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THURSDAY, APRIL 10

Novo Nordisk & Deep Digital: The Crucial Role of Nomenclature & Taxonomy

SESS-48

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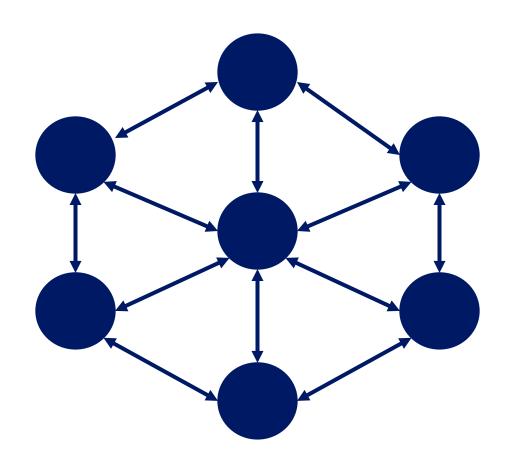


Nomenclature and Standardisation

Asset Framework

Our Organisation





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Data Foundation Goals



System Standardisation

- Create common definitions to enable analysis across MES, PI and LIMS data
- Remove ETL lag and have as close to realtime data as possible.

Organisational Standardisation

- Support the transition of knowledge across organisational units. (Tech Transfer)
- Reutilise knowledge when creating new production facilities

External Communication Standardisation

- Bringing acquired companies and partners more easily into the Novo Nordisk information landscape
- Providing a basis to communicate with external partners.

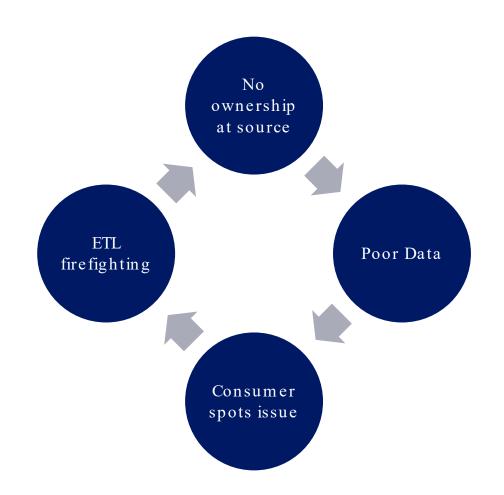
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Building a data foundation

Our challenge as an organisation is establishing a robust and reliable infrastructure to support data management, storage, and processing within an organization.

A key issue with this is the data quality loop.

The further you push data quality questions away from source, the further you get from the expertise to fix it.

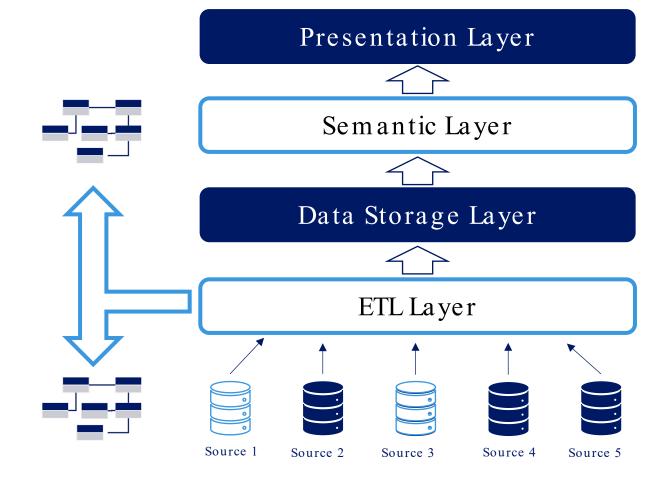




Building a data foundation

Implementation Focus

Our focus is implementing models, so they drive data quality at the source reducing the need for ETL and ensuring a better fit with a Semantic Layer.







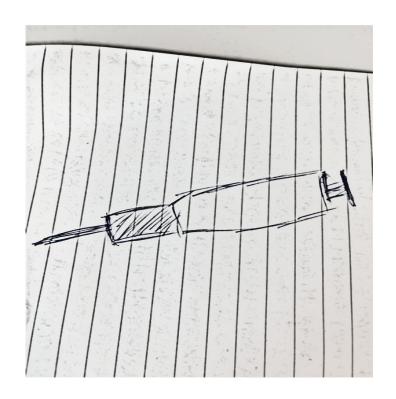


What do we need to create quality data

When building data products, our level of detail is often lacking.

Our perspective of business need basis is a sketch to be interpreted by system engineers.

Spending more time defining the key attributes of an object makes for a far better product.

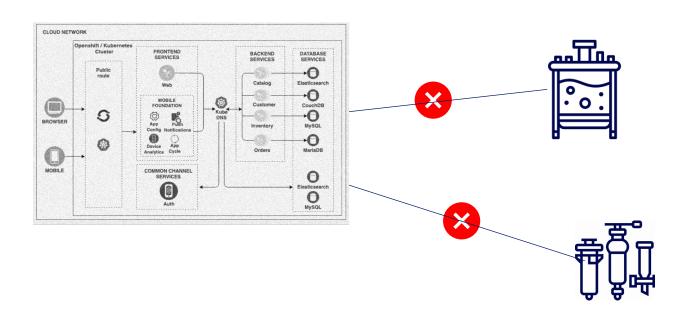






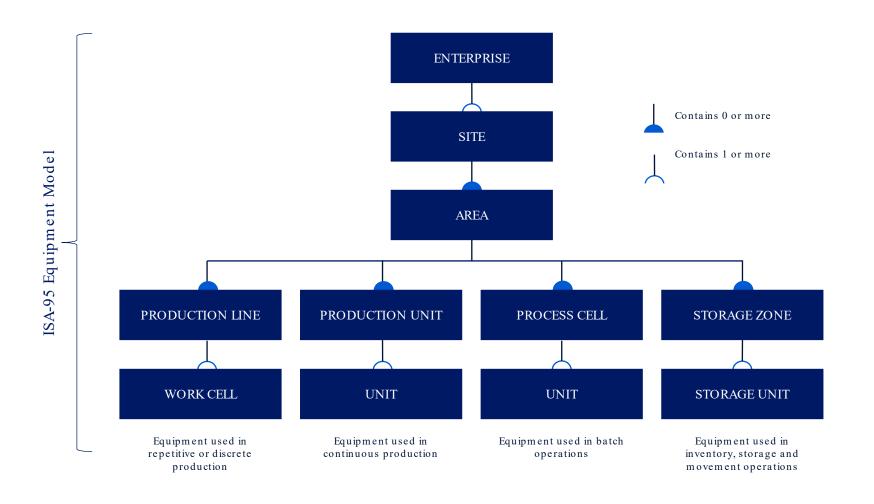
What do we need to create quality data

Much good work is undone by OEMs not being specified to communicate in a format that meets the need of the systems utilizing their data.

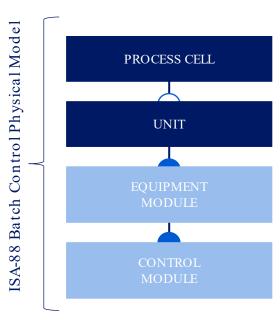


Standardisation: ISA-95 and ISA-88











ISA-88 Model Relationship Diagram

Procedural Control Model

Procedural Elements

Procedures

Unit Procedures

Operations

Phases

Phases

Physical Model

Equipment

Process Cells

Units

Units

Units

Equipment Modules

Process Model

Process Functionality

Process

Process Stage

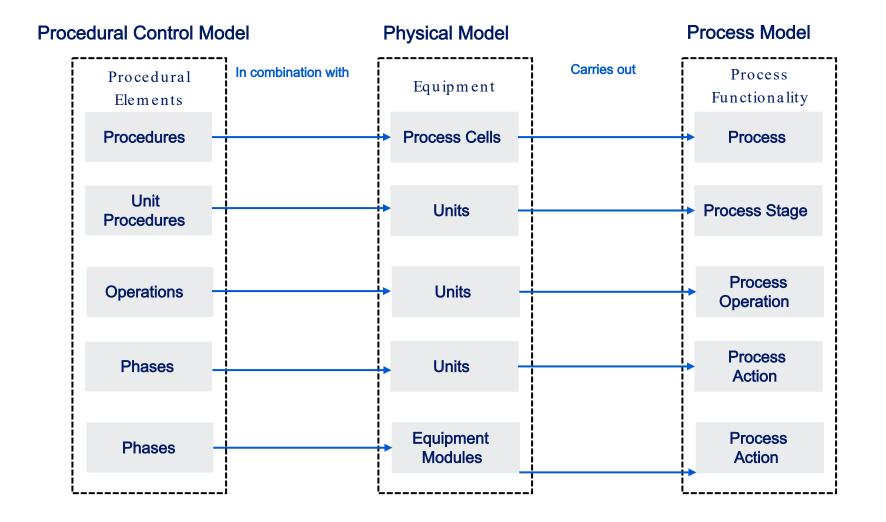
Process Operation

Process Action

Process Action

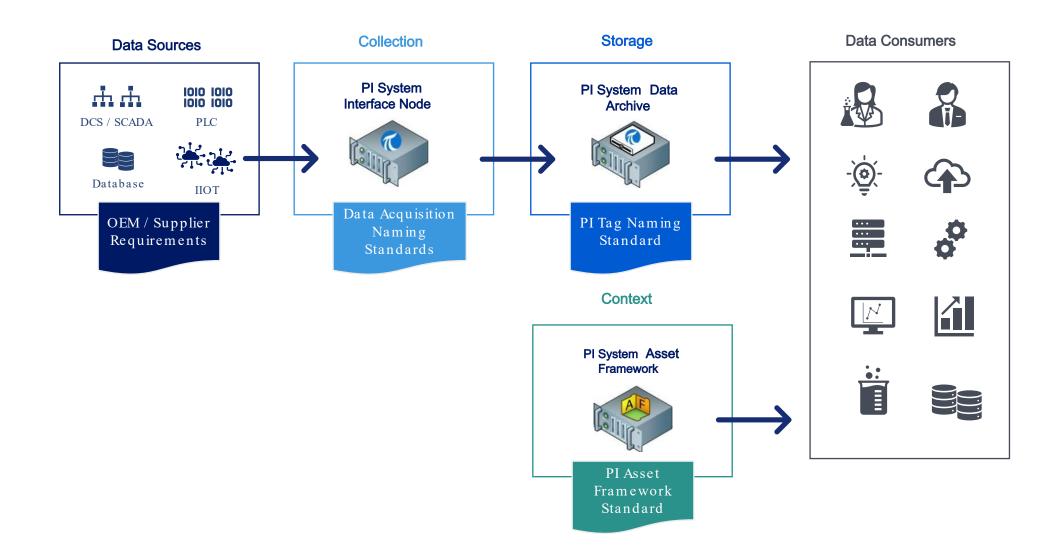
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ISA-88 Model Relationship Diagram



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Global PI System Standards



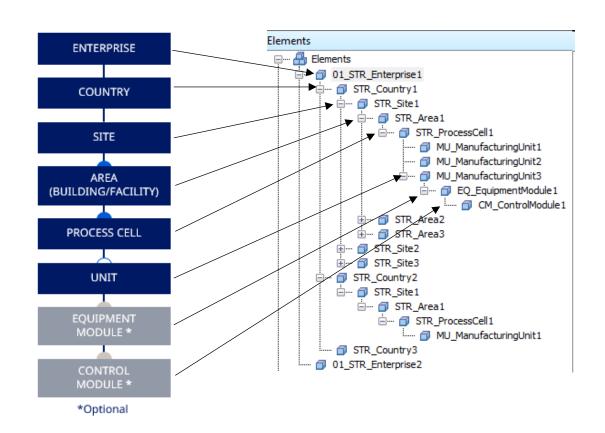


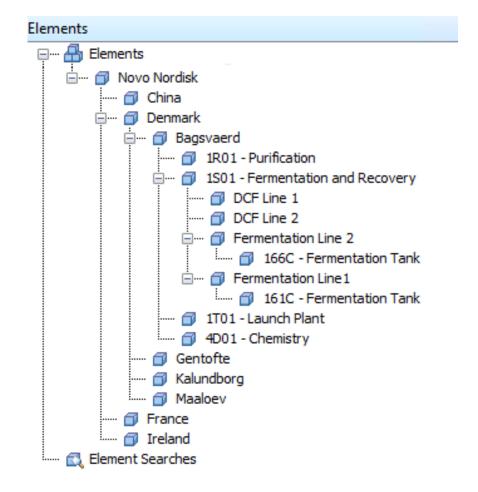
Global PI Tag Naming Standard

	Tag Example: DK_BA_	_18_	_161_C_	_TT001	_PV_G	XP				
Level 1	Country		DK							
Level 2	Site			ВА						
Level 3	Area/Building				18					
Level 4	Process Cell					161				
Level 5	Unit						С			
Level 6	Equipment Module (Category)									
Level 7	Control Module (Object/Device)							TT001		
Level 8	Tag (Attribute)								PV	
Level 9	GxP Classification									GXP

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Global PI Asset Framework Hierarchy

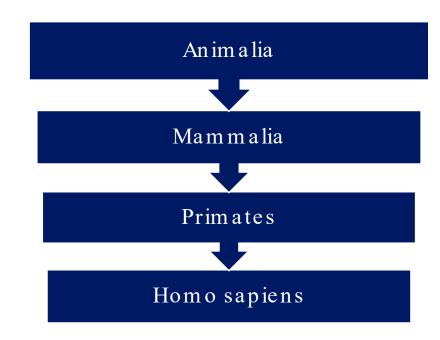




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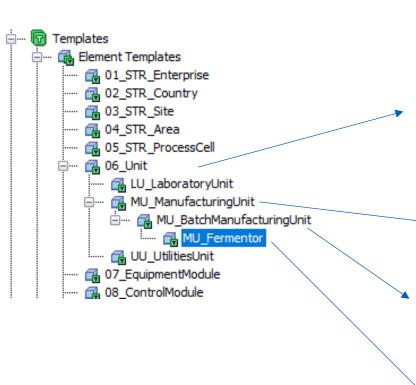
Taxonomy

- Prescribes structure and terminology.
- Applies rigor in specification, ensuring any newly discovered object must fit into one and only one classification or object.
- Inherits all the properties of the class above it but can also have additional properties



Global PI System Asset Framework









Filter		
/ i	♦ R Name	△ Description
	Template: 06_Unit	
	🖳 Area	Area in which unit is located
	Country Country	Country Name
	Element Name	Element Name
	🖳 Element Path	Path to asset in AF
	Manufacturer	Manufacturer of Unit
	■ Model	Model of Unit
	P&ID	Engineering Blueprint ID
	PAS-X ID	PAS-X Unit ID
	Process Cell	Area / Building / Facility
	SAP ID	SAP Unit ID
	Site	Site
	Site Code	2 Letter site code
	Unit Name	Local naming of unit
= 🚜	Template: MU_ManufacturingUnit	
	☐ BatchID	Batch ID
	Product	Product Name
	Recipe	Recipe Name
= 📆	Template: MU_BatchManufacturingU	nit
	Operation	Manufacturing process operation
	Phase	Manufacturing process action
	Procedure	Manufacturing process
	UnitProcedure	Manufacturing Unit Procedure
= 🚜	Template: MU_Fermentor	
Đ	Ammonia-PVState	Ammonia Process Value State
	🖳 Ammonia-Step	Ammonia Step
	■ B01-Speed-Output	B01 Speed Control Output

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ISA-88 Procedural Control

PI EVENT FRAME TEMPLATES

Procedural Control Model

Procedures Unit Procedures **Operations Phases** Phases

PI Event Frames

Procedure	
Unit Procedure	
Operation	
Phase	
Phase State	

Template	Derived Templates	ISA-88 alignment	Derived Template Name
PlBatch	Procedure	Procedures	Procedure.ProductXYZ
PlUnitBatch	UnitProcedure	Unit Procedures	UnitProcedure.TabletCoater_KA_HB
PISubBatch	Operation, Phase, PhaseState, Phase Step	Operations & Phases	Operation.TabletCoaterLoading_KA_HB





PI Event Frames – Attribution & Naming

Template	Attributes
Procedure	Manufacturing Order ID Product (Material Code) Recipe (Material Name) Batch ID / Lot ID Start Time End Time
UnitProcedure	Batch (e.g. ID / number) Recipe Name / ID Product (Material Code) Start Time End Time CPP/KPP/CQA (values or aggregated values)
Operation, Phase, Phase Step, PhaseState	Start Time End Time CPP/KPP/CQA (values or aggregated values)

lter		
■ 🗟 🖹 🛦 N	ame	Template
	ABCD/123456	Procedure
	─ ABCD/123456/221D	UnitProcedure
+ T	Loading	Operation
□	├─ Sterilising	Operation
₽	Heating	Phase
	Idle Idle	PhaseState
	Running	PhaseState
	Complete	PhaseState
	Cooling	Phase
	├─ Idle	PhaseState
	├─ Stopped	PhaseState
	Running	PhaseState

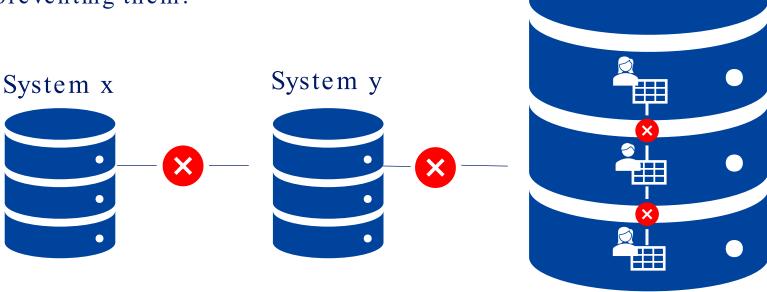


System Z



Standardisation across & within systems

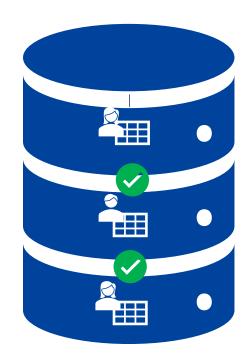
- Standardisation can help connect systems but it can also drive quality within systems.
- Users spend to much time fighting problems rather than being experts in preventing them.

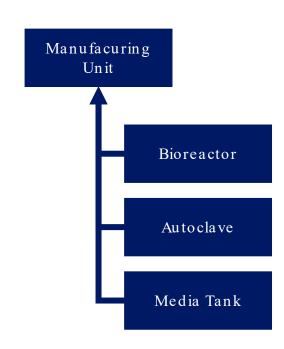


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Breaking down Silos within Silos





BioReactor Class

Static Attributes

- · SAP ID
- PID Reference
 Description
- Description
- LocationCoordinates
- Size

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- Batch ID
- Product ID
 Procedure ID
- Batch ActiveOperation Name
- Operation Name
 Operation Active
- Phase Name
 Phase Active

- Agitation Speed
- Density
 Inlet Flow
- Internal Temperature
- Jacket Temperature
- Level
 Material
- Outlet Flow
- CO2Pressure
- · Volume
 - t
- OUT Material
 LOT ID
 Material ID
 Material Name

AE & Audit

IN Material

Material ID

Material Name

Totalizer (Quantity)

Alarm Message

Event Message

Audit Message

Totalizer (Quantity)



Bioreactor

A bloreactor refers to any manufactured device or system that supports a biologically active environment. In one case, a bioreactor is a vessel in which a chemical process is carried out which involves organisms or biochemically active substances derived from such organisms. This process can offer one such organisms, This process can bioreactors are commonly oflindrical, ranging in size from liters to cubic metres, and are often made of stainless steel



Standardised data informs across domains and systems





Data Lake









CONSUMERS















STANDARDISED TAXONOMY













