

Implementing PI Data Infrastructure across LEO Pharma's Production Sites

By Poul Waagner Nielsen



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Poul Waagner Nielsen

Project Manager, Digitalisation Unit – LEO Pharma

Education



KVL, KU

M.Sc., Engineering

1984-1989



Work Experience



2019 -

Project Manager – Manufacturing Intelligence
LEO Pharma

2013 – 2019

Senior Specialist Consulting – Manufacturing Intelligence, Production & Logistics
NNE Pharmaplan A/S

2013 – 2013

Section Manager – Business Intelligence, Operations Analysis, Group Management
Teknologisk Institut DMRI

2012 – 2013

Supply Chain Area Specialist
Novo Nordisk A/S

2002 – 2012

Specialist – Business Intelligence, Project Management, Consulting
NEE Pharmaplan A/S

1998 – 2002

Production Manager
Toms

1997 – 1998

IT Consultant
NCN Systems A/S

1993 – 1997

Service Manager
Tetra Pak



A Leader in Medical Dermatology

+10 bn DKK
turnover in 2018

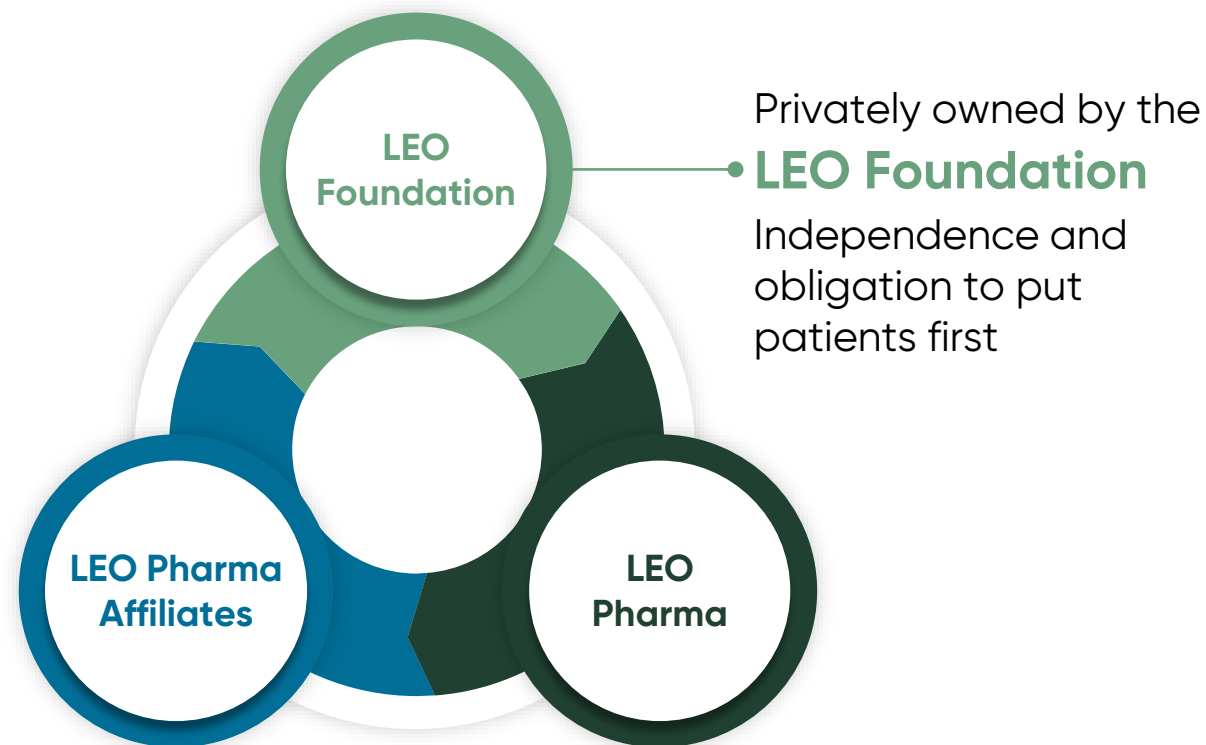
+20% of turnover
invested in R&D

Products sold in more
than **130** countries

5,500 employees

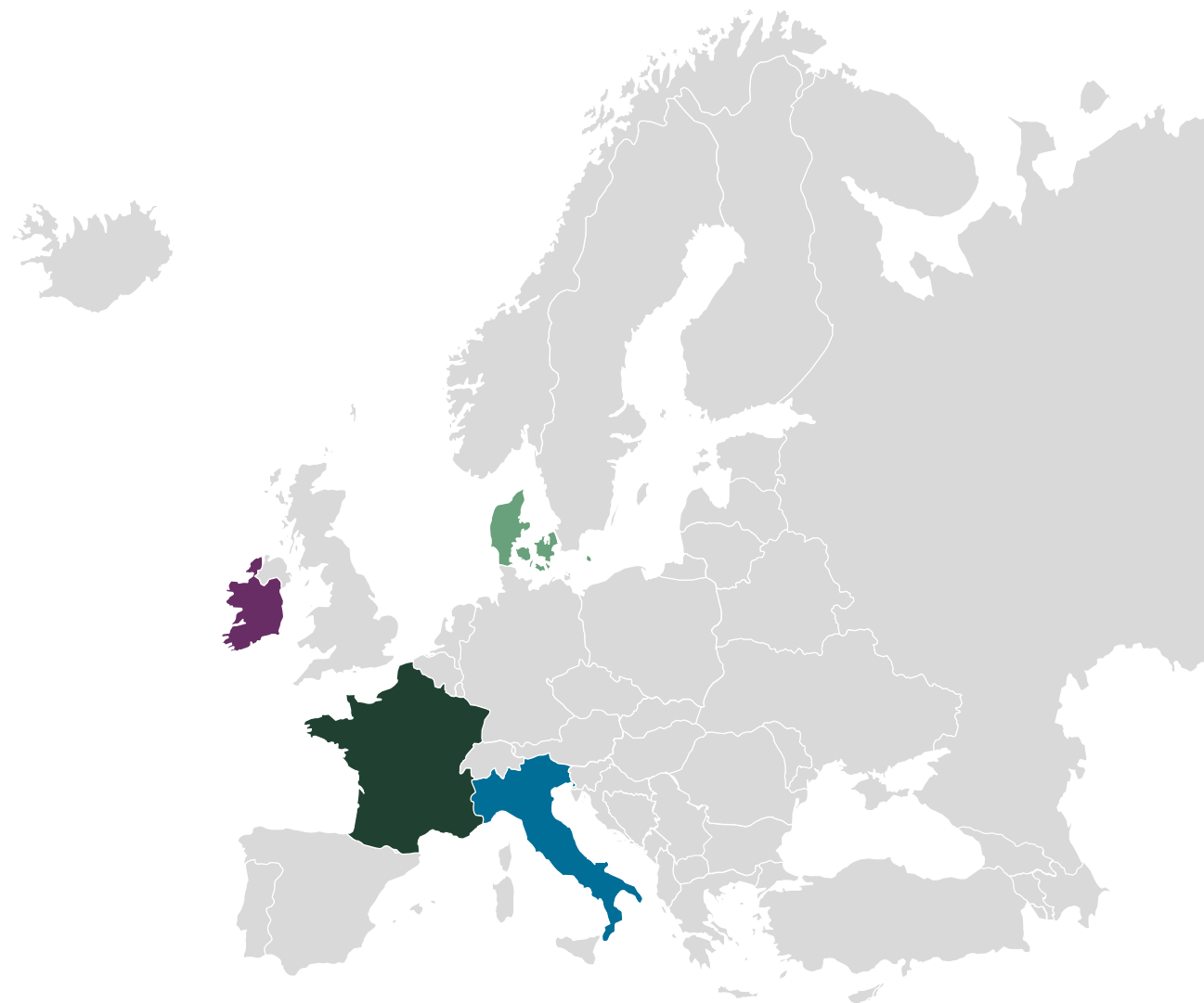
750 scientists and
specialists

Founded in Denmark
in **1908**



LEO Pharma Production Sites

	API Ballerup	Calcipotriol
	API Ballerup	Fucidin® API
	FGM Ballerup	Topicals, Steriles and Tables
	Esbjerg	innohep® API
	FGM Dublin	Topicals
	Cork	innohep® API
	Vernouillet	Syringes
	Segrate	Topicals



DIGITALIZATION PROGRAM

Production Digitalization Program

Implementation Tracks

		Driver
1	Production Historian	Enable LEO Pharma to make decisions and process optimizations based on data to strengthen science, technological and data analytic capabilities.
2	APC / PAT	Advanced Process Control and Process Analytical Technology to improve yield & OEE
3	Augmented Reality	Augmented Reality to support production processes
4	Electronic Batch Records	Electronic Batch Records with workflow enforcement. Electronic workflow for approval of batch documentation (paperless)
5	Business Intelligence (BI)	Use BI to ease the use of data and take actions based on data – Data Driven Culture
6	Robotic Process Automation (RPA)	Automation of “White colour work”. Set up robotics for business processes that are repeatable and time consuming.
7	Maintenance Management	CMMS to drive optimisation & standardisation of maintenance & spare part management across all production sites
8	Systems standardisation	Standardise the Automation and Manufacturing IT systems to global standards to improve compliance and reduce maintenance cost
9	Paperless Qualification & Validation	Making the qualification and validation process standard, electronic and paperless.



Project Investments

FTE's with required skillsets

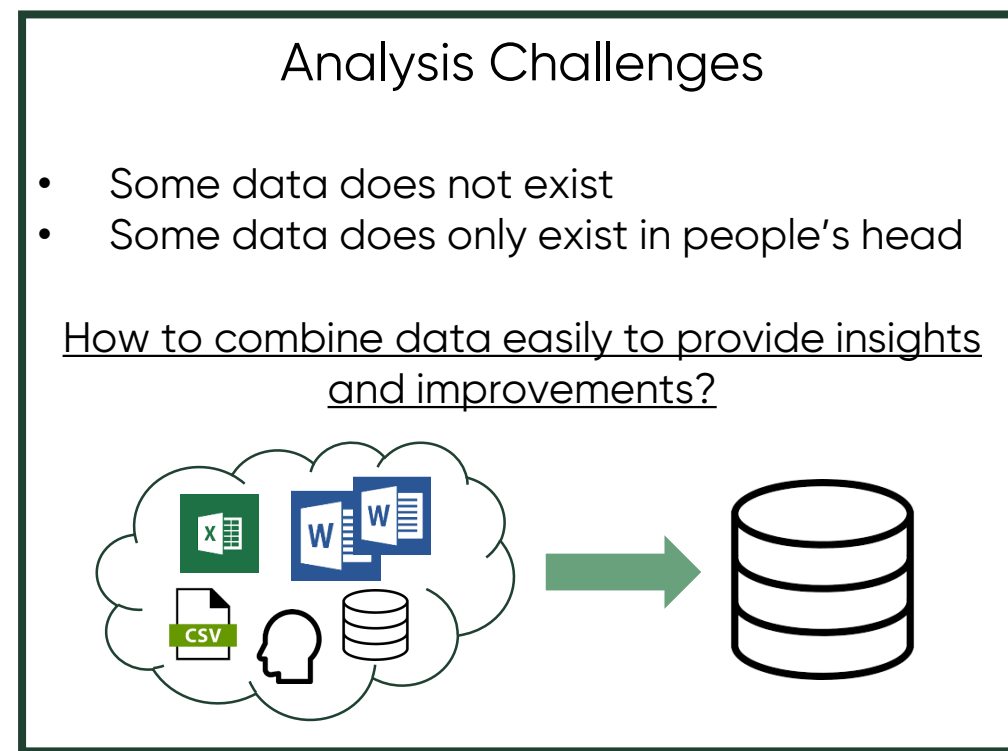
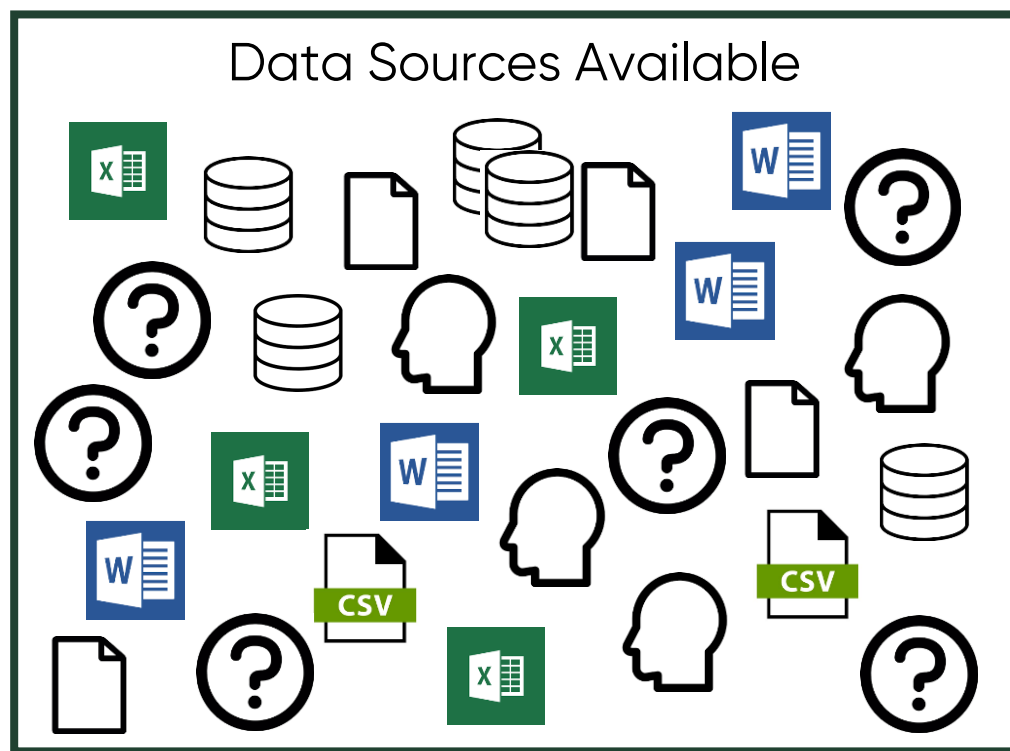


Aspiration	
Now	End State
No central data collection	Yield ↑
Installing APC / PAT	Yield ↑ Waste & Cost ↓ Quality ↑
Manual processes and errors	Changeover time ↓
Many FTE's	FTE ↓ Deviations ↓ Product quality ↑
Many FTE's	FTE ↓
-	FTE ↓
Many FTE's	FTE ↓
80+ systems	25 systems
Paper based process	All validations electronic



Current State: Multiple Data Sources and Lacking Data

... makes analysis and optimizations impossible or difficult



Digitalization Program — Production Historian



GOTHENBURG 2019

Approach – Production Historian

Digitalization Program

Initiative – Implement Production Historian across all LEO Pharma sites

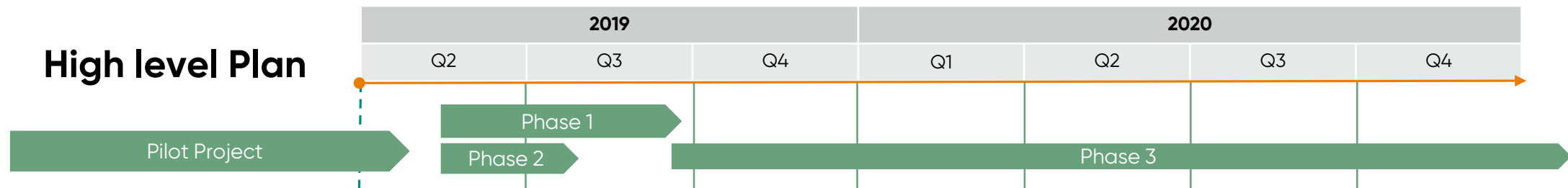
Pilot

Get historian experience, increase yield

LEO Pharma Global PI

Implement PI System across all LEO Pharma sites

High level Plan



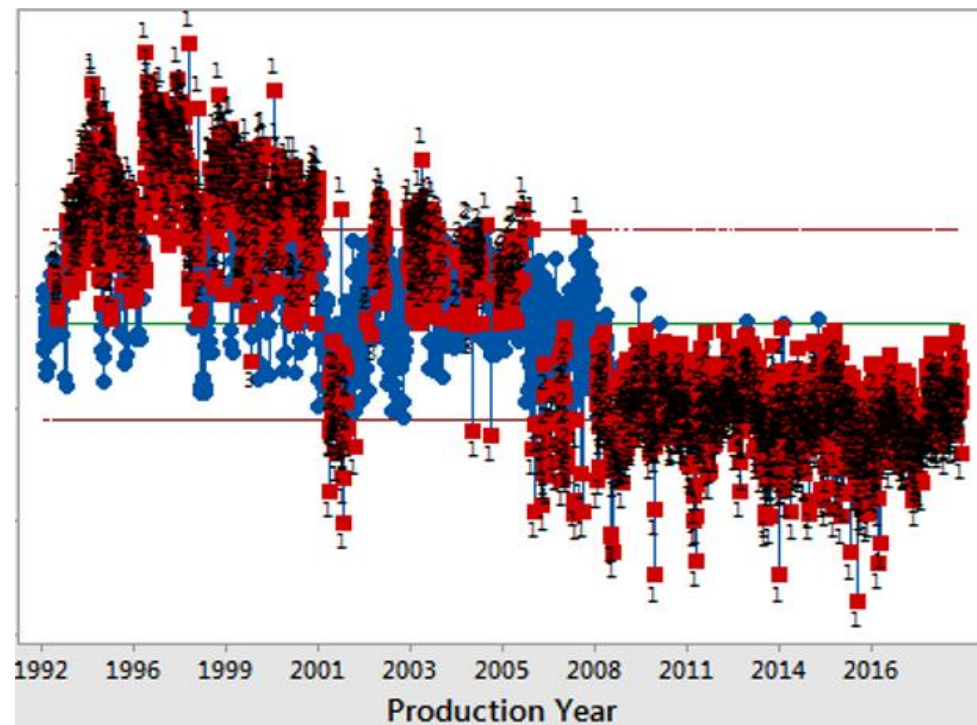
Fucidin Yield and the FAR Factory

Pilot Project

- Declining yield in fermentation
- Variation in process times in recovery

All new API Plant to replace Old in 3 years

- Decision to use PI to improve Yield and Increase insight
- Use knowledge to build a better and more effective new API plant
- Experience to bring to the later Global PI Project



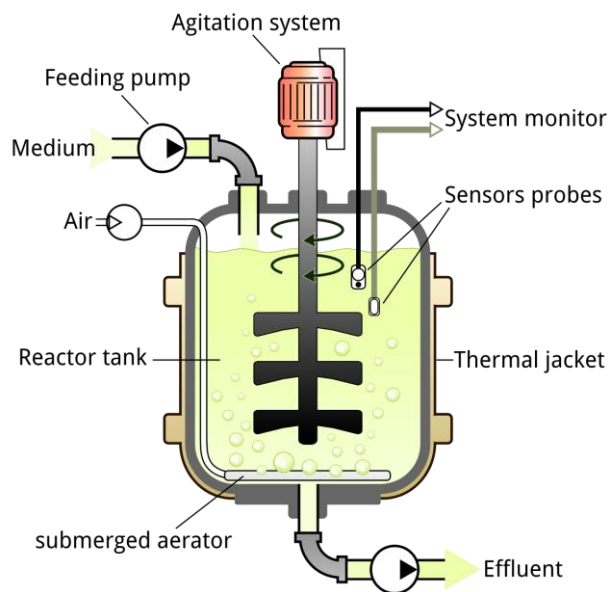
FAR Fucidin®
— API Plant Project



Fucidin® API Before

Pilot Project

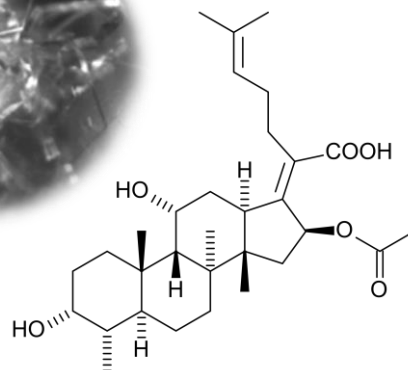
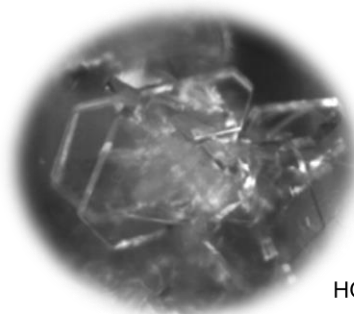
Fermentation



Simple measurements:

- Temperature, level alarm, air flow
- Off-line manual measurements

Recovery Process



Simple measurements:

- Temperature, level, flow etc.

Data

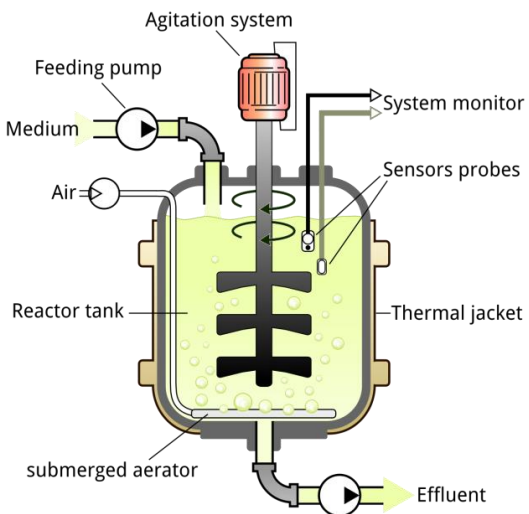
Historical data is paper based

- Getting only the most basic data is very time consuming

PAT Fucidin® API – After

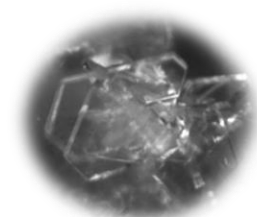
Pilot Project

Fermentation – 16 fermenters



6 new advanced measurements

Recovery Process



new advanced measurements

LIMS results



Pilot – Fermentors



Manuel data



PI Archive, AF/EF Vision, WebAPI



Process knowledge for Fermentation and Crystallization specialists
→ **Yield optimization**

Project by
LEO IT / HCL
(Infrastructure)
NNE (PI Installation)
LEO Automation

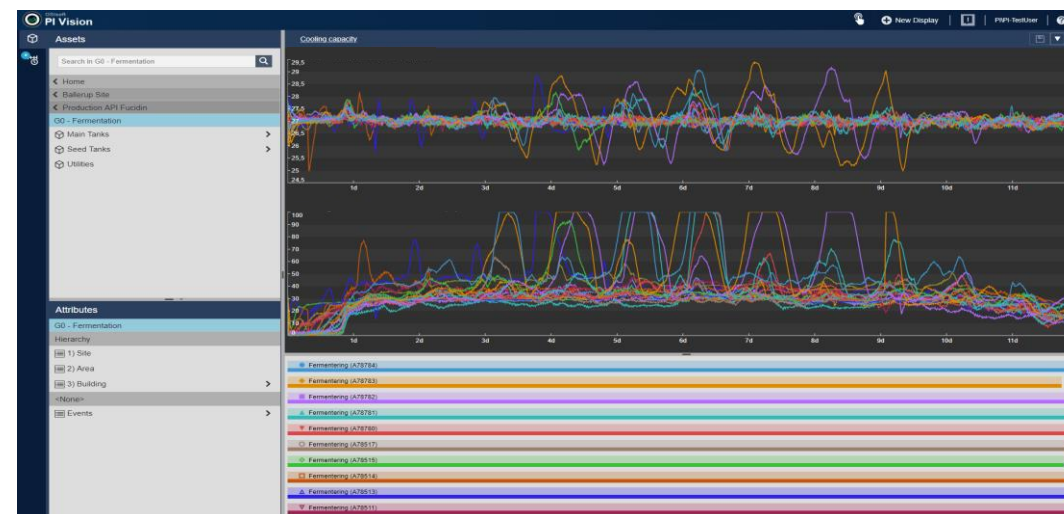


Utilization of Data

Pilot Project

PI Vision

- Very strong and flexible. Key tool for Chemist and Analyst for trending and optimization



PI Web API

- Offers robust and flexible data extraction features, used extensively to extract denormalized data for usage in 3'rd part tools

File Home Insert Page Layout Formulas Data Review View Developer Help Tell me what you want to do

B14

FABI PI - Query tool based on PI WEB API

Basefilters for EventFrames				Event Attributes (static at end)		Tags / Attributes	
StartTime	16-06-2019	EndTime	28-06-2019	1) Site		Agitator-Acc-Power-C	
Interval	1h	EventFrameFilter	*term*	2) Area		Q2-In-C	
AssetFilter	*Tank F10			5) Element		Broth-Temp-M	
				BatchID		<unit>_BIT13_value	
						<unit>_BITM0123_E_Value	
						<unit>_BITM0123_M_Value	

Execute

	A	B	D	E	F	G	H	J	K	M	N	O	P
	EventName	Site	Element	BatchID	Batch	BatchStartIn	UnitStart	DurationBatch	DurationUnit	Agitator-Acc-f	Val	Broth-Temp-f	<unit>_BIT13
1													
2	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	0	0	0,349986255	39,25443	26,0074425	26,0074425
3	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	60	60	2,56443453	73,08756	26,0621586	26,0621586
4	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	120	120	5,144045	72,9261	26,0517445	26,0517445
5	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	180	180	7,714464	73,00426	26,0511856	26,0511856
6	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	240	240	10,2724009	72,99815	25,99435	25,99435
7	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	300	300	12,8384857	72,85934	26,0660605	26,0660605
8	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	360	360	15,4349489	72,93671	26,0233727	26,0233727
9	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	420	420	18,003252	72,99536	25,9549026	25,9549026
10	Fermenting - Tank F10	Ballerup Site	Tank F10 C03287	C03287	C03287	16-06-2019 06:41	G11398	480	480	20,57888	72,96348	26,0074086	26,0074086



Pilot – Conclusion

The Pilot provided us with confidence in proceeding with the full scale rollout of PI



CHALLENGES

- Declining yield in current fermentation
- Process optimize for design of new plant
- LEO needed experience with PI

SOLUTION

- Use the PI System to collect and contextualize data from process, LIMS and new sensors

BENEFITS

- Significant yield increase
- Scale of new plant could be reduced due to yield increase
- A vibrant data-community for chemist and researchers
- Easy accessible data in denormalized format
- Created drive from users to get a Global PI Infrastructure

LEO Pharma Global PI System Project



Implementation of **one common data historian system** across LEO Pharma production sites and systems

Purpose

Enable LEO Pharma to make **decision and process optimizations based on data** to strengthen science, technological and data analytic capabilities

How

The project will make production data from all facilities available in **one common system** to support data analysis and future optimizations. OSIsoft PI software has been selected as the standard historian system for LEO Pharma

Partnering with TQS Integration from concept to end for PI Implementation

Approach & Outcome

Phase 1: Infrastructure & OSIsoft Implementation

- Infrastructure installed locally on five sites
- OSIsoft PI software implemented and validated

Phase 2: Site Assessments and Analysis

- Site specific needs identified and described
- Site prioritized roll-out plan ready

Phase 3: Site Roll-out

- PI integrated to available data sources on local sites
- PI ready for supplying structured data



Overview – Environment and Data

Key information Environment

Production Environment

- Central PI Server – Collective (High Availability)
- PI Visualization Suite
- RTReports
- PCS – Pi Collection Suite
- Approx 100.000 tags
- Interface API – Collective physical on each site
- S88 adherence for AF/EF

Dev/Comissioning Environment

- Ancillary
- Interface API – Collective physical on each site

Collective seen as vital for connection redundancy and for patching friendliness.

Data Scope

Site	Plant(s)	Time Series	A&E	Physical Unit Context	Procedural Batch context
Ballerup	API (FABI)	(Yes)	(Yes)	(Yes)	(Yes)
	API (FAR)	(Yes)	(Yes)	(Yes)	(Yes)
	API (Z3-12,G4)	(Yes)	(Yes)	(Yes)	(Yes)
	Formulation	(Yes)	(Yes)	(Yes)	(Yes)
	Pack/Fill	(Yes)	(Yes)	(Yes)	No(*2)
	Utility / BMS	(Yes)	(Yes)	(Yes)	No
Esbjerg	API	(Yes)	(Yes)	(Yes)	(Yes)
	Utility / BMS	(Yes)	(Yes)	(Yes)	No
Cork	API	(Yes)	(Yes)	(Yes)	(Yes)
	Utility / BMS	(Yes)	(Yes)	(Yes)	No
Dublin	Formulation	(Yes)	(Yes)	(Yes)	(Yes)
	Pack/Fill	(Yes)	(Yes)	(Yes)	No(*2)
	Utility / BMS	(Yes)	(Yes)	(Yes)	No
Vernoulliet	Formulation	(Yes)	(Yes)	(Yes)	(Yes)
	Pack/Fill	(Yes)	(Yes)	(Yes)	No(*2)
	Utility / BMS	(Yes)	(Yes)	(Yes)	No

Project Scope to enable momentum

In Scope



- Establish a Production Data Platform with Global PI Server and Site Interfaces
- Establish data collection from Equipment available on Factory LAN
- Create Asset and Events where available
- Establish GxP Reporting & Visualization platform
- Make Production data hub available for analyzing, export, integrating with other sources
- Provide training for PI-Users on how to make batch reports, visualization and extract data

Out of Scope



- Collect data if OSIsoft standard interfaces do not exist
- Collect data from odd sources (e.g. Excel or obsolete equipment)
- Establish connection to equipment not on Factory LAN
- Design and qualify batch reports (*)
- Make KPI's, Analysis and data extracts (*)

PI System Project Plan

Phases	Activities	2019										2020												2021								
		Apr	Maj	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	Maj	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr						
PROJECT PHASES	✓ Concept																															
	✓ Infrastructure Implementation	Concept phase complete									Dependency – Factory LAN split complete 31 Oct																					
	✓ PI Software Installation										Infrastructure ready																					
	✓ Site Assessment										Validated Platform ready																					
SITE ROLL-OUT an DRAFT TIMETABLE To be detailed and set finally Sept 2019	✓ Esbjerg								Decide Site Roll-out					★ Go-live																		
	✓ Cork															★ Go-live																
	✓ Ballerup API (Z3,G4)																	★ Go-live														
	✓ Ballerup FVA																				★ Go-live											
	✓ Dublin																						★ Go-live									
	✓ Vernoulliet																								★ Go-live							
	✓ FAR (done by FAR)																						FAR to set time									
ORGANIZATIONAL CHANGE MANAGEMENT	✓ Core Story + Comms Plan																															
	✓ Training Prep																															
BENEFIT REALISATION & BUSINESS SUPPORT	✓ Prepare Benefits Realisation plan & Hyper Care plan																															

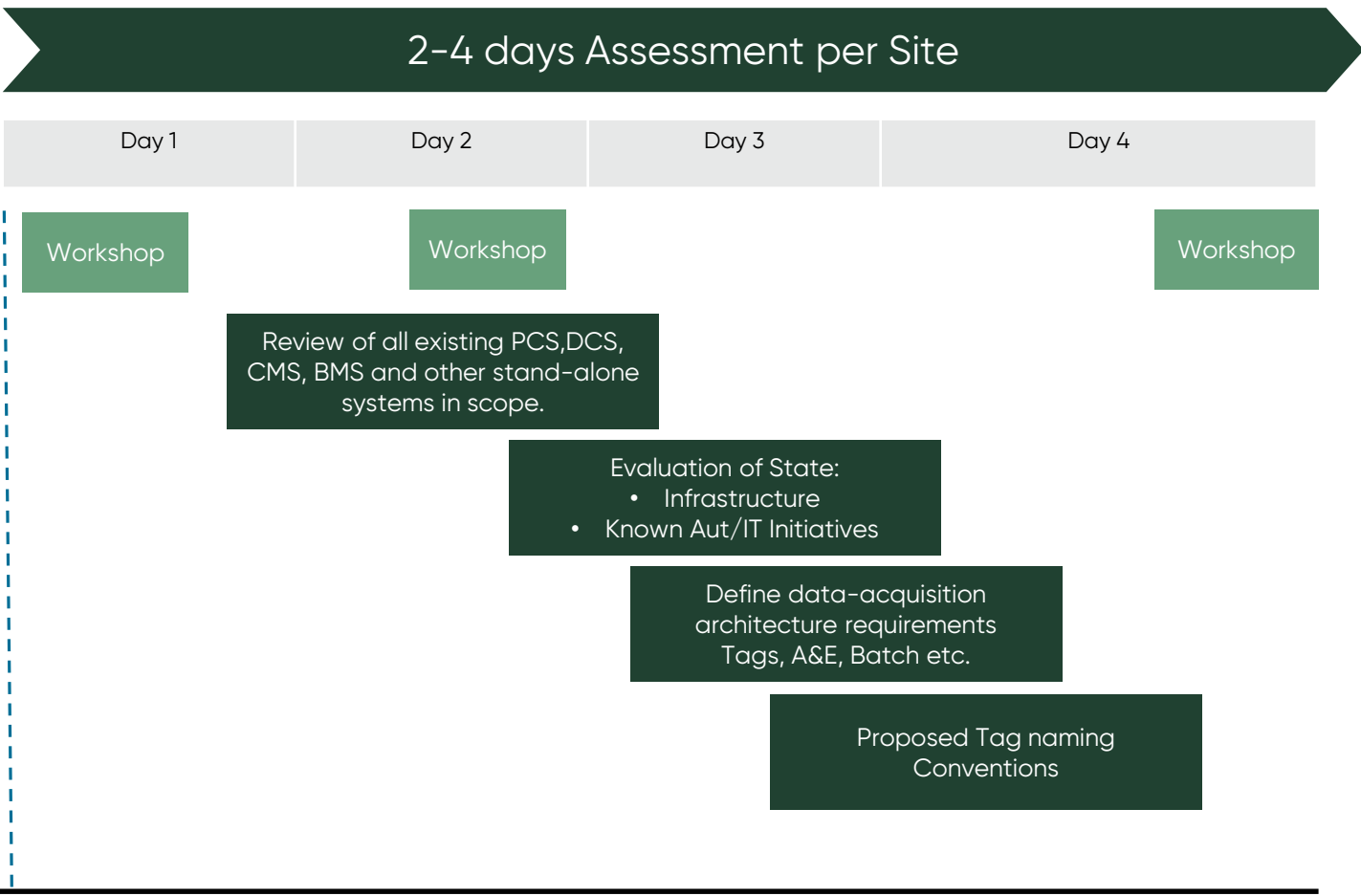
Site Assessment

Follows TQS efficient setup
Deep diving into each site.



TQS & Site SME's

TQS works on-site with Ad hoc involvement of Site SME's



After finalizing all Site assessments
TQS compiles recommendations to whole setup

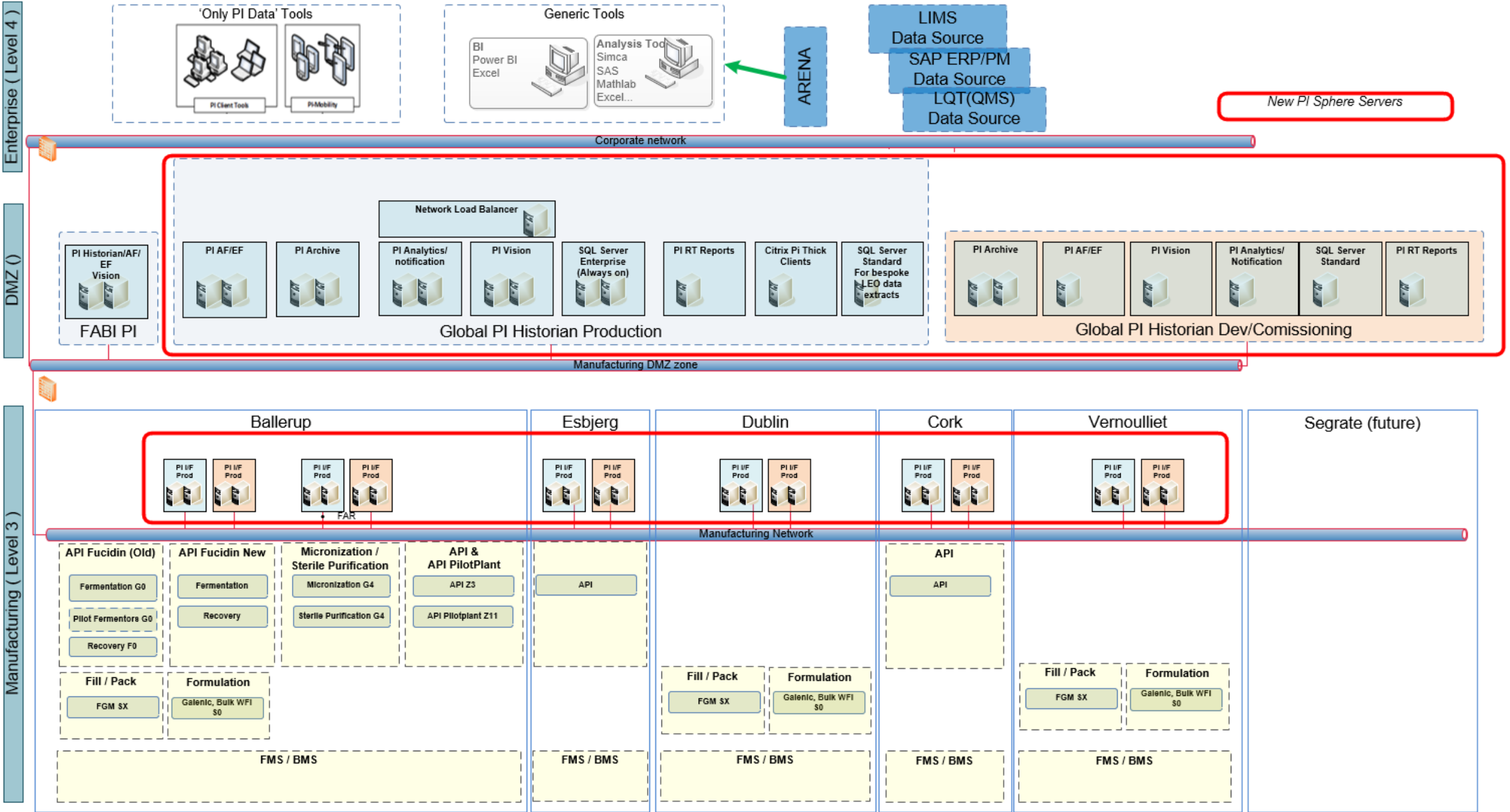
- TQS Conclusion report
- Batch Context/Event Frame Config
 - Group data sources in
 - On-Network and needed
 - Needed but not on network
 - Not needed
 - Network & System Architecture details
 - Security Implementation
 - TQS Validation Approach overview
 - Training recommendations
 - Historical data migration options
 - Daily Operations Excellence
 - Integration recommendations
 - Roll-Out plan recommendation per site and global
 - Implementation cost



Enterprise (Level 4)

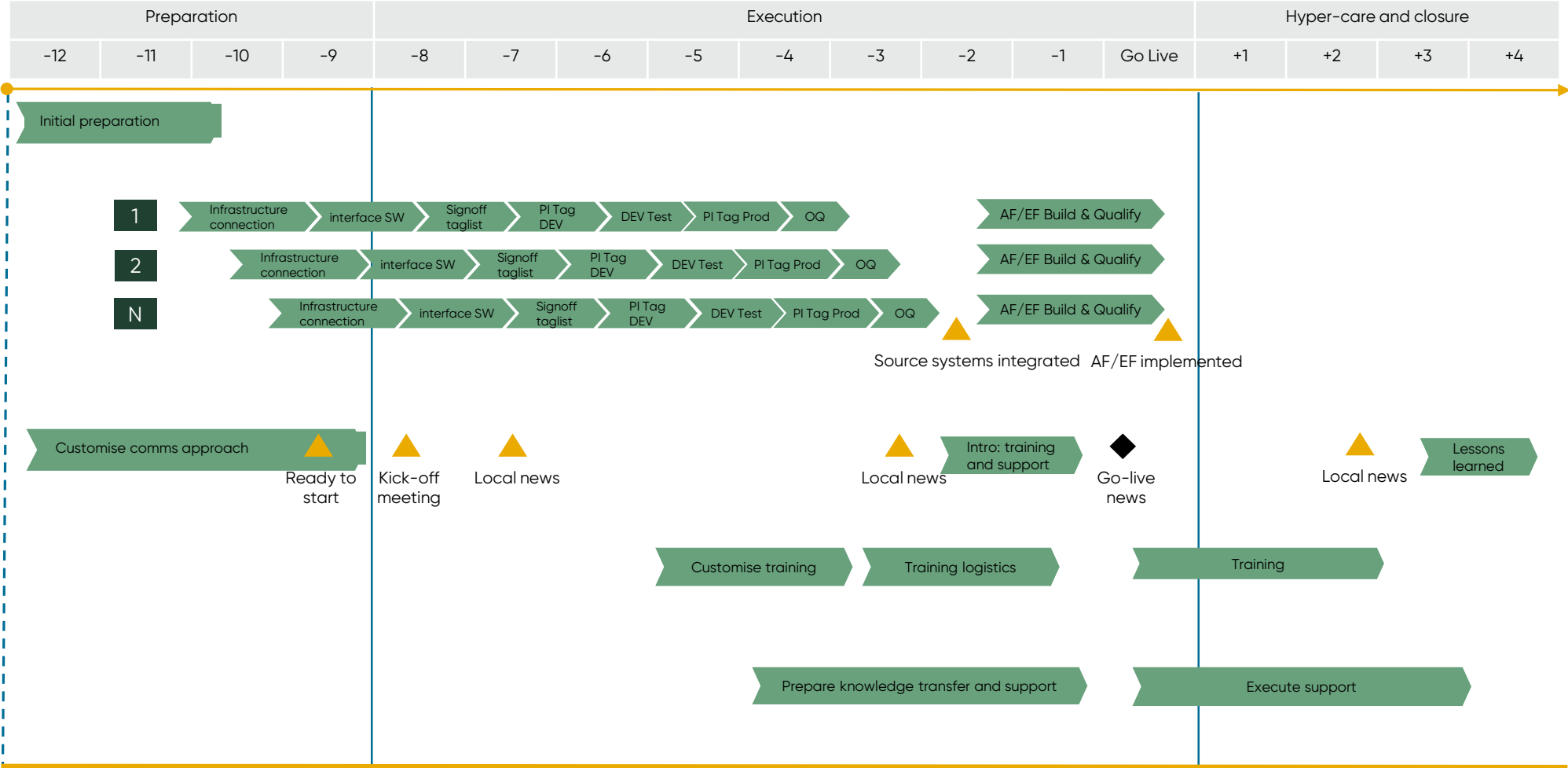
DMZ ()

Manufacturing (Level 3)

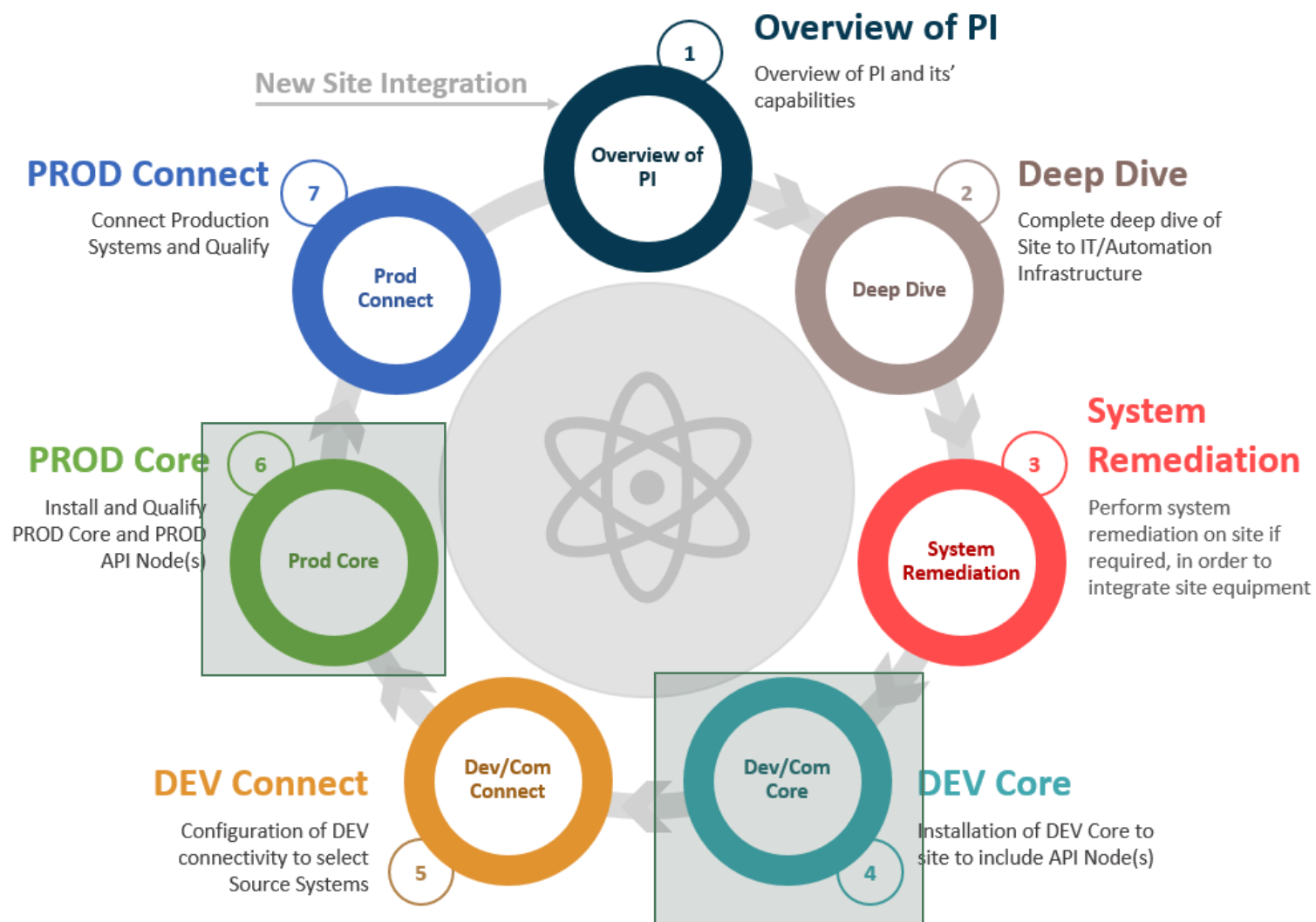


Roll out plan for each site

- Preparation
- Source System Connections (Standardized Approach)
- Communication
- Training
- Life cycle support

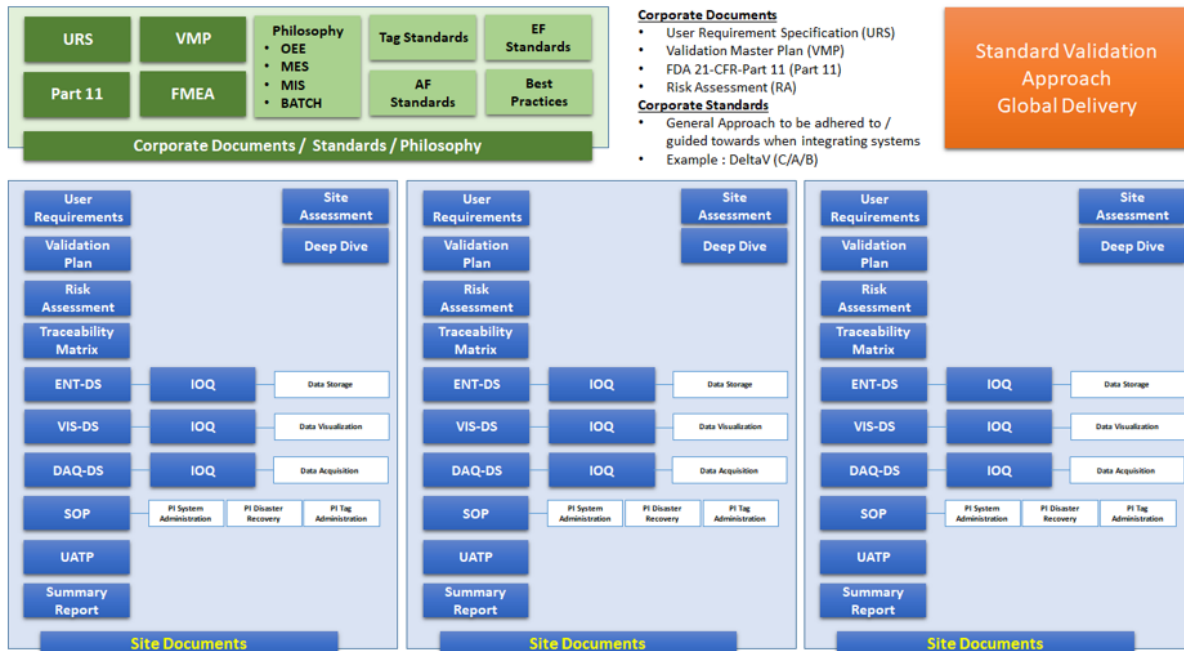


Connecting Source Systems

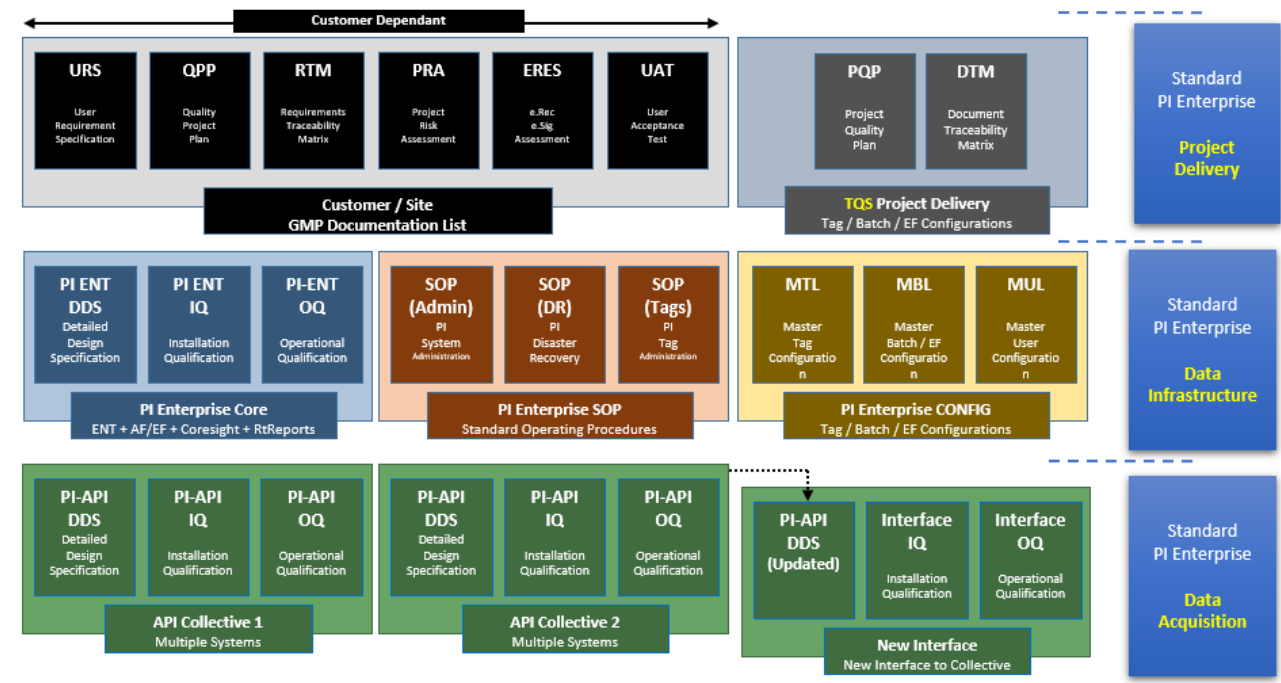


Validation Approach

Central Documents - Green



Site Implementation



Why Focus on Building the Data Warehouse

Why focus on building the data warehouse and not on concrete data usage cases ?

1.

We do not know how we might use them tomorrow and with which tools

2.

So we will build the best production data warehouse that can fulfill future unknown demands by focusing on contextualizing and standardizing

3.

The flexibility of AF/EF and standard interfacing set us free to this approach

4.

Enable self-service

- Liberal arts impact - Access structured data w/o IT experts and projects
- Horizontal Architecture, freedom of tools
- Production Data-Hub serving other systems (e.g. SAP/PM, EBR, Power BI)

Global PI Project – Conclusion



CHALLENGES

- Collect Data from 300+ sources on 5 locations
- Keep focus during project
- Engagement of stakeholders
- Impact on production

SOLUTION

- Use the PI Data Infrastructure
- Clear scope and de-scope
- Focusing on the Data Warehouse building
- Validation Strategy available
- Central Governance
- Organizational Change
Management focus on training and engagement when solution is ready

EXPECTED BENEFITS

- Platform for production data across all production sites.
- Enable self-service for users releasing large potential for optimization, yield increase
- Enable other systems to get data from PI SAP/PM, EBR, Power BI
- Data readiness for future hyped technologies when they reach maturity e.g. AI.



Summary

1

Pilot proved yield optimization potential and convinced us to implement Historian on all our sites.

2

Tight scope on building the Data Warehouse and application platform, not on using data. PI AF/EF flexibility enables this decoupling.

3

Centralized approach on infrastructure and validation reduces complexity and roll out time.

Questions?

Please wait for
the **microphone**

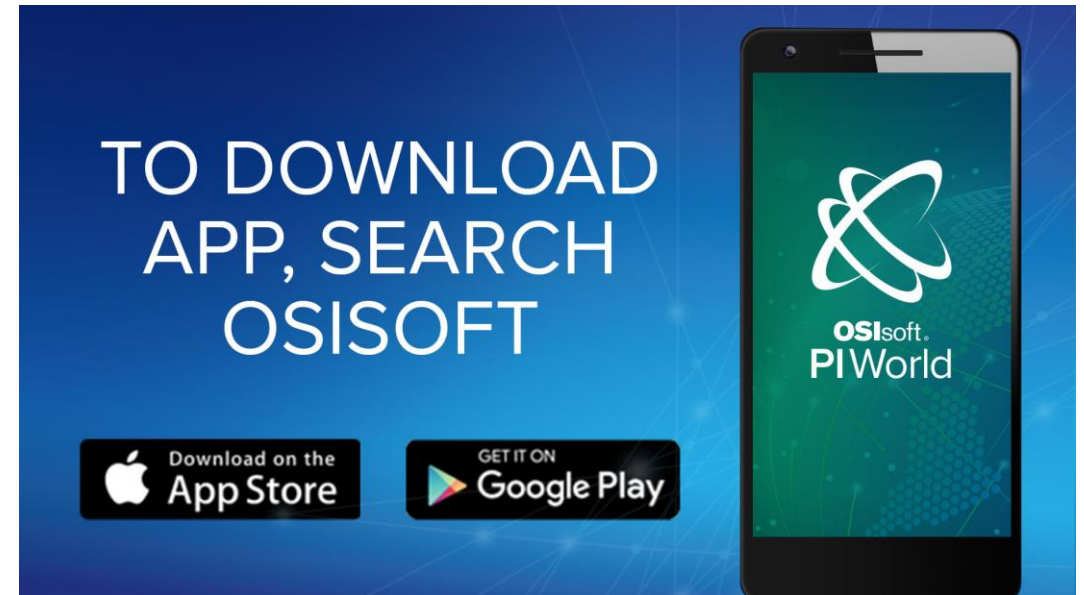
State your
name & company



Please remember to...

Complete Survey!

Navigate to this session in
mobile agenda for survey



謝謝 KEA LEBOHA
 DZIĖKUJĘ CI NGIYABONGA TEŞEKKÜR EDERIM GRACIES
 DANKIE TERIMA KASIH DANKON TANK TAPADH LEAT SALAMAT
 КӨСӨӨНӨМ СПАСИБО РАКМЕТ СІЗГЕ
 GO RAIBH MAITH AGAT БЛАГОДАРЯ GRACIAS
 TI БЛАГОДАРАМ MAHADSANID
 TAK DANKE RAHMAT MERCI
 HATUR NUHUN CẢM ƠN BẠN
 WAZVIITA
 FALEMINDERIT
 OSlsoft.
PIWorld
THANKYOU
 MULŢUMESC
 HVALA FAAFETAI
 ESKERRIK ASKO
 HVALA ХВАЛА ВАМ
 TEŞEKKÜR EDERIM
 GRAZIE
 DI OU MÈSI
 ĎAKUJEM
 MATUR NUWUN
 SIPAS JI WERE TERIMA KASIH
 UA TSAUG RAU KOJ
 TI БЛАГОДАРАМ
 СИПОС

