



Creating a global PI Solutions Store to Ease Site Deployment and Increase Compliance

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Presentation Agenda

- About GSK Vaccines
- The Automation Strategy & OSIsoft PI
- OSIsoft PI and EA
- What we want to achieve: OSIsoft PI Solutions Store
- Implementation & Qualification Approach
- Key Partners
- Deep dive on the PI Solutions store concept
- Conclusion

A partnership on the verge of a malaria breakthrough

In Africa a child dies from malaria every minute

30 years and counting

We've been working with the PATH Malaria Vaccine Initiative, with backing from the Bill & Melinda Gates Foundation to develop a vaccine against this disease. This would be a world first.

We've been working on this for more than 30 years and because it will only be used among children in some of the world's poorest countries we've committed to make it available on a not-for-profit basis¹.

1. GSK 2014 Annual Report, p.25



Who we are



Pharmaceuticals

We develop and make medicines to treat a range of conditions including respiratory diseases and HIV/AIDS



1.9bn

packs of medicines in 2017



Vaccines

We research and make vaccines for children and adults that protect against infectious diseases



798m

doses of vaccines in 2017



Consumer Healthcare

We make a range of consumer healthcare products in four categories: Wellness, Skin health, Oral health and Nutrition



6.2bn

consumer

healthcare products in 2017

Our strong vaccines pipeline – March 2017

Compound	Type	Phase 2	Phase 3	Submitted
Shingrix [†] (Zoster Vaccine)	recombinant			✓
MMR	live attenuated		✓ (US)	
Ebola [†]	recombinant viral vector	✓		
Group B Streptococcus	conjugated	✓		
S. Pneumoniae next generation [†]	recombinant – conjugated	✓		
COPD [†]	recombinant	✓		
Hepatitis C [†]	recombinant viral vector	✓		
Malaria next generation [†]	recombinant	✓		
Men ABCWY	recombinant – conjugated	✓		
Shigella [†]	conjugated and outer membrane	✓		
Tuberculosis [†]	recombinant	✓		
RSV	recombinant	✓		
RSV	replication-defective recombinant viral vector	✓		
HIV [†]	recombinant proteins	✓		

Source: GSK 2016 Annual Report, p.247

† In-license or other relationship with third party – * Option-based alliance with Valneva

Our performance – 2017

£5.2bn

Total turnover

17%

of Group turnover



Top 3 sales drivers 2017

Meningitis

Paediatric & adult

Infanrix/Pediarix

Paediatric & adult

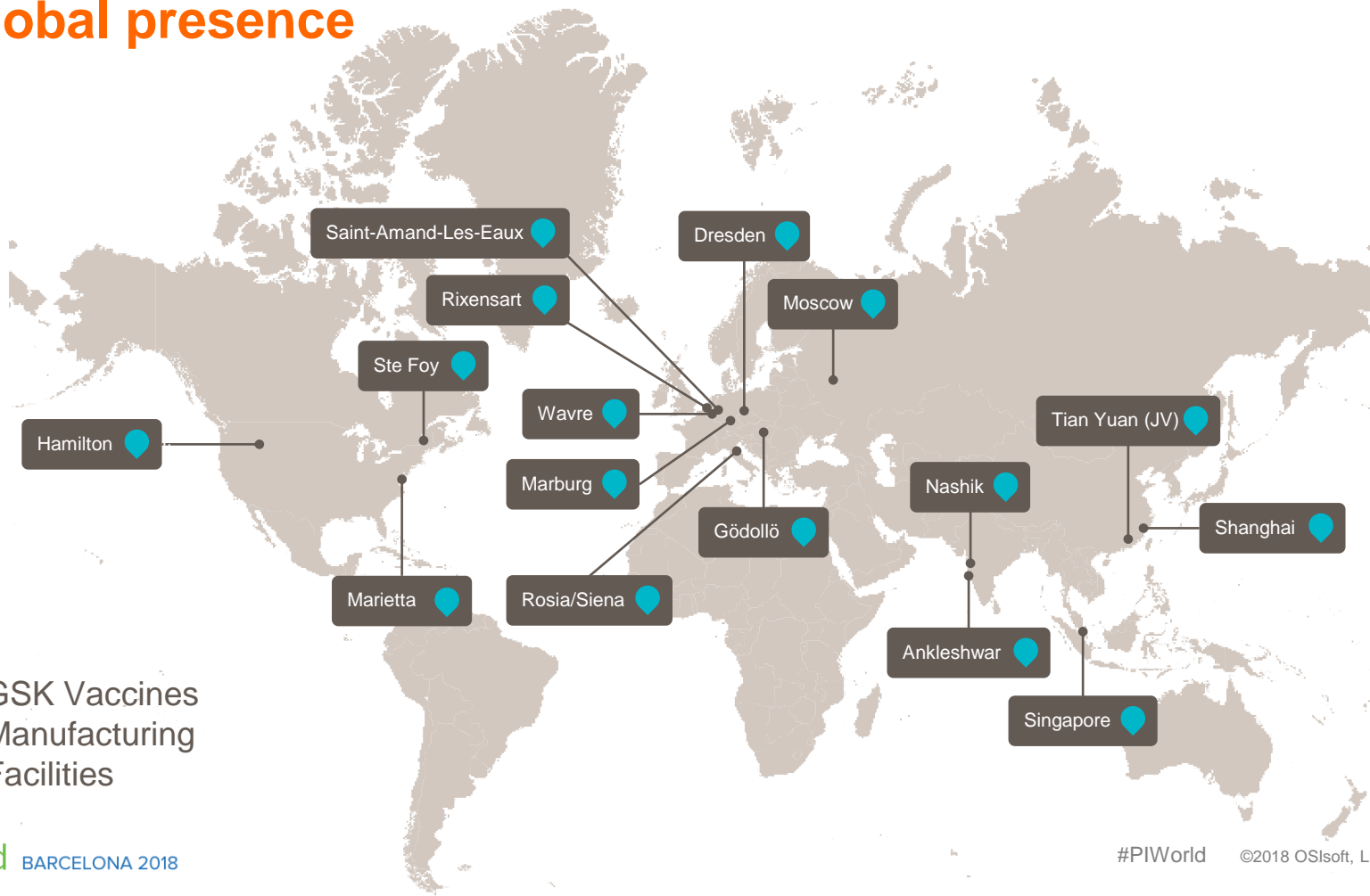
Hepatitis

Paediatric & adult








Source: GSK 2017 Annual Report

Our global presence

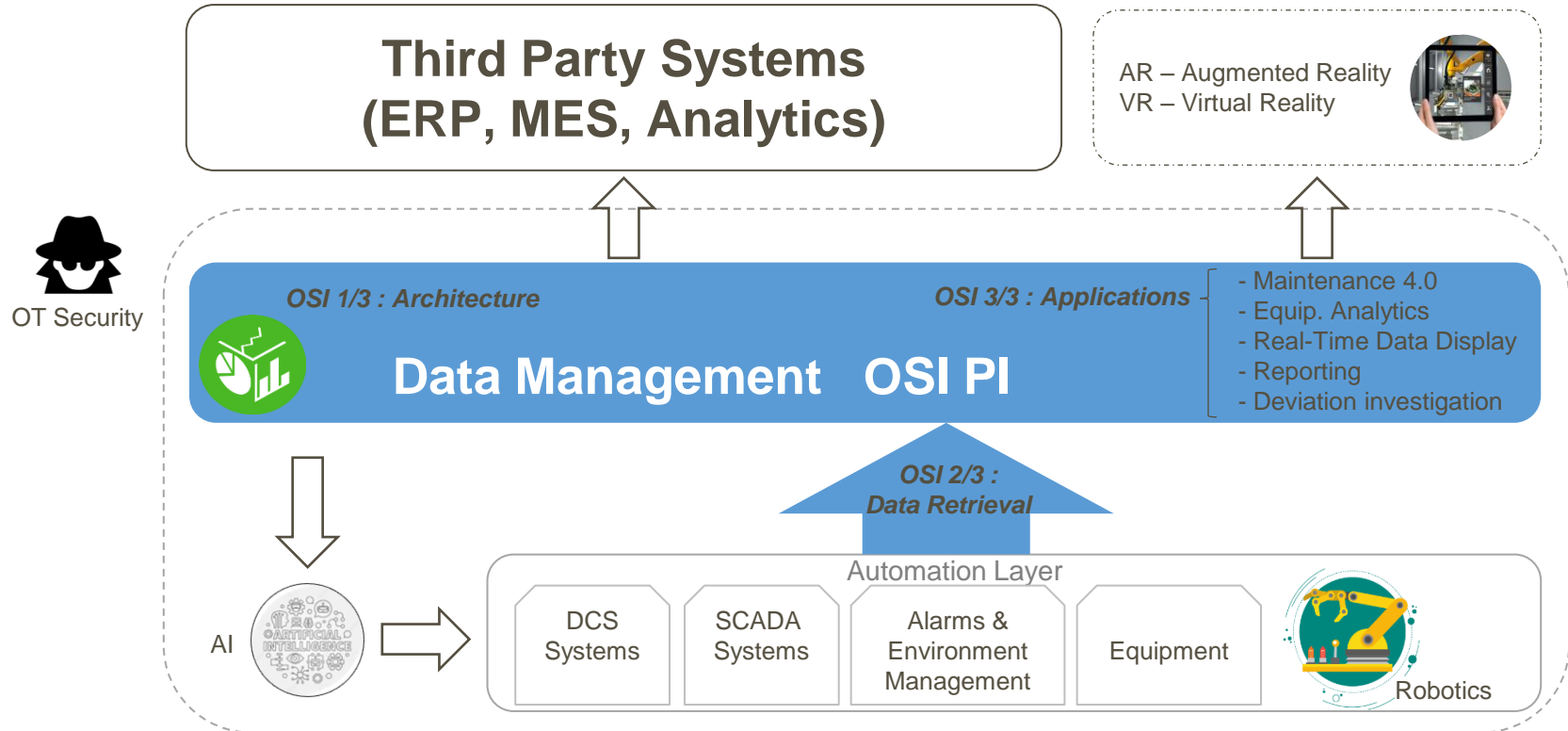


GSK Vaccines
Manufacturing
Facilities

The five automation strategic pillars

 Robotics	 Augmented capabilities	 OT Security	 AI	 Data Management
<p>Arm robot in aseptic area (isolator), cobots, automatic EM reader, robotics for secondary</p>	<p>In 2017, GSK Vaccines decided to work with OSIsoft PI products and OSIsoft Enterprise Agreement to develop the Data Management strategic pillar</p> <p>Closing gaps in automation skills thanks to wearable technologies and continuous digital guidance, monitoring and support.</p>	<p>Reduce cyber security risks on Operational Technology systems. Build a defence in depth OT infrastructure</p>	<p>Follow the market trend and GSK partners on AI solutions to enhance production capabilities.</p>	<p>Collect data from process control in a compliant way, generate paperless batch record, real time data analytics, CPV, OEE, Dashboard, CBM</p>

OSI PI at the heart of the automation strategy



Why choosing PI and OSIsoft EA?

Enterprise Agreement will accelerate our sites deployment.
Licenses & service fully available

1. Accelerate sites deployment



2. Best-in-class system



Benchmarks and Pharmaceuticals references show OSIsoft PI as the best system for Data Historian

Use existing internal knowledge for the benefit of all sites.
Involved local sites

3. Leverage on existing



4. Build Strong Partnership



Enterprise Agreement helps to build quickly a strong partnership with OSIsoft

PI Solutions store concept



« Collaborative, multi-site approach to develop and publish a business solution using OSIsoft tools. Following defined guidances to allow quickly to share and implement same solution on other sites »

PI Solutions store – Examples

Solutions

Facilities

Maintenance 4.0

CBM & Predictive

Alarms Analytics

Equipment & PCS

EMS Analytics

Room analytics / HV AC Qualification

Deviation Investigation

PI-DataLink, PI-Vision & RT-Reports

Energy Analytics

« **Standard packaged solutions** implemented through OSI data and tools and related to a specific **topic** like “Environmental Monitoring System”, “Alarms management”, “Energy Monitoring”, ... »

Equipments (Std objects)

« Create System or Equipment “**OSI Templates**” with OSI’s tools

(Reporting, Display, Formulation) and analytics possibilities (OEE, Machine Learning, ...)

→ **Standard applicability** on any **system or equipment** »

Reporting

(GMP or not)

Digital Dashboard

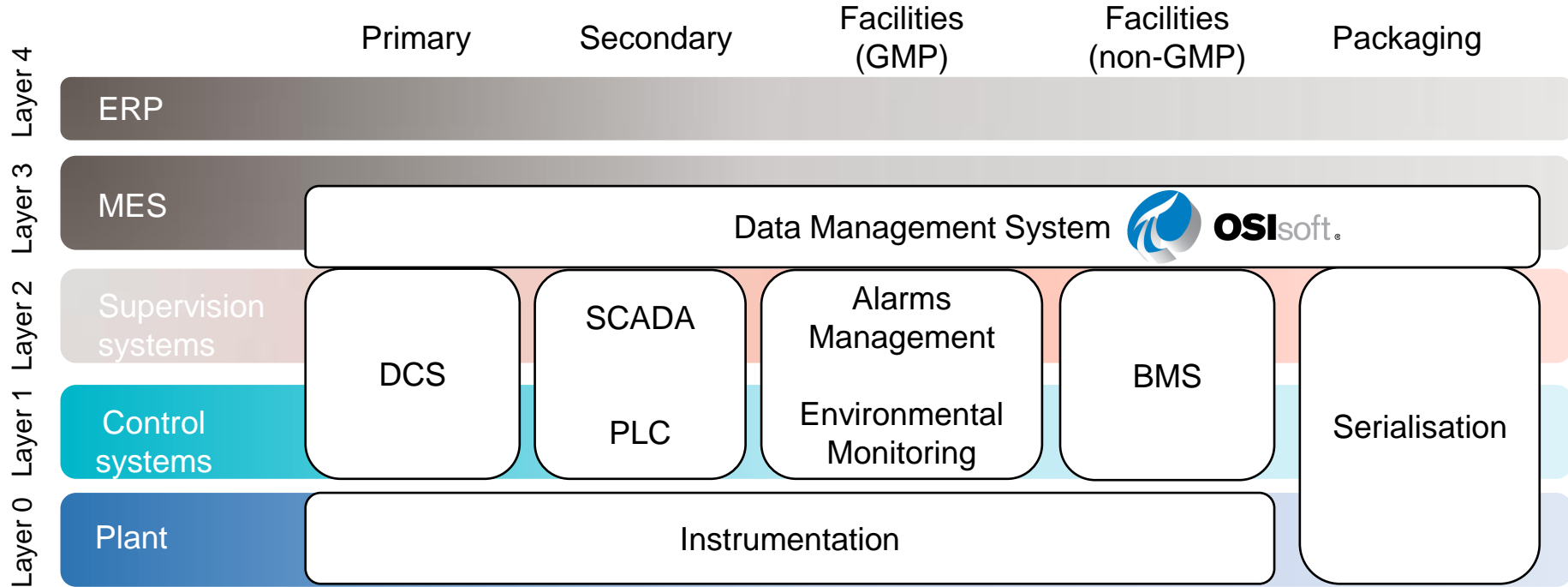
Realtime data display

Process Analytics

Machine Learning

OEE, Analytics ...

OSIsoft PI system into ISA-95 layers



The key drivers for a global approach

Deployment in parallel on different sites. System's functionalities & performance defined once

1. Accelerate sites deployment



2. Reduce system downtime



Global qualification efforts can be leverage to reduce downtime needed for on-site qualification

Global approach already used for EMS deployment (53 instances). ROI after 5 instances

3. Proven methodology



4. Aligned and Standard



Standard solution for compliance issues (Data Integrity, retention). Improve support performance

The PI infrastructure qualification approach

Step 1

Already available



Data Archive



Asset Framework



Event Frames



PI Vision

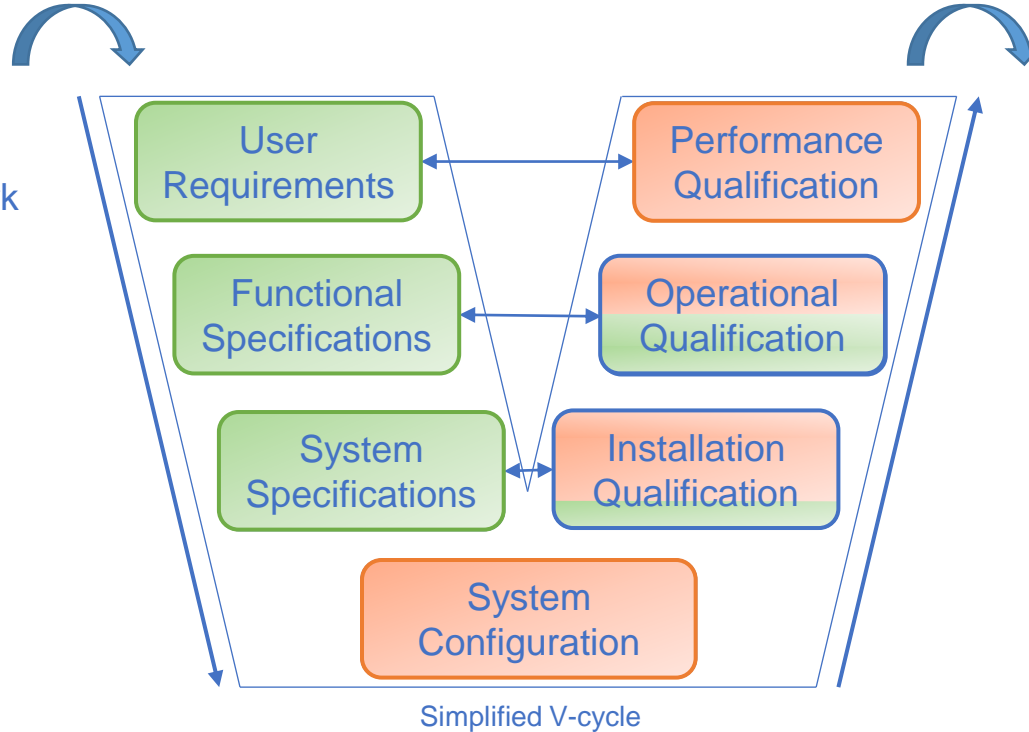


PI DataLink

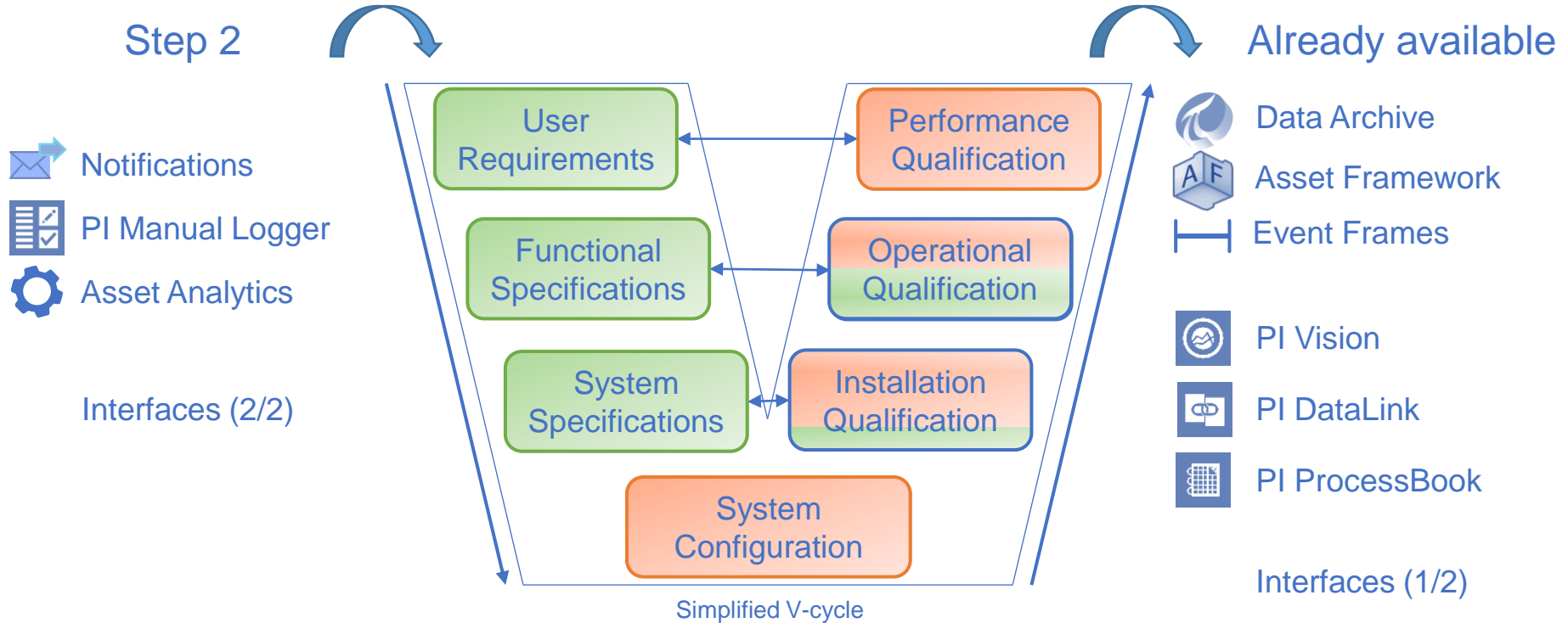


PI ProcessBook

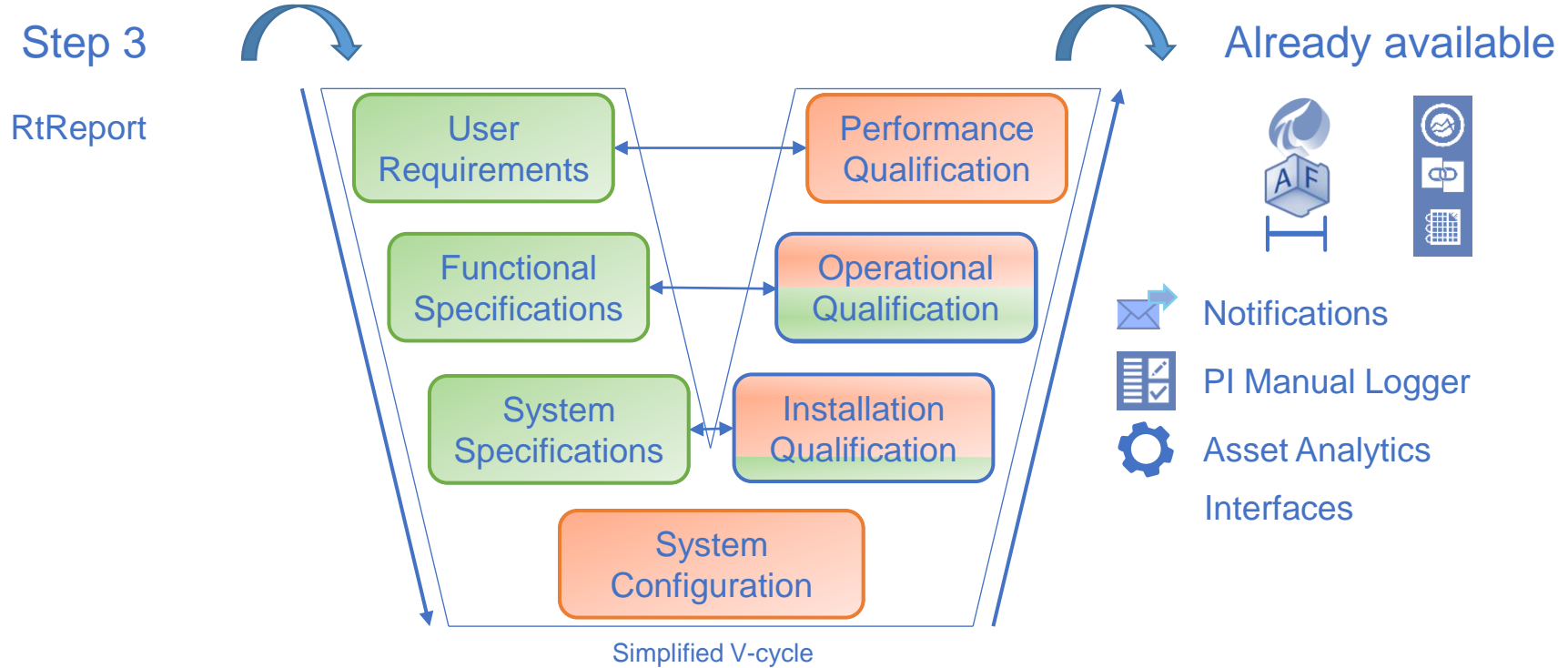
Interfaces (1/2)



The PI infrastructure qualification approach



The PI infrastructure qualification approach



Key partners for global qualification

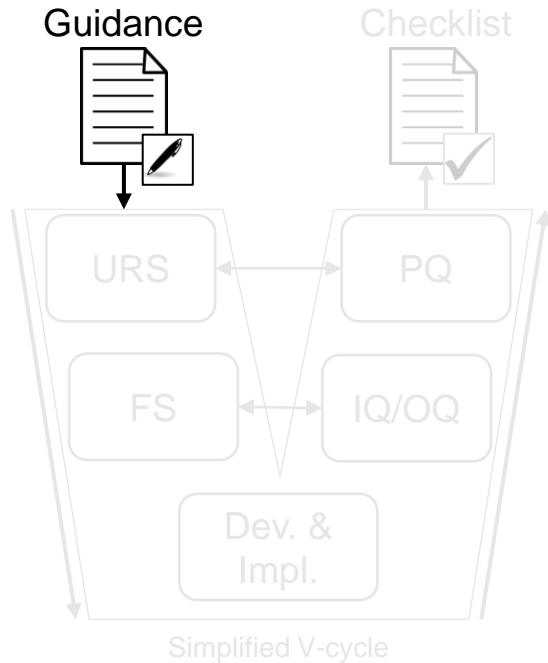


PI Solutions store concept



Deep dive on standard objects
for equipment and the
methodology for the PI solution
development

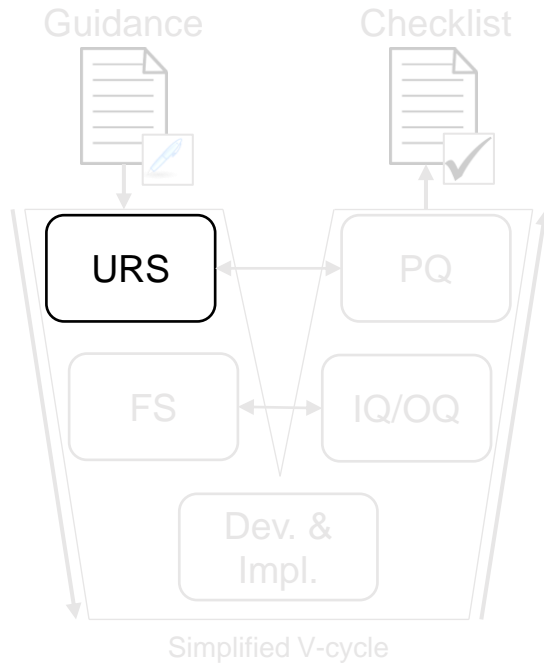
Methodology for a PI solution development



Global guidance as a pre-requisite for solution development and implementation:

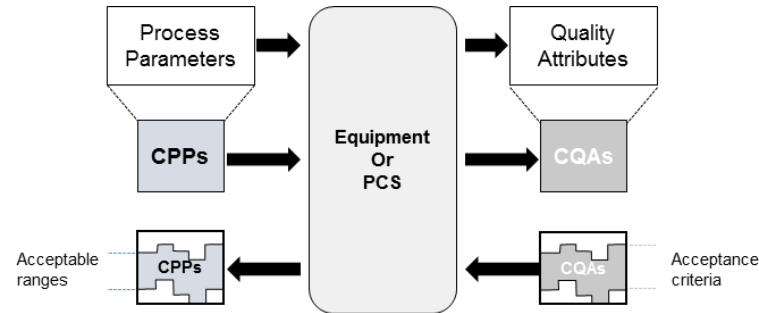
- Describe the **methodology**
- Define the **minimum mandatory principles** to follow to be approved and published on the global PI solutions store

Methodology for a PI solution development

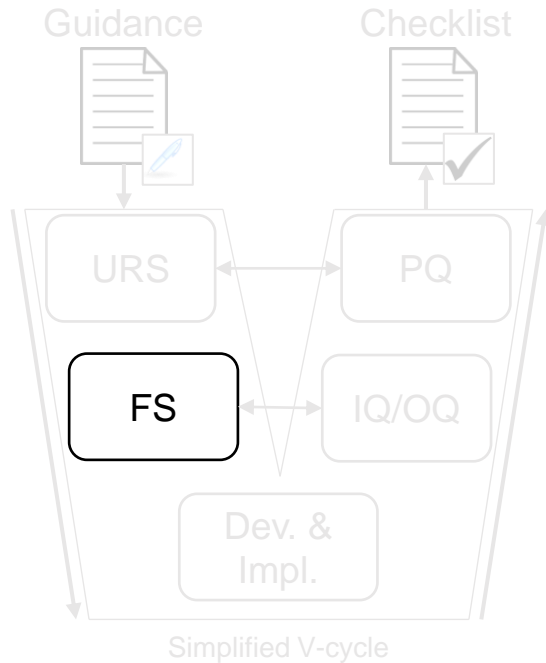


User Requirement Specifications (URS):

- Define the critical list of parameters and quality attributes for a specific equipment or PCS system.
- Task owner: Equipment or PCS system **SME**
- Delivery: Critical list (**URS**).



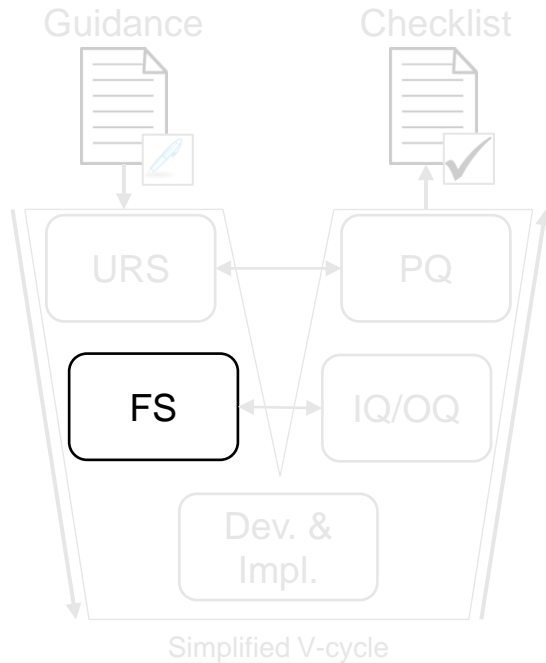
Methodology for a PI solution development



Functional Specifications (FS):

- CPP & CQA list deep **understanding** and **other attributes definitions** (Maintenance, OEE, KPI, ...).
Ensure that each parameters and attributes are defined (PI point link, mathematical function to use, linked to batch phase or operation, ...).
- Task owner: **SMEs/Data Scientist/OSI Expert**
- Delivery: FS (Functional Specifications).

Methodology for a PI solution development

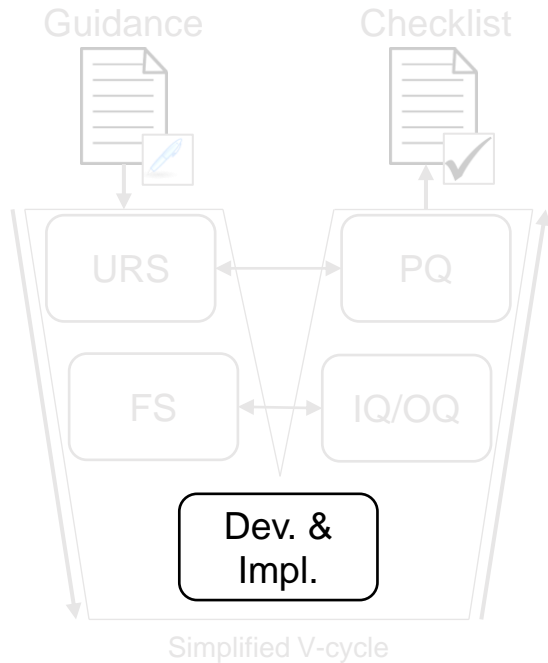


FS Content:

- Link CPP, CQA and other parameters into :
 - PI AF: List of time series Pi-Points, Attributes (Asset details, Batch Infos, Maintenance, ...)
 - Analytics: Functions and calculations
 - Event frames and batch attributes
- Standard Displays in PI Vision and/or PI DataLink
- Standard Reports (using RtReport) for equipment status, audit trails, alarms, batches, ...



Methodology for a PI solution development



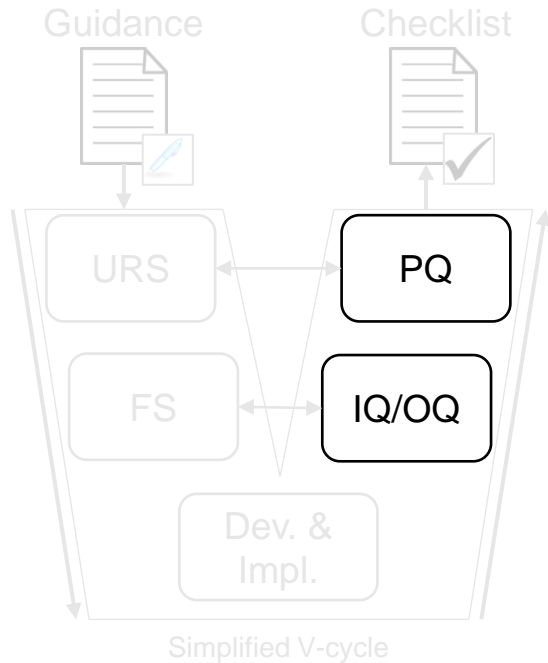
Dev. & Implementation:

- Design specification redaction (DS).
- FS + DS → Parametrization and/or Development on OSI PI.
- AGILE Methodology on **DEV** infrastructure with **SMEs/Data Scientist/OSI Expert**



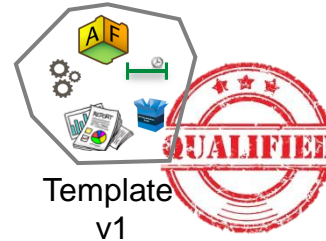
Template V1.0

Methodology for a PI solution development

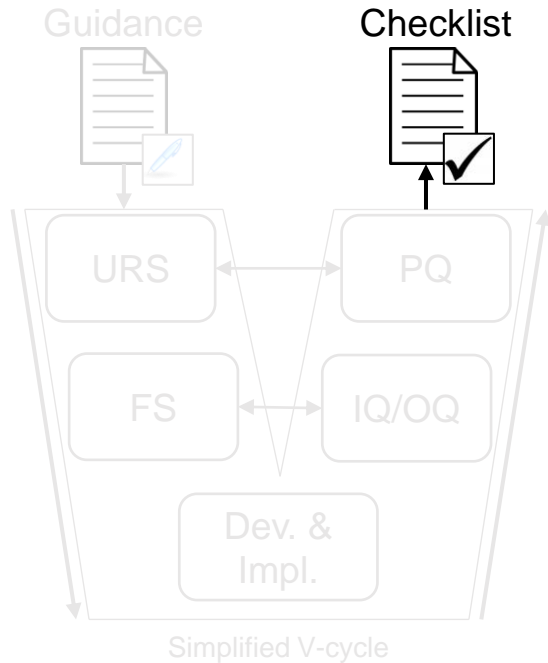


Central Qualification:

- IQ : Installation Qualification
 - OQ : Operational Qualification
 - PQ : Performance Qualification
- } Functional Qualification
- Template v1 fully qualified



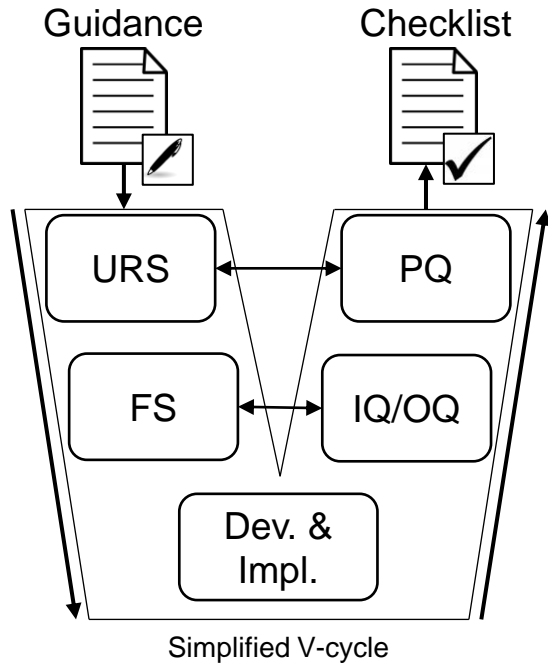
Methodology for a PI solution development



Checklist for PI solutions store integration:

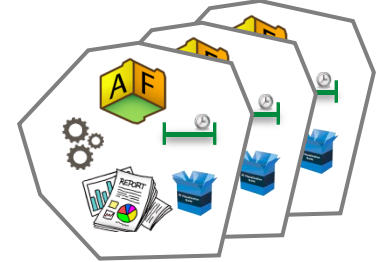
- Verify compliance with the global guidance
- Check if the minimum mandatory principles have been followed

Methodology for a PI solution development



Local implementation:

- Provide pre-validated package :
 - Standard specifications documents
 - Standard local qualification protocol→ Fast deployment.
- Data standardization / Equipment:
 - Independent of manufacturer/model : Minimum outputs requirements at basic design phase
 - Easy data compare between equipment



GlaxoSmithKline Vaccines

Creating a global PI Solutions Store to Ease Site Deployment and Increase Compliance

OSIsoft PI at the heart of the Automation strategy, as enabler for data compliance and analytics



CHALLENGE

Align and accelerate OSIsoft PI deployment in parallel on several manufacturing sites

- Several sites implementation to manage in parallel
- Minimize the local efforts for implementation & qualification

SOLUTION

Global qualification approach of OSIsoft tools with pre-qualified and documented modules

- Strong partnership with OSIsoft (EA) and PAS integrator
- Involvement of local sites in the budget estimate and scope definition

RESULTS

60% reduction of local qualification effort. Aligned solution thanks to sites involvement

- Similar approach for other systems: ROI after 5 instances implementation
- Expected to quickly increase the solutions available thanks to the collaborative approach

Contact Information



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Questions?

Please wait for
the **microphone**

State your
name & company



Please rate this session in the mobile app!



