Lean validation as part of standard PI System deployments at J&J

Presented by **Carl Van Laer**

Standardized PI System deployment

Vision
One PI System
One reliable source of integrated data used to drive the business, available anywhere, anytime, to anyone

Standardize   Enable   Implement

Globally

"The use of the software delivery lifecycle (SDLC) and the electronic tools made it possible to roll out the regional instance for the Americas in a significantly shorter time than in the past. Never before did we execute an OSIsoft PI System project without any wet signatures"

Nikunj Dani, PDMS Proj. Man.

Janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

Business Challenge

- How to implement Enterprise wide PI System fast and cost effective?

Solution

- Standardize deployment & validation approach
- Reuse documents / test scripts
- Use electronic tools instead of paper

Results and Benefits

- Significant cheaper and faster PI System deployments
- Foundation for 1 global PI System for Janssen

Topics

- Johnson State College (JSC) in Johnson & Johnson
- PI System at JSC
- SPIRIT – standardization of the PI System World at JSC
- SPIRIT – Deployment – Validation approach
- SPIRIT – Deployment – Validation approach – roadmap
- SPIRIT – Deployment – Validation approach – benefits
- Q&A

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Johnson & Johnson

+/- 250 companies in 57 countries

+/- 128.000 employees

Total sales (2013) 71.3 billion USD

Johnson & Johnson

✓ **JSC Pharmaceutical** Medicines

(on prescription)
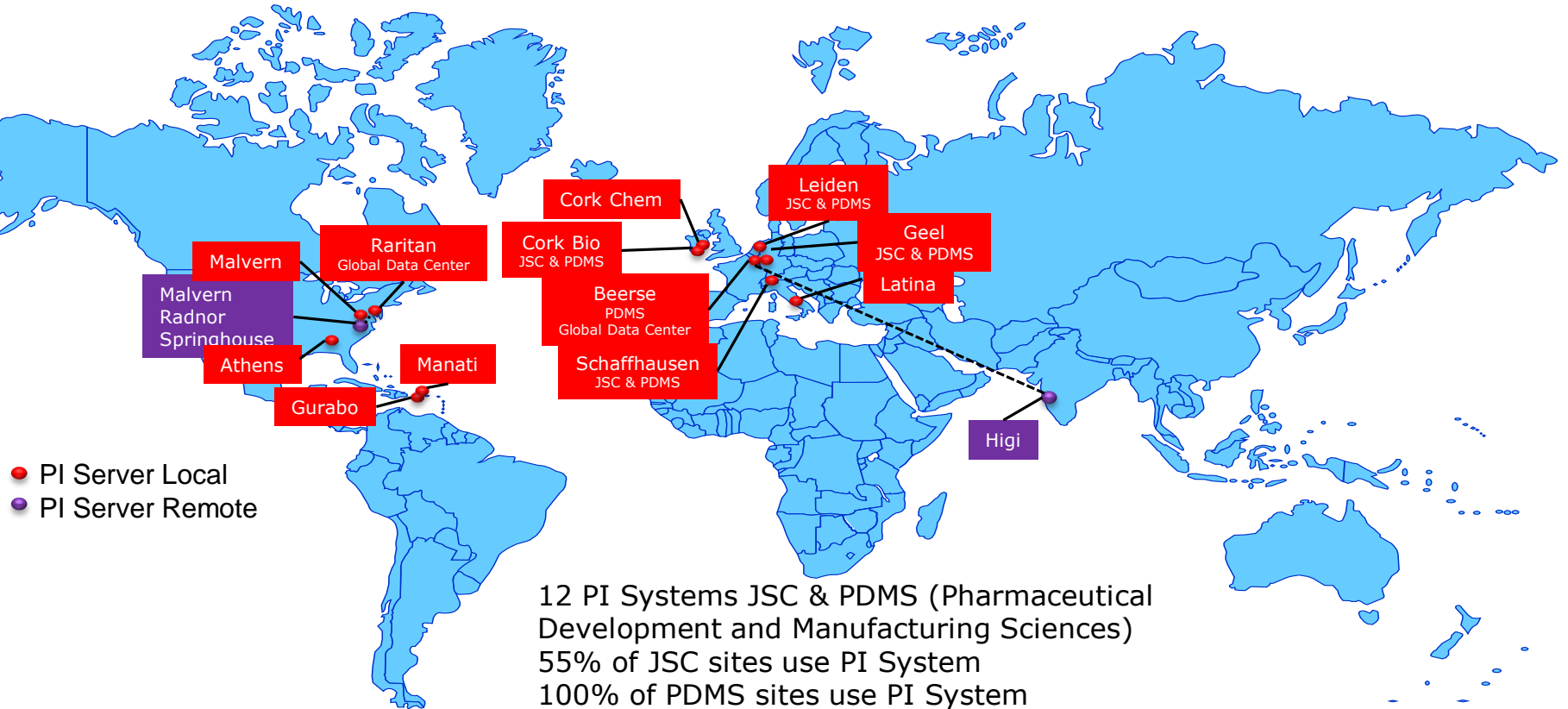
✓ Consumer
Products for hair & skin care, baby care, OTC

✓ MD&D
Products for hospitals, clinics and doctors' practices (sterile products, blood tests, …)

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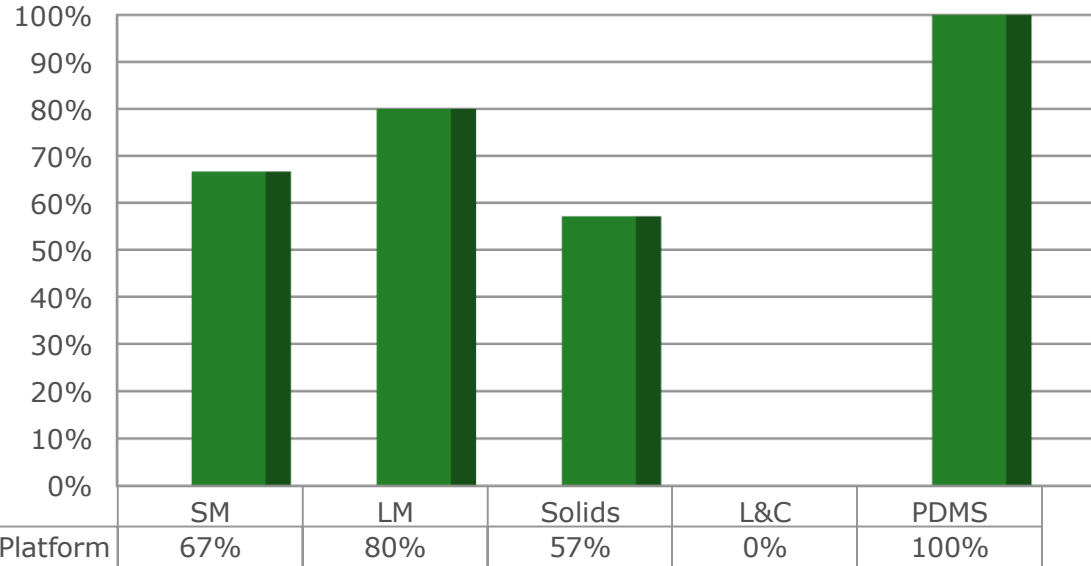- Q&A

PI Architecture Overview (Current)

PI Server Local
PI Server Remote

Malvern
Raritan
Global Data Center
Malvern
Radnor
Springhouse
Athens
Gurabo
Manati
Cork Chem
Cork Bio
JSC & PDMS
Beerse
PDMS
Global Data Center
Schaffhausen
JSC & PDMS
Leiden
JSC & PDMS
Geel
JSC & PDMS
Latina
Higi

12 PI Systems JSC & PDMS (Pharmaceutical
Development and Manufacturing Sciences)
55% of JSC sites use PI System
100% of PDMS sites use PI System

As Is Status - JSC & PDMS

% Sites with PI System - by Platform

% of Sites with PI System by Platform	SM	LM	Solids	L&C	PDMS
■ % Sites with PI by Platform	67%	80%	57%	0%	100%

As Is Status - JSC & PDMS

Equipment Network Connectivity – by Platform
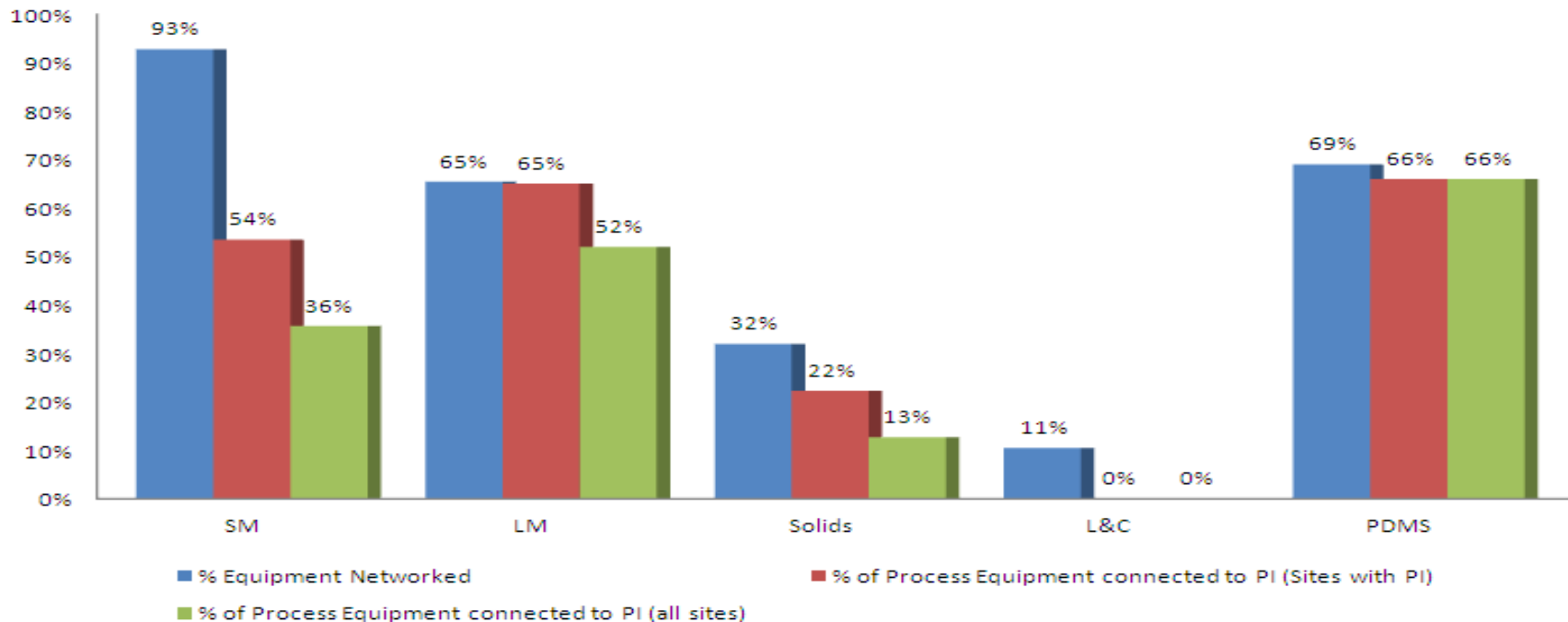
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- **S**tandard **PI** System **R**ollout **I**mplemented **T**ogether

Vision

One PI System
One reliable source of integrated data used to drive the business, available anywhere, anytime, to anyone

PI System

Vision

One PI System

One reliable source of integrated data used to drive the business , available anywhere, anytime, to anyone

Standardize

Enable

JSC Site

PDMS Site

CMO Site

JNJ Site

Implement
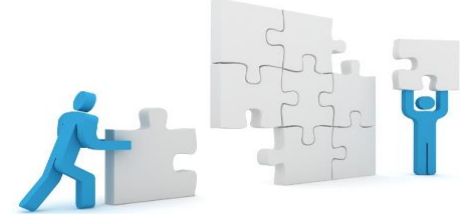
Globally

Vision

Integrated Data Management

Continued Process Verification (CQA's and CPP's)

Efficiency (Batch Reporting & Automatic Data Capture)

Design to Value

Vision

One PI System

One reliable source of integrated data used to drive the business, available anywhere, anytime, to anyone

Standardize   Enable   Implement

JSC Site   PDMS Site

CMO Site   JNJ Site

Globally

Real time Process Visualisation

Process Analytical Technology (PAT)

JSCRELIABILITY

CUSTOMER   **COMPLIANCE**   **COST**

From Information to Value
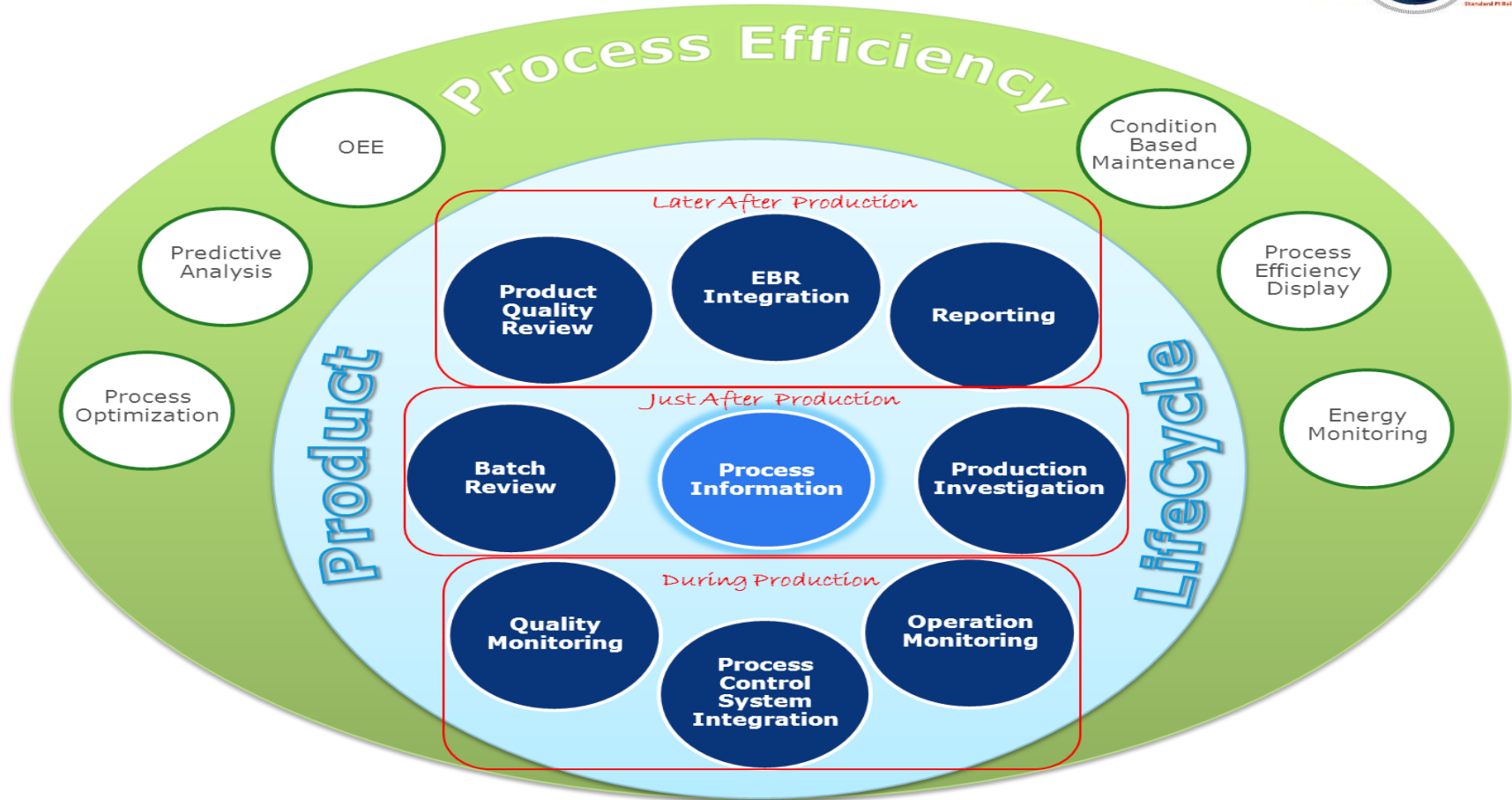
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Standards

Deployment

Deployment – Validation

- **Business objectives of SPIRIT**
  - **Make data of different sites / organizations available in 1 virtual PI System platform**
  - **Standardize on**
    - **Content**
    - **Deployment**
    - **Visualization**
    - **Reporting**
  - **Make PI System deployments**
    - **Faster**
    - **Cheaper**

Deployment

Deployment – Validation: How was it in the past?

- **No standardization (different setup, functionality, tools)**
  - **Content**
  - **Deployment**
  - **Visualization**
  - **Reporting**

- **Local validation procedures**

- **On paper**

=> No LEAN PI System deployments

Deployment

Deployment – Validation

- **What's wrong with the current validation approach?**
  - **Not supporting business objectives of SPIRIT**
  - **Paper documents (in local language) not suitable for regional/global instances**
  - **Cannot have different validation approaches for parts of regional/global instances**
  - **Not LEAN**
    - **Re-invent wheel**
    - **Not cost effective**
  - **COTS system with different validation approach ⇔ inspections?**

Deployment

Deployment – Validation – WE NEED

- **To make it LEAN to support business**
  - **Agile**
  - **Cost effective**

- **To comply to same legislation:**
  - **Align our view on what this means**
  - **Agree on the way forward how to do this**

- **To define roadmap on how to 'migrate' to unified validation approach**

Deployment

Deployment – Validation approach (1)

- **IT unified approach**
  - $\Rightarrow$ **J&J IT SDLC**

- **No paper**
  - **Electronic documents – Docspace (Documentum)**
    - **Including approval workflows**
  - **Electronic test scripts – HP/QC**
    - **Including approval workflows, execution, review**

- **Usable for all type of implementations**
  - **Local / Regional / Global**

Deployment – test cockpit

PIMS_RARITAN PE Tests (Production) (incl. Test Set Reviews)

TS_EXEC_STATUS	(All)	▼
TS_STATUS	(All)	▼
CY_STATUS	(All)	▼
TC_EXEC_DATE	(All)	▼

Count of TS_NAME	TC_STATUS ▼		
CY_CYCLE	**Not Completed**	**Passed**	**Grand Total**
PIMS_RARITAN00000001-PE-AIS-DM-PI_Archive_Reprocessing	1	1	2
PIMS_RARITAN00000001-PE-AIS-DM-PI_Batch_Context_Migration		3	3
PIMS_RARITAN00000001-PE-AIS-DM-PI_Data_Migration		4	4
PIMS_RARITAN00000001-PE-AIS-DM-PI_RtReports_Migration		3	3
PIMS_RARITAN00000001-PE-AIS-DM-PI_WebParts_Migration		3	3
Grand Total	1	14	15

Deployment

Deployment – Validation approach (2)

- **LEAN (1)**
  - **Product** dependent documents – create/approve once

  - **Regional dependent documents (basic infrastructure) – create/approve once for each instance (EMEA, NA, ASPAC)**

  - **Local (site) dependent documents – create/approve once for each site connected to regional instance using standard templates**

Deployment

Deployment – Validation approach (3)

- **LEAN (2)**
  - **JSC wide SOP/WI - create/approve once**
  - **Reusable test scripts (create/approve once: execute many)**
  - **Risk based approach (GAMP 5) for PI System object validation**
    - **PI Tags**
    - **PI AF elements**
    - **PI Interfaces**
    - **...**

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Deployment

Deployment – Validation Business Case

- **Business cases identified during validation workshop to start using new validation approach**
  - **"Regionalization" - mandatory**
  - **HW/SW upgrade - evaluation**
  - **New implementations - mandatory**
  - **High support from global organization Center of Excellence (CoE) during full lifecycle of system (installation, operation, decommissioning)**

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Deployment – Validation – Benefits

- **Re-use of documents: Less creation/review/approval**

Benefits - less man-days needed		
Implementation	Min	Max
Local	10	15
Regional	20	30
Global	20	30

- **Re-usable test scripts**

Benefits - less man-days needed		
Implementation	Min	Max
Creation / approval	40	50
Execution / Review / Follow up	10	20

- **Exploit Enterprise Agreement (EA)**

- OSIsoft ⇔ SI – 10-20 mandays
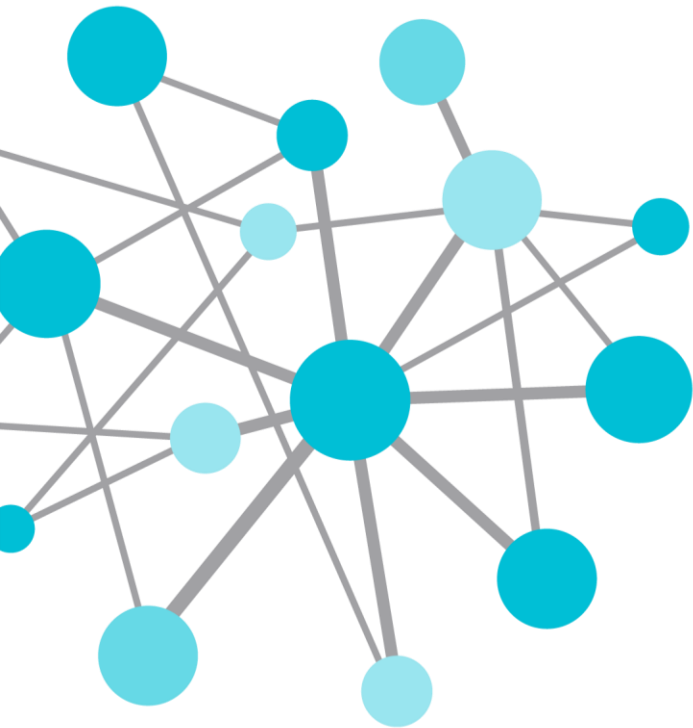
Deployment

Deployment – Validation – benefits

- Inspections
  - Uniform validation of PI System across Enterprise = No Surprises
  - No paper
    - All documents readily available
    - All executed test scripts / reviews readily available

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- J&J – Janssen Pharmaceutica

THANK YOU

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