

Novo Nordisk

Global Serialisation Programme

GS1 Conference

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Peter Mardov-Egvang,
Senior Regulatory Intelligence Manager



Agenda

- 1** Novo Nordisk at a glance
- 2** Serialisation and Novo Nordisk
- 3** Impact on Novo Nordisk
- 4** Expectations to GS1 and standardisation
- 5** Novo Nordisk Global Serialisation Programme recipe
- 6** Q & A

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Novo Nordisk at a glance



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

- diabetes care (Victoza®, Prandin® etc.)
- Insulin (NovoLog®, NovoLog® Mix etc.)
- injection devices (FlexPen®, NovoPen® etc.)

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

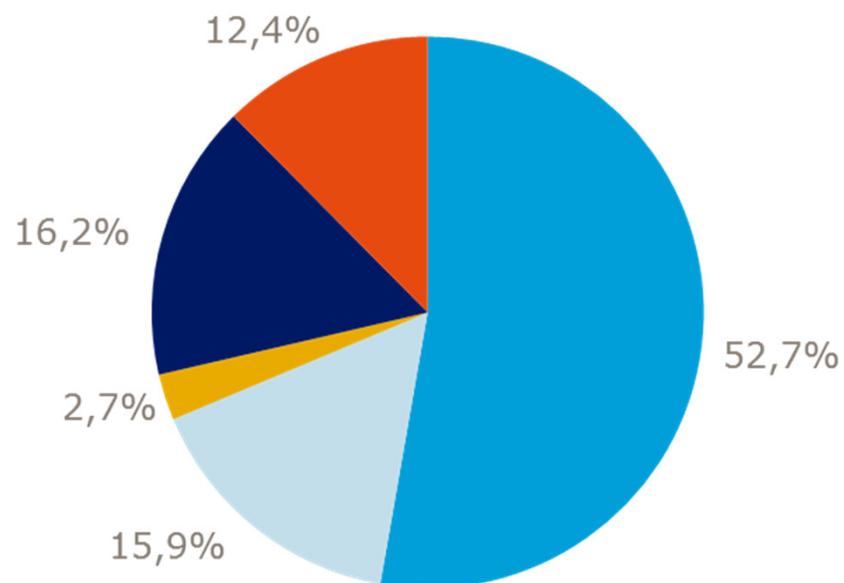
- haemostasis management (NovoSeven® etc.)
- growth hormone therapy (Norditropin®)
- hormone replacement therapy (Vagifem® etc.)



More than 40,000 employees around the world

Employees by region
in 75 countries

- North America
- Europe*
- International Operations
- Region China
- Japan & Korea



¹ Includes headquarter functions, R&D, productions sites and sales office

Our global presence

- **Global headquarters**

Denmark

- **5 Regional headquarters**

China, Japan (Japan & Korea),
Switzerland (Europe and IO), US

- **5 Strategic production sites**

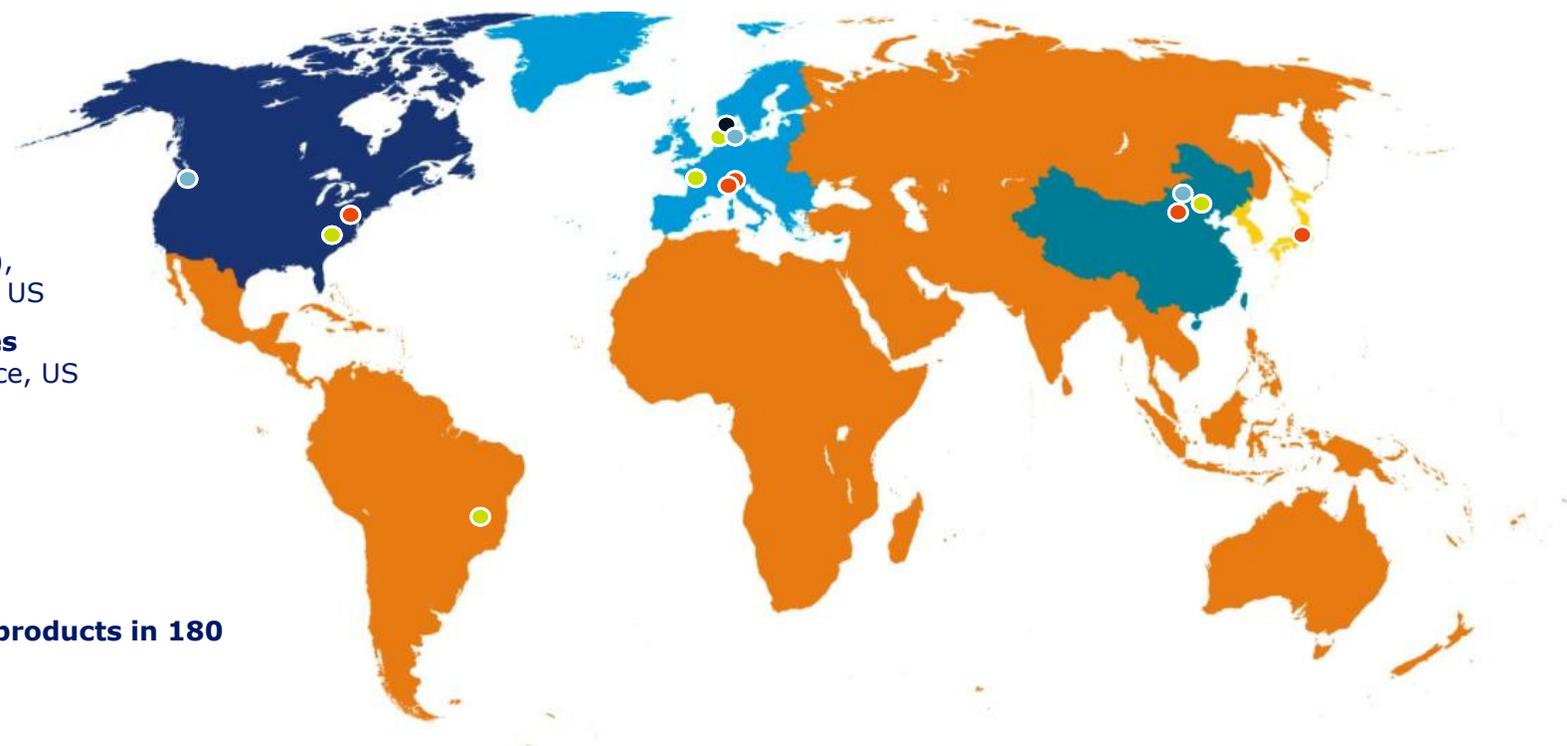
Brazil, China, Denmark, France, US

- **3 strategic R&D centres**

China, Denmark, US

75 affiliates

Novo Nordisk markets its products in 180 countries worldwide



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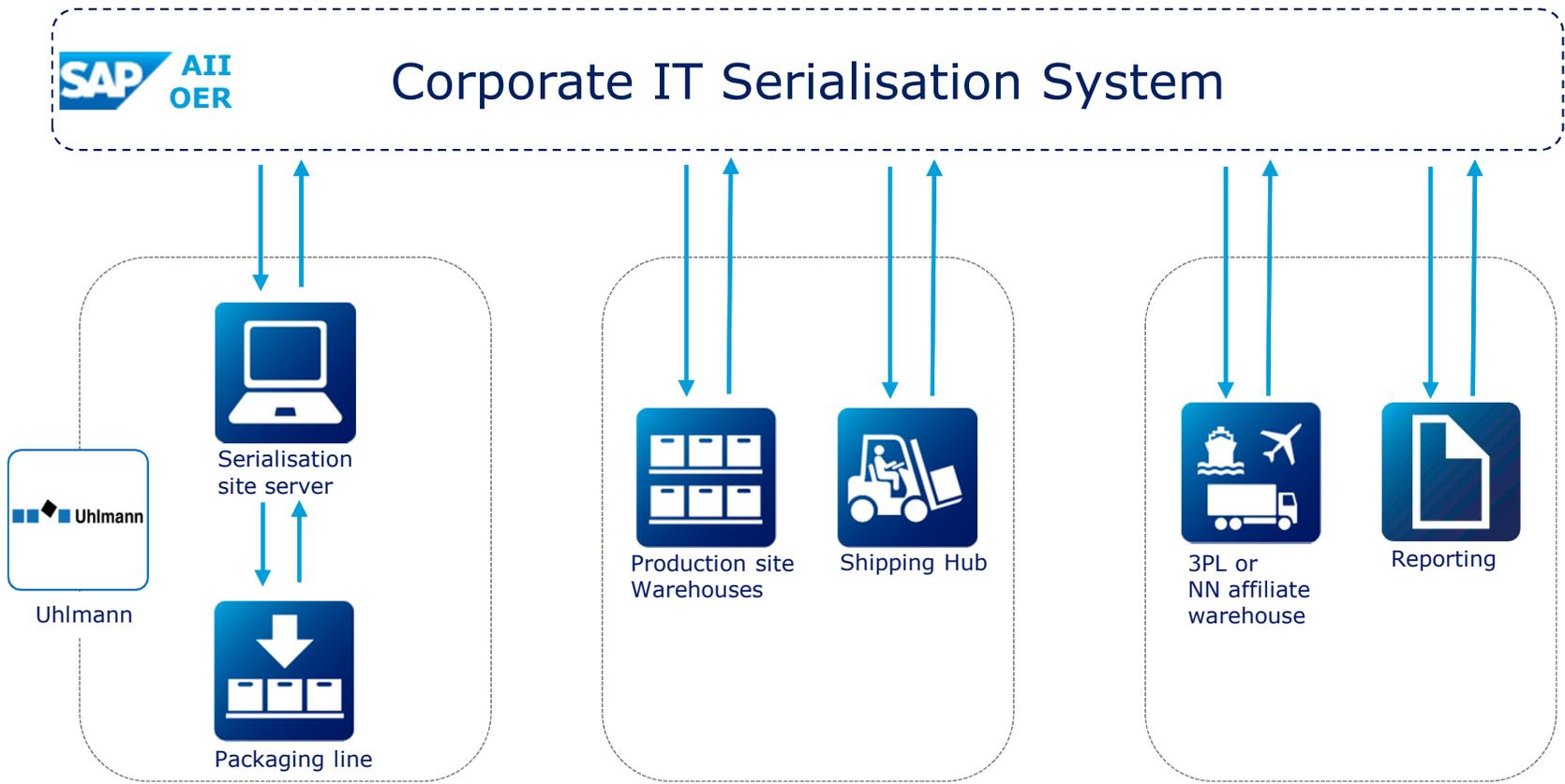


KATIE NORTON
USA
Katie has type 1 diabetes

Why we need Serialisation in Novo Nordisk?

- **To increase patient safety**
- To comply with regulatory requirements to ensure access to the global markets

Novo Nordisk's Serialisation solution



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Challenges for Novo Nordisk



DELIVERY



- Overall Equipment Efficiency (OEE)
- Shut down
- Capacity

ORGANISATIONAL CHANGE MANAGEMENT



- Stakeholders
- Business processes
- Resources
- Collaboration

STANDARDISED REQUIREMENT



- Regulatory
- Technical
- Supply Chain
- Artwork

VENDOR MANAGEMENT



- Collaboration
- Variety of vendors

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Expectations to GS1 and standardisation

Novo Nordisk appreciates GS1 standards, because they...

- ✓ ...keep implementation costs lower
- ✓ ...make it simpler for companies to implement requirements
- ✓ ...set direction for type of solution
- ✓ ...have the ability to align several requirements into one technical standard.

Novo Nordisk also expects that GS1...

- ✓ ...takes the technical dialog when a new country has a requirement/industry groups to ensure the GS1 standards are communicated
- ✓ ...must become a powerful player who can work to ensure a standardised approach across the world
- ✓ ...develops simple, efficient solutions that also ensure patient safety

Expectations to GS1 and standardisation

EXAMPLE:

Showing when GS1 standards works well...

Saudi Arabia authorities had a specific requirement that didn't follow the standard for what a 2D barcode and Human readable information should contain. The impact of implementing the extra part of the requirement is very challenging for companies.

- *The collaboration between the Pharma industry and GS1 resulted in a change to the requirement which is now aligned with the GS1 standard.*

Expectations to GS1 and standardisation

EXAMPLES:

Showing when GS1 standards can create uncertainty for the pharma industry

- **If GS1 would recommend both “dark on light” and “light on dark” barcodes in the guidelines it would remove some of the uncertainty of using laser technology as print technology**
 - *If GS1 recommends accepting “light on dark” it would support that scanners further out in the distribution chain would be configured for inverted barcodes. Currently GS1 is not pushing for acceptance of “light on dark” barcodes*
- **For pharmaceutical products a Human readable expiry date is very important for the customers and required by the authorities. Introducing the GS1 data matrix sets the standard for date formats inside the data matrix**
 - A human readable interpretation of the GS1 data matrix implies date formats that are very hard to understand (YYMMDD) for the end users. This can force pharma companies to print both the human readable interpretation of the expiry date and a more understandable version of the expiry date e.g MM/YYYY or YYYY/MM/DD

STANDARDISED REQUIREMENTS

Challenge:

How can we overcome...

...having to work with the uncertainty of regulatory requirements and at the same time building solutions that fit with not standardised technical requirements, supply chain requirements and artwork requirements?

Solution:



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Novo Nordisk Global Serialisation Programme recipe

- ✓ System standardisation and flexibility
- ✓ Proven technology
- ✓ Strict and documented procedures for communication and collaboration with Regulatory Affairs and Supply Chain
- ✓ Top Management involvement
- ✓ Only trusted vendors, high resources flexibility



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Q & A



