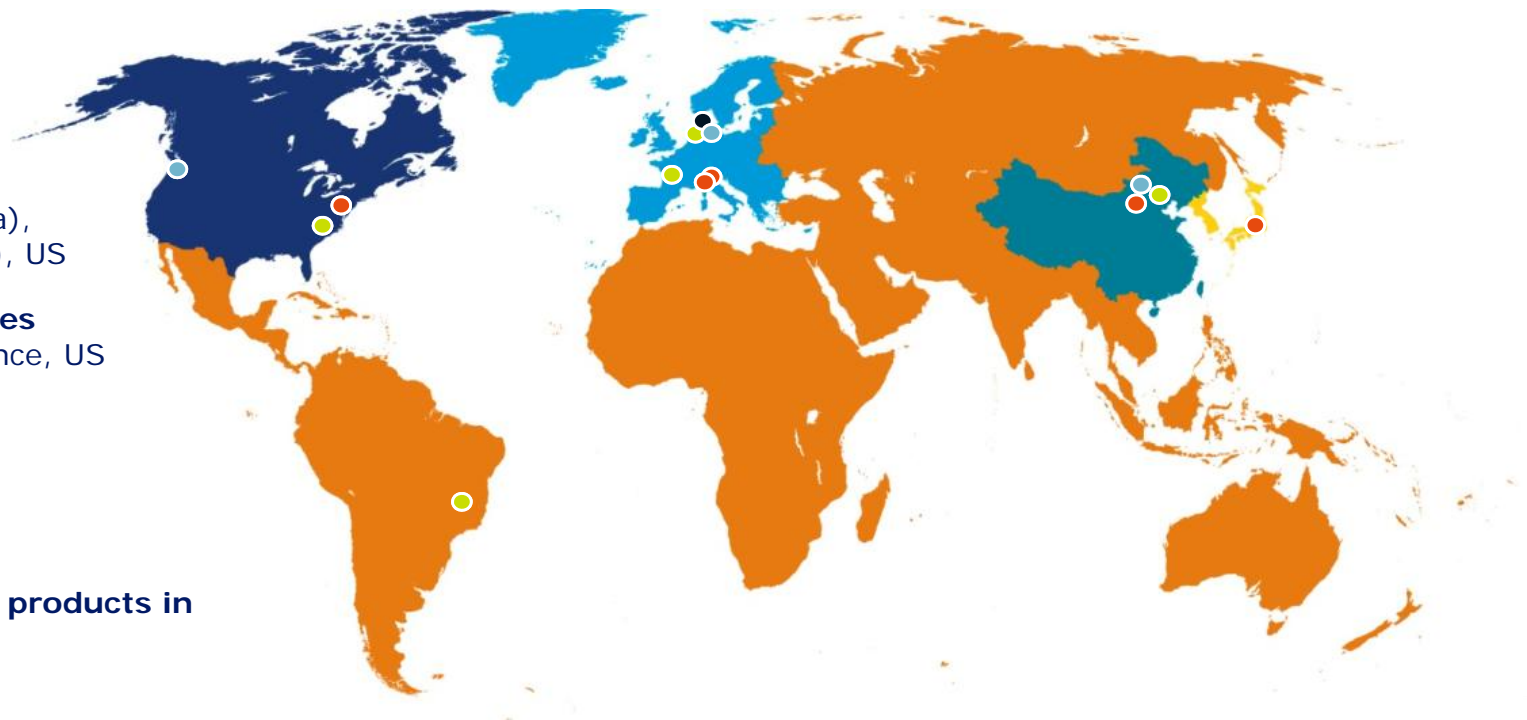
VICTOR DA SILVA  
Victor has severe haemophilia A  
Brazil

# Our global presence

- **Global headquarters**  
Denmark
- **5 Regional headquarters**  
China, Japan (Japan & Korea),  
Switzerland (Europe and IO), US
- **5 Strategic production sites**  
Brazil, China, Denmark, France, US
- **3 strategic R&D centres**  
China, Denmark, US

**75 affiliates**

**Novo Nordisk markets its products in  
180 countries worldwide**

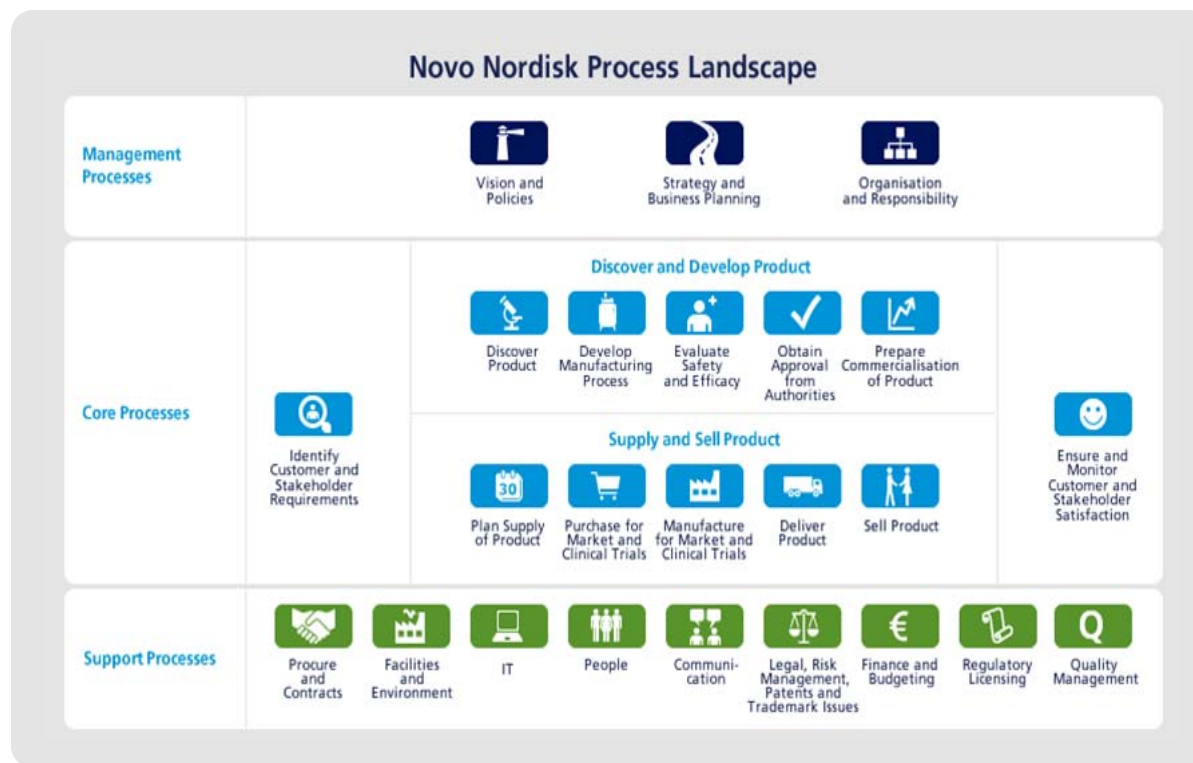




# Novo Nordisk Process Landscape

Overview of:

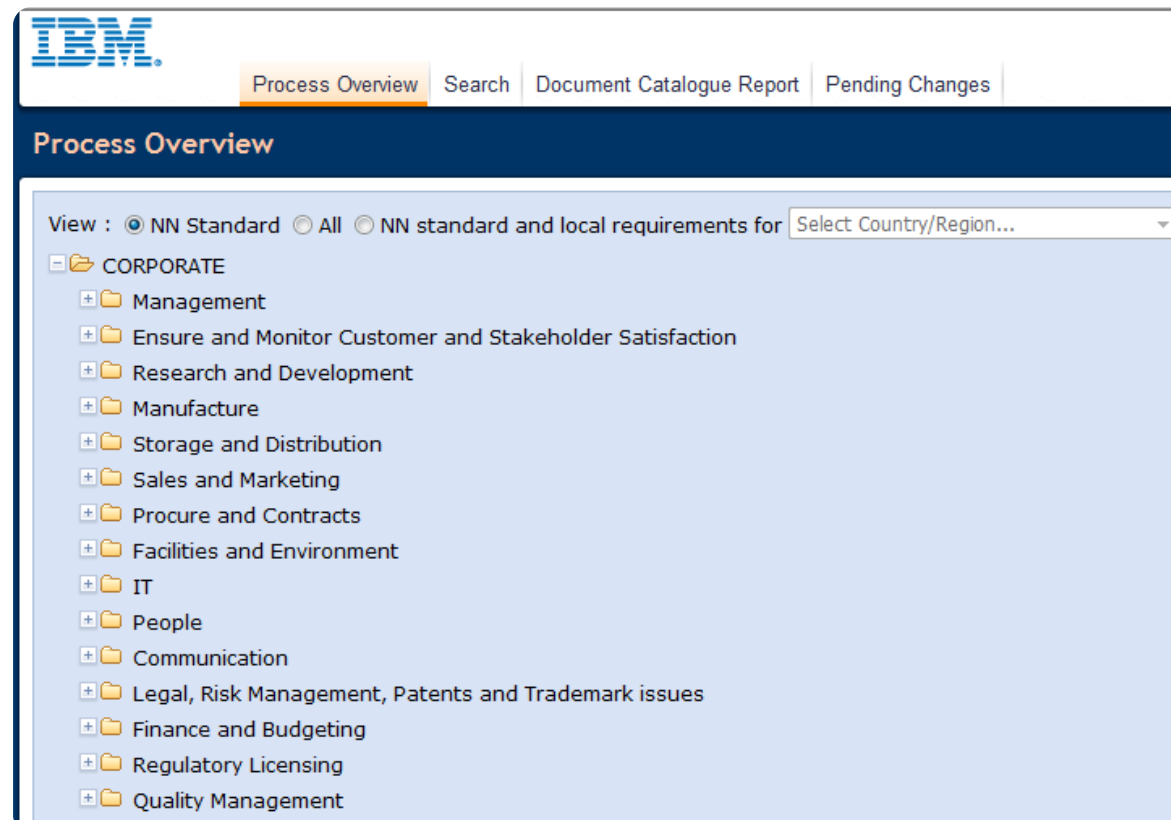
- QA
- Process Experts
- SOPs
- Records Management requirements
- And more..



# Records Management Process Landscape

## Overview of:

- Classification
- Retrieval
- Retention
- And more..



The screenshot displays the IBM Records Management Process Overview interface. At the top left is the IBM logo. The navigation bar includes tabs for "Process Overview" (selected), "Search", "Document Catalogue Report", and "Pending Changes". Below the navigation bar, the "Process Overview" section is titled. It features a "View" section with radio buttons for "NN Standard" (selected), "All", and "NN standard and local requirements for", followed by a dropdown menu labeled "Select Country/Region...". The main content area shows a hierarchical tree structure under the "CORPORATE" folder, listing various business units and functions, each with a plus sign icon to its left:

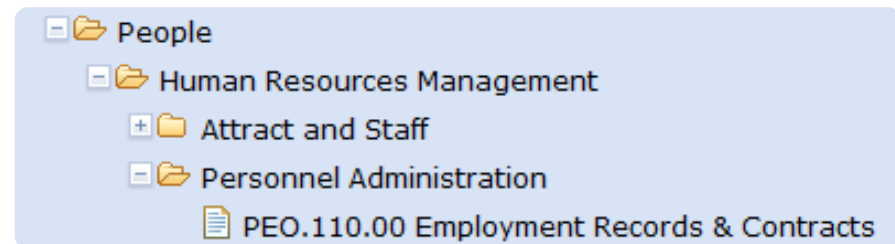
- CORPORATE
  - Management
  - Ensure and Monitor Customer and Stakeholder Satisfaction
  - Research and Development
  - Manufacture
  - Storage and Distribution
  - Sales and Marketing
  - Procure and Contracts
  - Facilities and Environment
  - IT
  - People
  - Communication
  - Legal, Risk Management, Patents and Trademark issues
  - Finance and Budgeting
  - Regulatory Licensing
  - Quality Management

## We define classes of files according to their business function

This works well for files on paper:

- Stand alone records
- Related to one specific class of files

But we are challenged by records that are used in multiple contexts in the it-systems.



# The same data can be used for multiple functions



ALDO ALEJANDRO CHIARELLI  
Technical, Quality & Reg. Director  
Novo Nordisk, Argentina

- As a Pharma company Novo Nordisk must comply with GxP regulations (Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice etc.)
- To comply Novo Nordisk must be able to trace the person who performed GxP regulated activities (who signed what etc.)
- Some of the documentation goes back decades and is archived
- The archive needs basic employee data such as name and department of the employee in question at the given time to trace the documentation
- This way a subpart of the data in the HR system becomes GxP critical. The retention period for this subpart of data is 20 years longer than the basic employee data.



## Example of archiving challenge

- Database with clinical data is kept online but has not been accessed for years.
- Cost of keeping the database running is about 150.000 Euro per year. The retention period for this type of data is 75 years.
- The it-landscape at Novo Nordisk counts thousands of databases of all types.



THOMAS JUNKER ALSTED  
& WEI LIU  
Research & Development  
Novo Nordisk, Denmark

# RMC work process

- Define the record (maybe no need to archive!)
- Select archive approach
  - Export data to RMC archive database (next one will also consider **MOREQ2010** recommendations)
  - Archive in the system that produced the data
  - Archive whole database (Novo Nordisk does not have a standard methodology – we hope the **E-Ark project** will deliver a solution that can be implemented)
- Document all decisions



PETRA VAN DEN BERG  
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