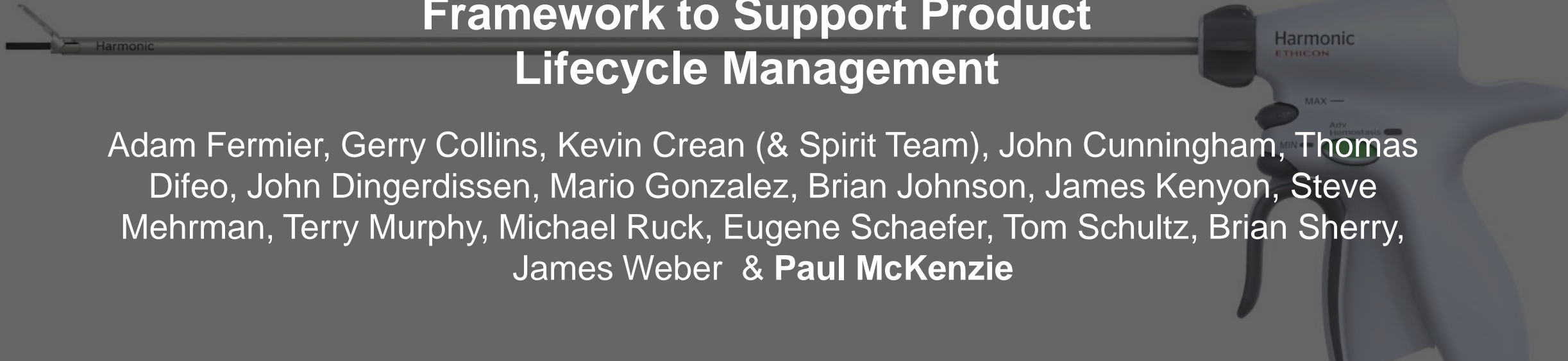# Lab to Patient Model Implementing a Recipe Based Framework to Support Product Lifecycle Management

Adam Fermier, Gerry Collins, Kevin Crean (& Spirit Team), John Cunningham, Thomas Difeo, John Dingerdissen, Mario Gonzalez, Brian Johnson, James Kenyon, Steve Mehrman, Terry Murphy, Michael Ruck, Eugene Schaefer, Tom Schultz, Brian Sherry, James Weber & **Paul McKenzie**

AGENDA

- My Journey with OSIsoft

- Product Lifecycle Management
  - Update on Recipe Framework (Content/Execution/Visualization)
  - Update on Data Efforts across JNJ

- What am I learning in Device ?

- Transformation Needed
  - How OSIsoft can help ?

My Journey with Recipe and How PI Fit In ?

Early 1990s - **POINTS**
- Excitement over 500, 2000 or more points
- Worrying what/why to promote to PI

Mid 1990s – **PLANTS**
- Utility & Alarm Monitoring
- Running Plants More Efficiently

Late 1990s/Early 2000s – **PROCESS**
- **S88** Standards for Select Process Segments (API)
- OSIsoft – PI ProcessBook & EVT (Satyam !!)
- **Enterprise Agreements**

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My Journey with Recipe and How PI Fit In ?

The 2000s - **Batch**
- S88 Expanding into Other Areas (Drug Product)
- S95 Starting to Drive Interface Standards
- "Review by Exception"

  - non Process Data Needed to Release Batches
- OSIsoft – RtReports, Asset Framework (AF)

Today – Product Life Cycle Management
- Need End to End Visibility of Product

  - From R&D Thru Commercial

  - From Raw Material to Patient

  - Thru use by customer in field   ??

The Numbers Game

- ➢ > 200
- ➢ > 2000
- ➢ >18000
- ➢ 29
- ➢ 130
- ➢ 0

Individual Product Families

SKUs

Raw Material SKUs

Internal Sites

External Sites

Products Made all Internally

	External Mfg	Procurement	Total
# of Partners	108	480	588
# of Sites	130	614	744
# of SKUs	2000	18,000	20,000

Recipe Framework

Link to the Regulatory Filing

CONTENT
 Product & process
Critical Parameters & Steps
 Structured in S88 Format

Regulatory Filing in Recipe Format

Site Executable Recipe

VISUALIZATION
Critical Parameters & Steps
Context rich data

EXECUTION
Data generated in S88 Format
Contains additional site details
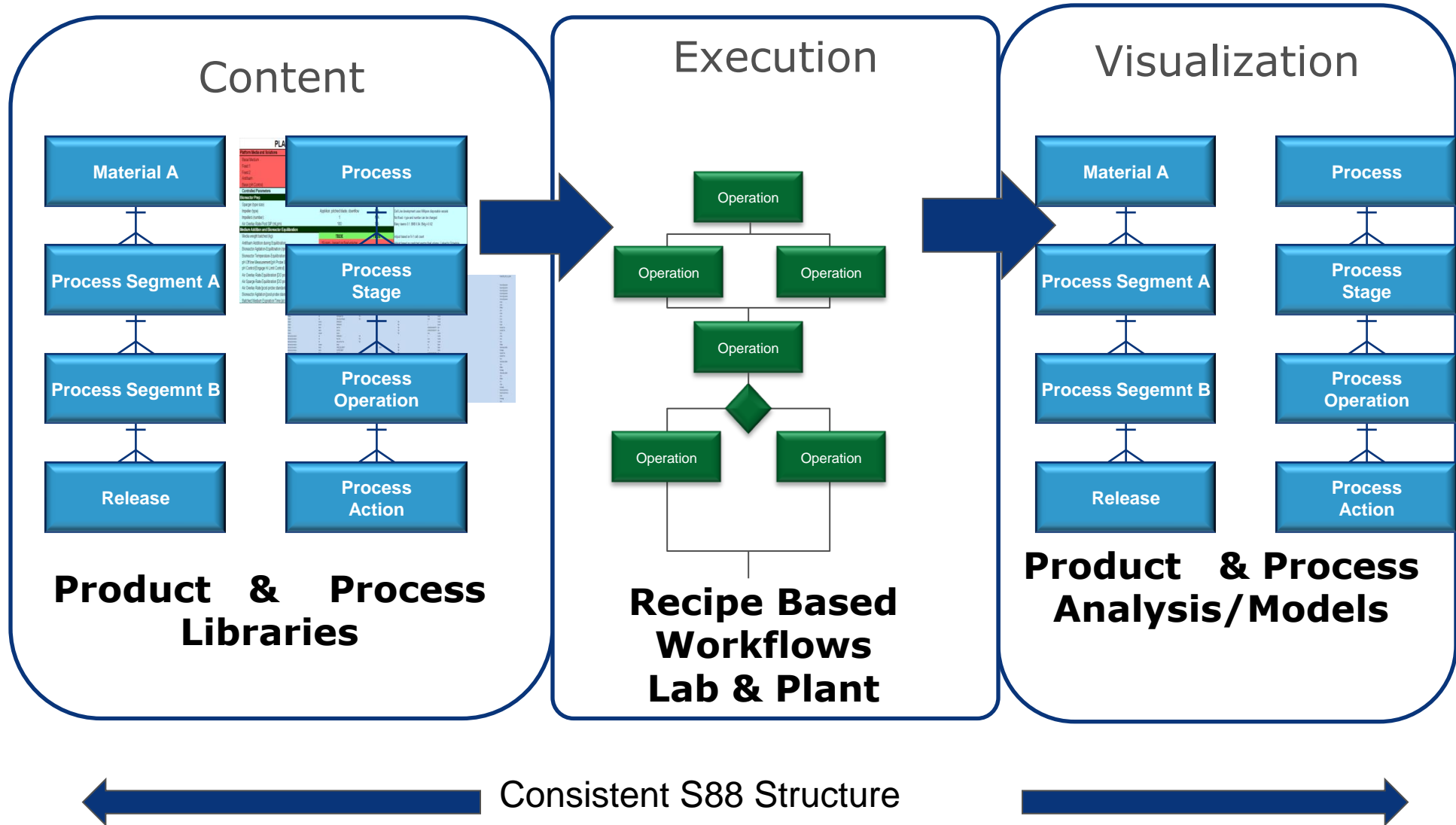
End to End View of Product
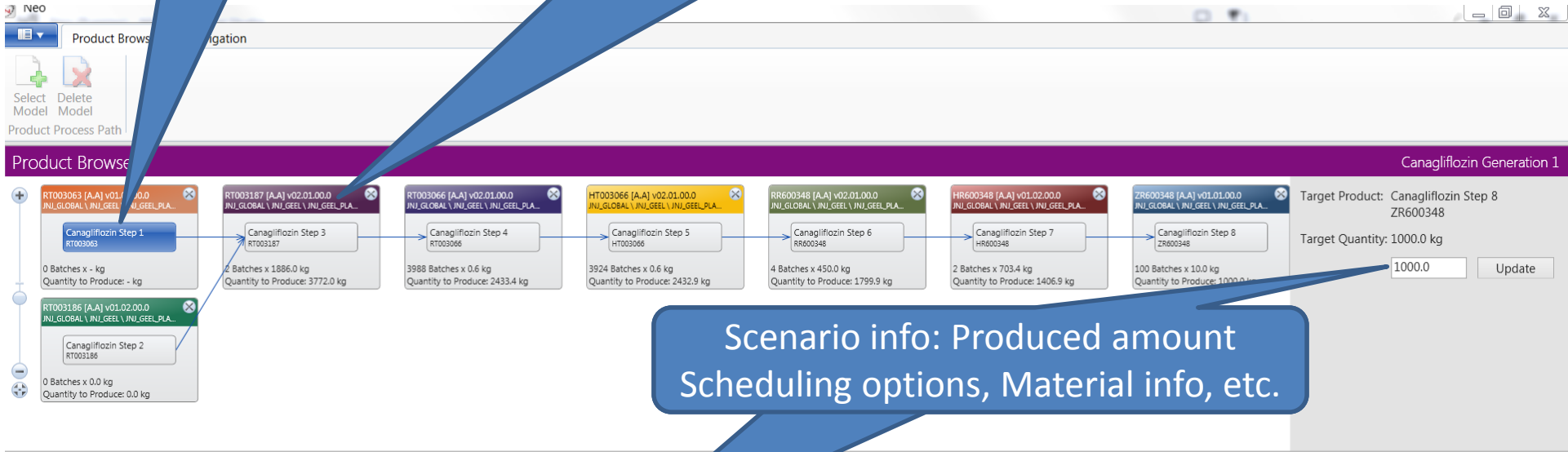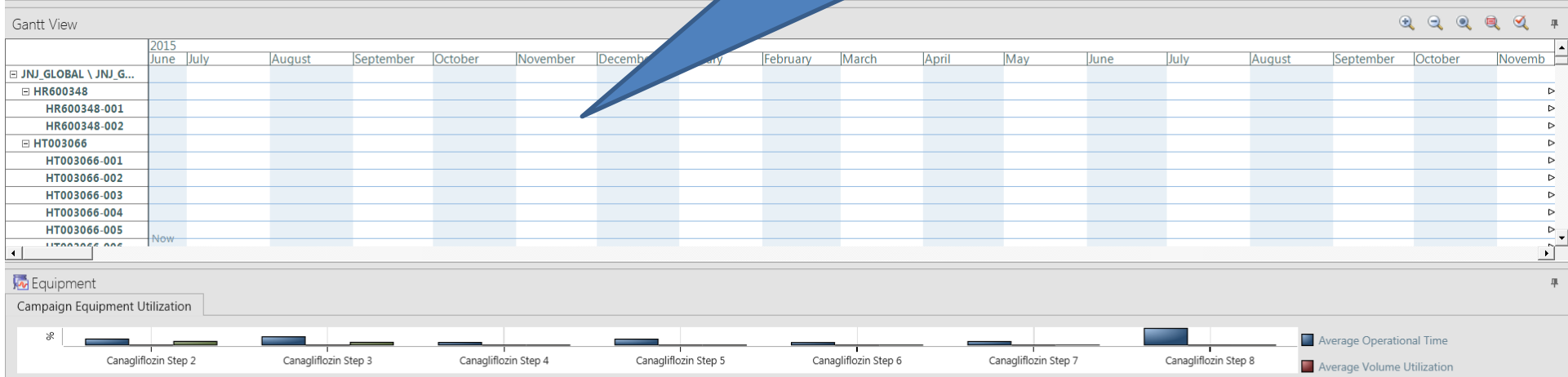
General Recipe – Process Definition with Quality Constraints

CQA for Chiral Purity mapped to CPPP for wash quantity

Mobility

- PI System **available** via IT Standard JNJMOBILITY Network *(Edge Client)*

- **Process and Energy** Data visualized on iPads/ iPhones

- Data from **any** location with the PI System can be visualized on wireless devices. PI Cloud Access! –Possibility of more freedom of data access from outside JNJ.

- **Connected** with Global Mobility Team
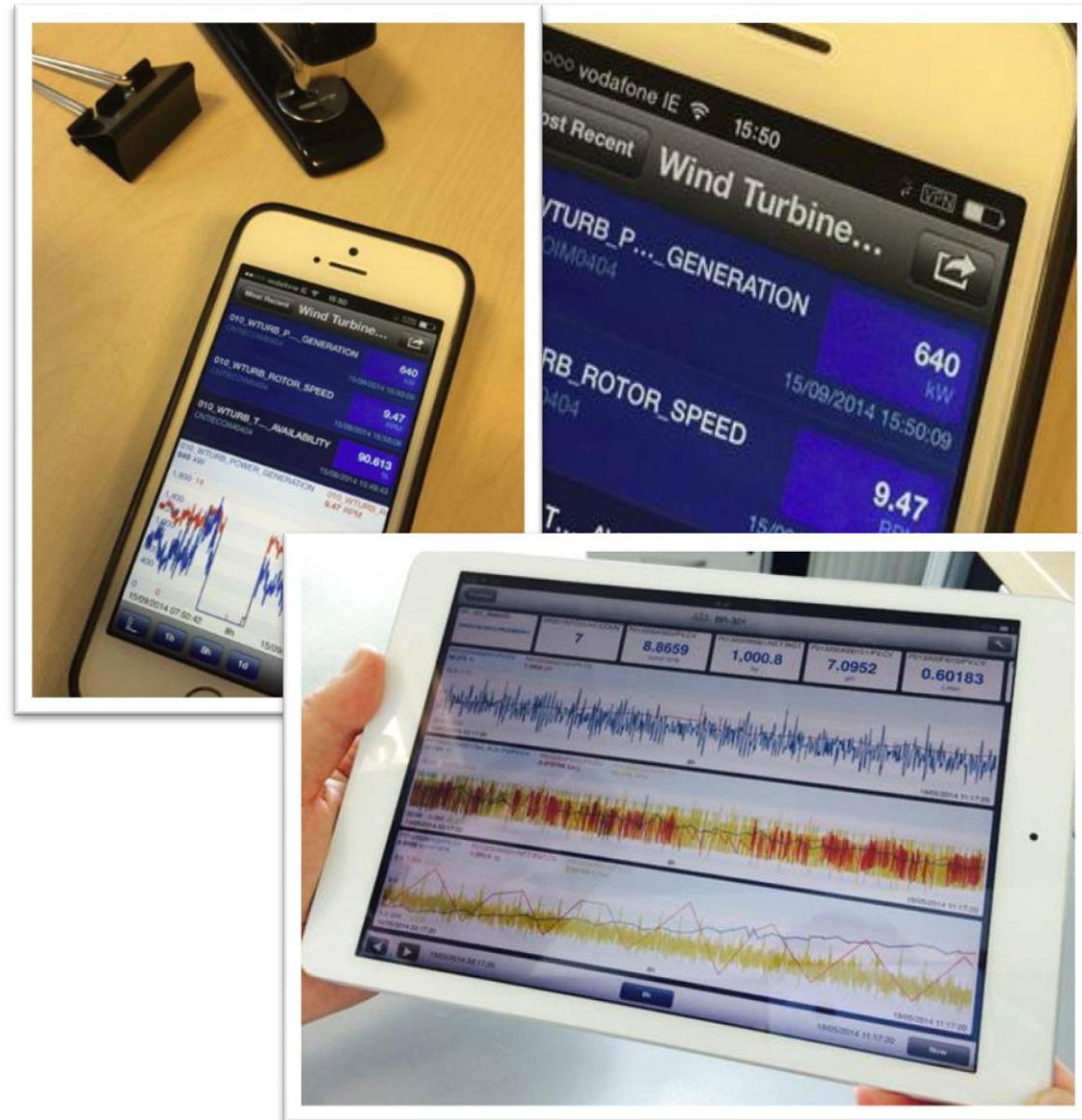
PI Cloud Connect

- External Partner AF Template and Elements to **SPIRIT Global Standard and** Integrated to **JNJ Global AF DB -** Automatically visualized on SPIRIT Process Visualization Module
- External Partner Team: SPIRIT, OSI Soft and Partner.
- Connecting with Global IT – Security Assessment on application approach, data integrity and alignment with JNJ Global Standards.
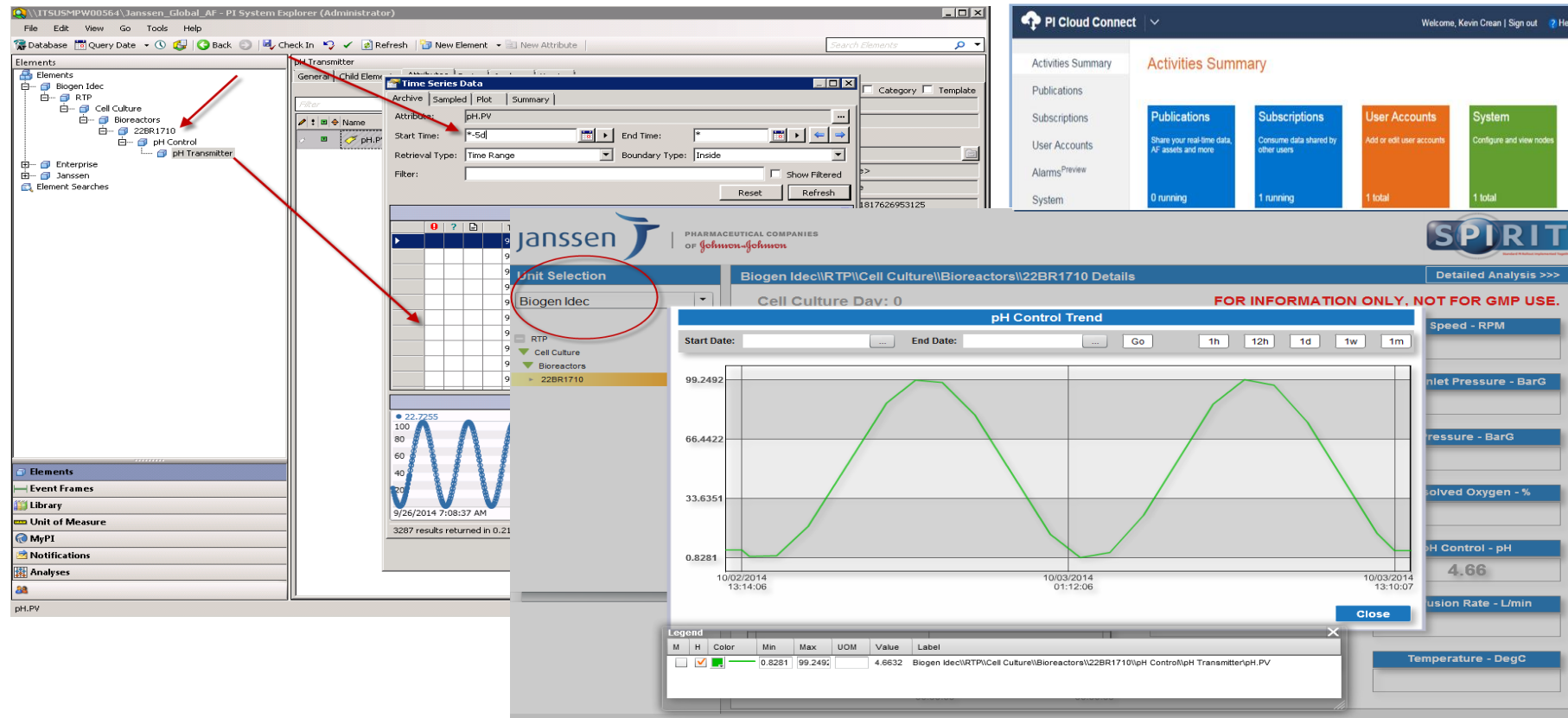
Global Content - Connecting PI Cross Platform/ Cross Sector Capability

Regional PI Servers – Supporting Sites with **NO LOCAL INSTANCE**

Global AF Server S88 Model – *Interconnecting all PI System across all site and platforms – **11 Pharma Sites Connected***

- Consumer
- Pharma
- MD&D

http://gisfv.jnj.com/facilityviewer/index.html
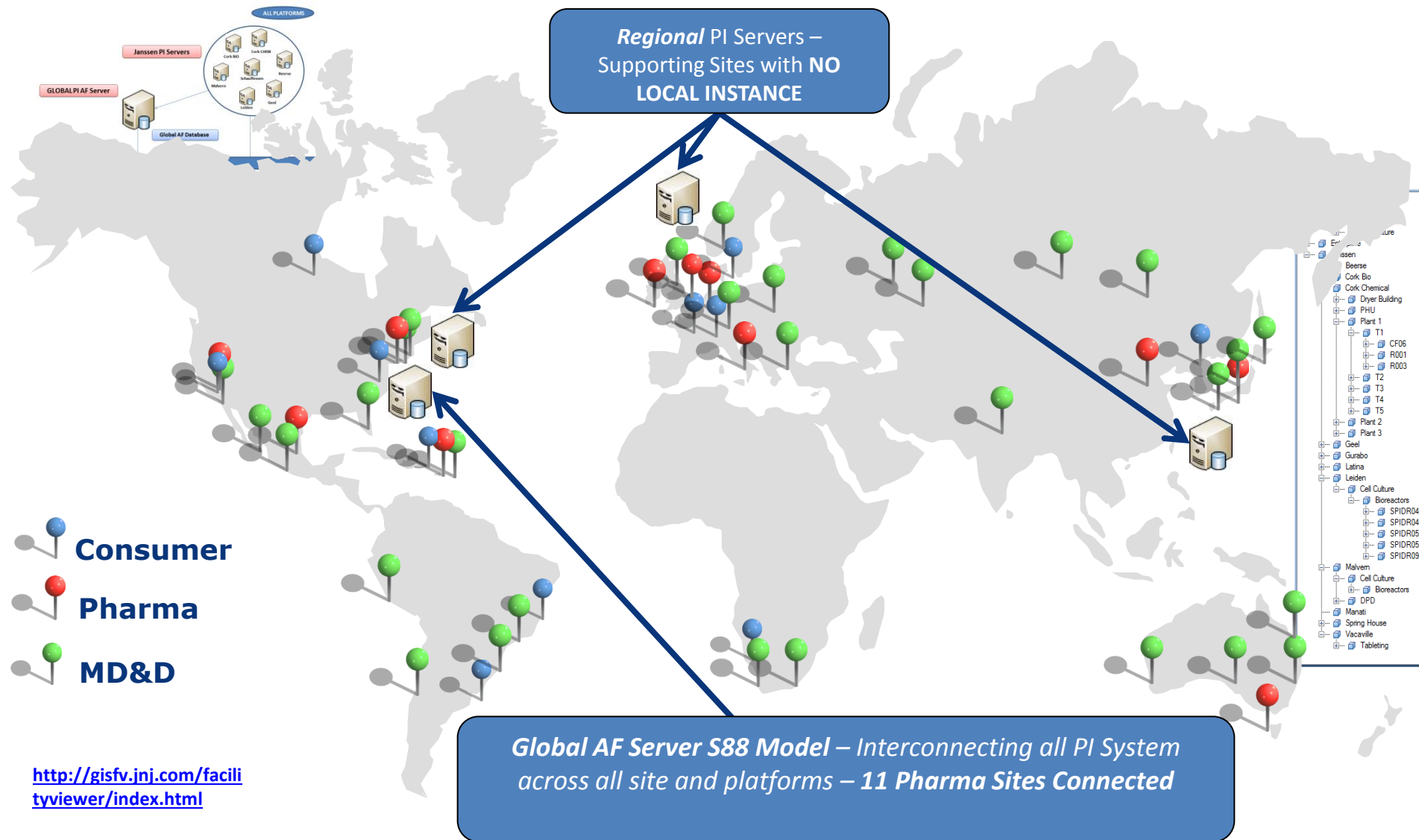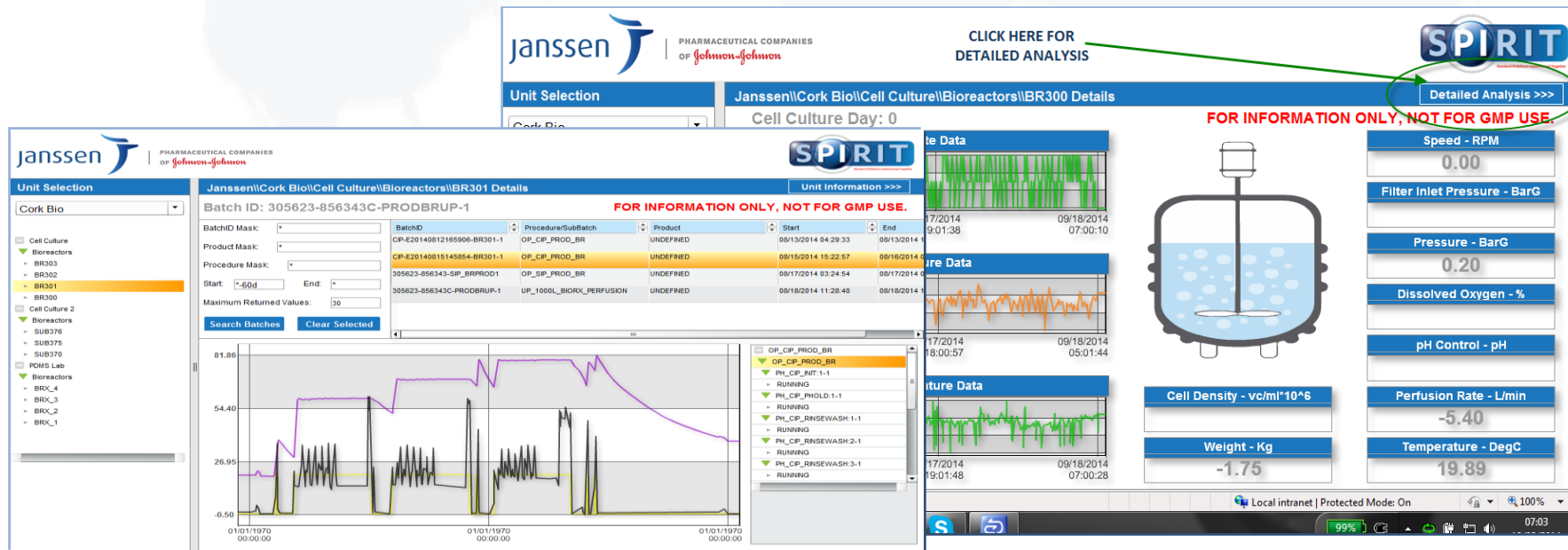
Global Interconnected Standard Visualization
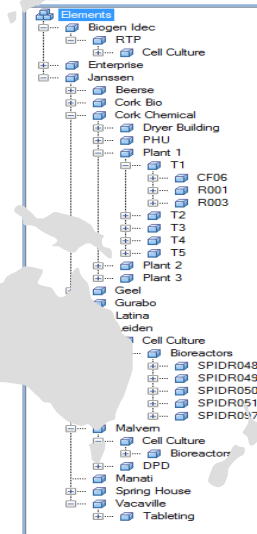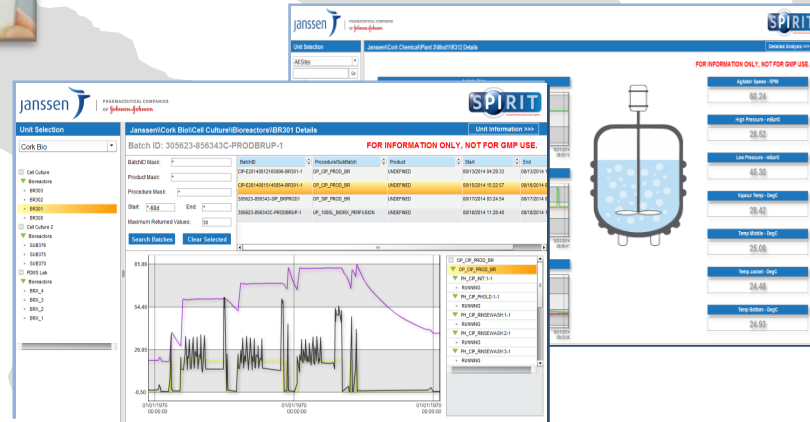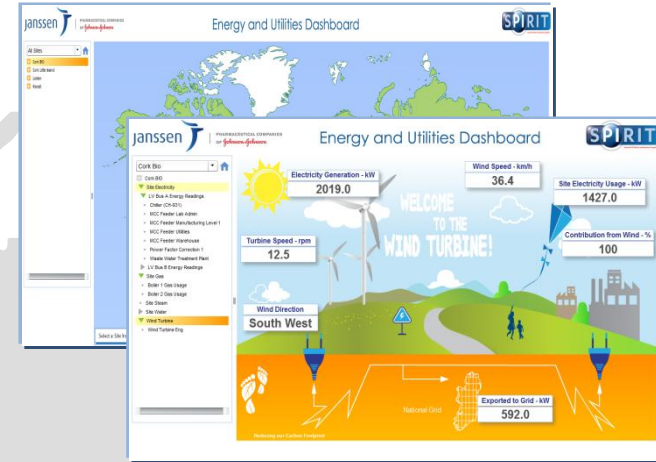
Global Interconnected Standard Visualization

- Interconnect – All JNJ PI Servers / Unit Data
- Regionalized PI Coresight – US and EMEA
- Regionalized Livepoint – EMEA
- Standard Application Implementation Approach – JNJ and Developers
- Defining the approach together across the enterprise.

Data Intelligence

http://jaciecopis5:7823/livepointclient3.1Mod7.swf?url=jaciecopis5&login=open2&nopasswd=1

Global AF & Energy Monitoring
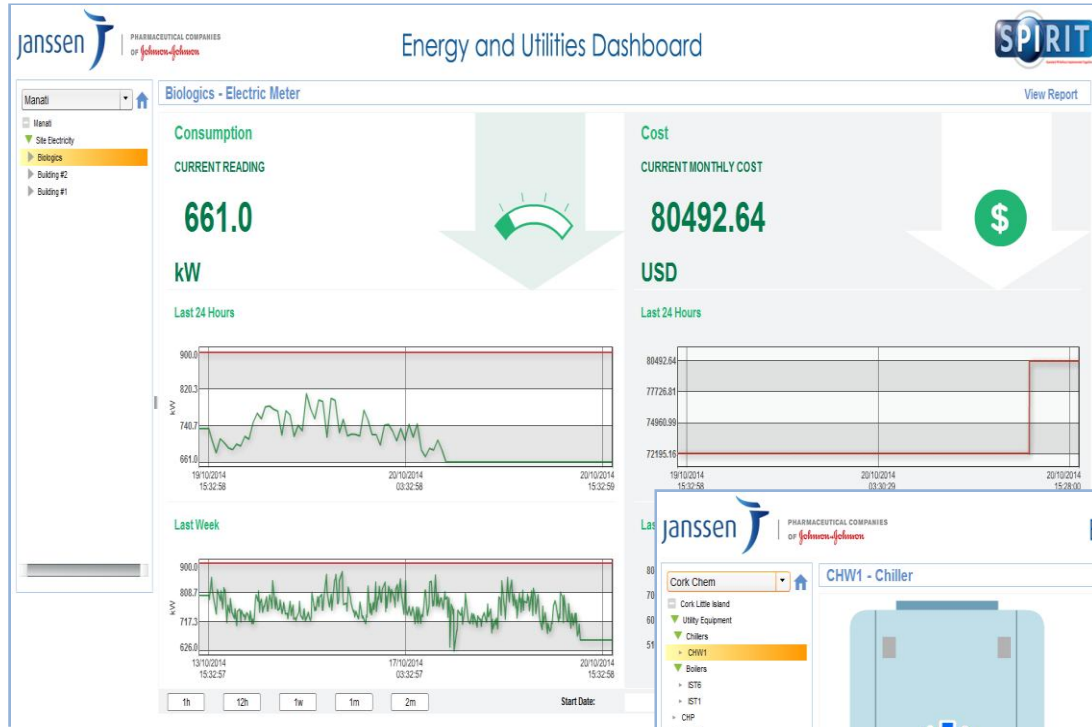
- **First!** Meter Templates – Standardized Visualizing Usage
- **Now!** Commenced definition of Content Standards for Utility Equipment
- **Now!** Visual template linked to Global AF
- **Same Approach** – Any site/ anywhere

APPLICATION LINK

http://jaciecopis5:7823/livepointclient3.1Mod14.swf?url=jaciecopis5&login=openenergy&nopasswd=1
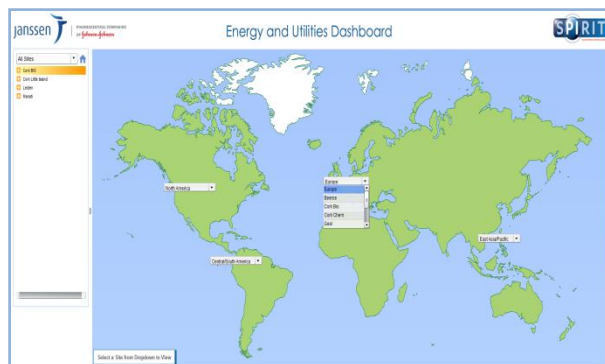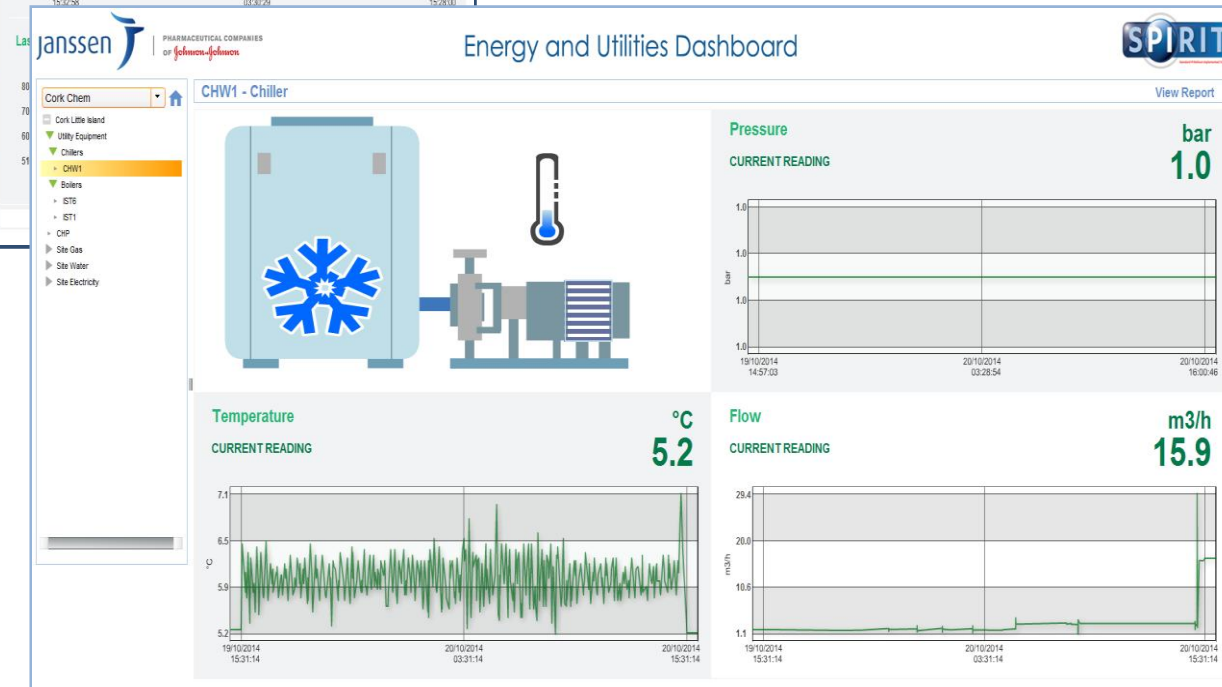
Fette Standardization

WORK STREAMS

Business Manufacturing Operation Management

Business Process Modeling
- Recipe and Parameters Definition
- Recipe Execution
- Alarm and Events Mng
- Review and Reporting

Fette System Lifecycle
- URS
- Commissioning & Qualification
- Operational Management and Control procedures

Standard PI Framework

Global Fette Standard PI Templatization

Global Interconnected Standard Visualization

Implementation Playbook

Integrated Virtual Fette Lab
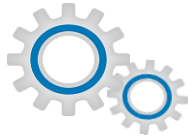
Off-line Fette System Simulator

Establishing a collaboration Fette-centric platform and knowledge repository

BENEFITS

- Design and deploy a set of standards and practices governing the PI integration of FETTE technology
- Optimize manufacturing operation processes throughout product lifecycle
- Enable effective end-to-end integrated data management
- Forge internal collaboration by sharing best common practices, process education and training

TEAM

- **Business Point of Contact :** Serve as focal point of information concerning PI system usage, business benefit actualization, change agent, operational readiness, potential improvement & optimization opportunities.
- **Technical Team:** Responsible for the implementation, availability, support and maintenance of technology solutions and applications.

Continued Process Verification
Single approach for Automation
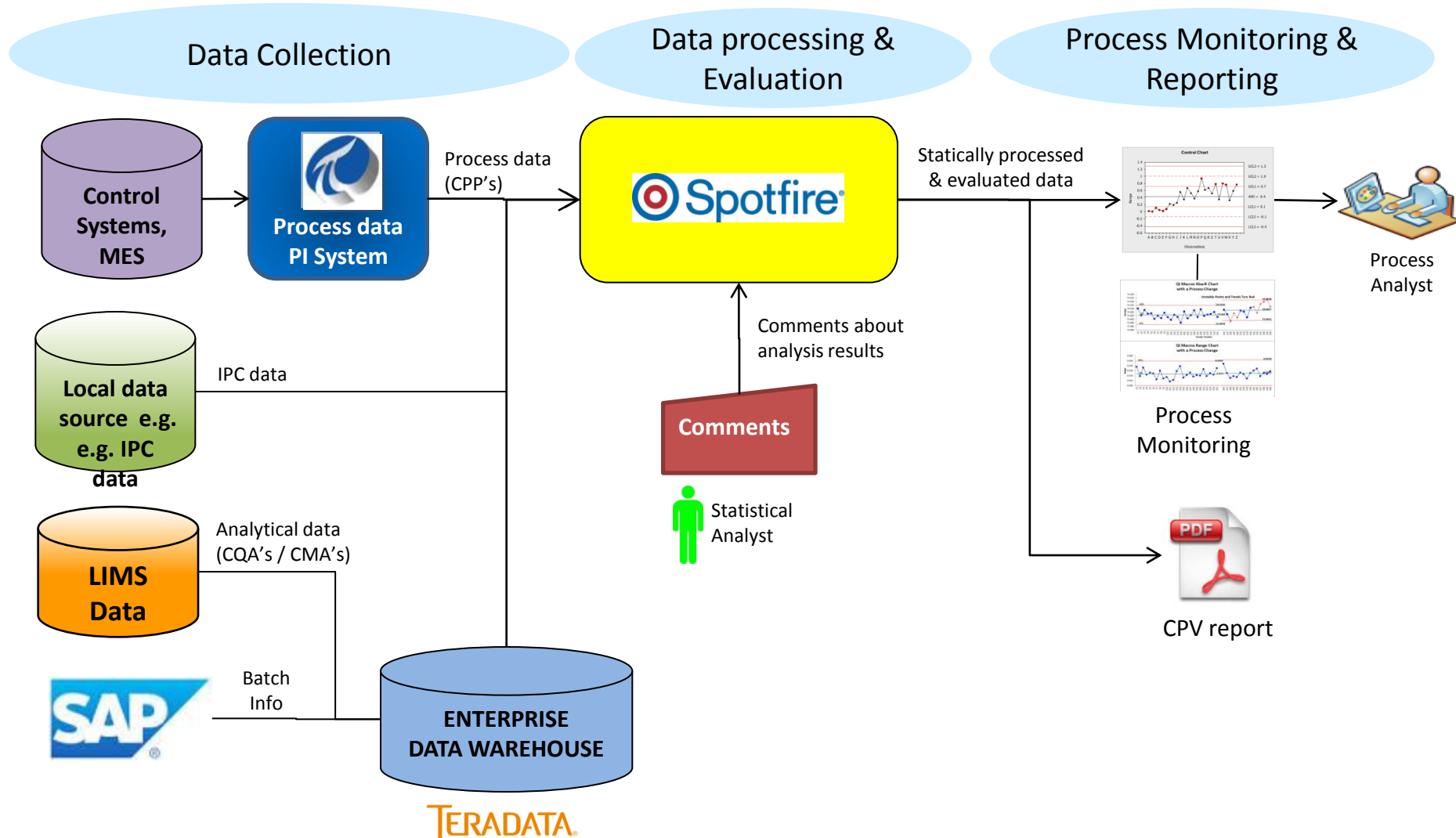
What I am realizing now that I am in Medical Device !!!

Digital World

Physical World

??
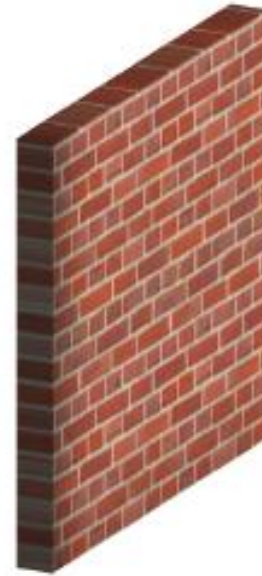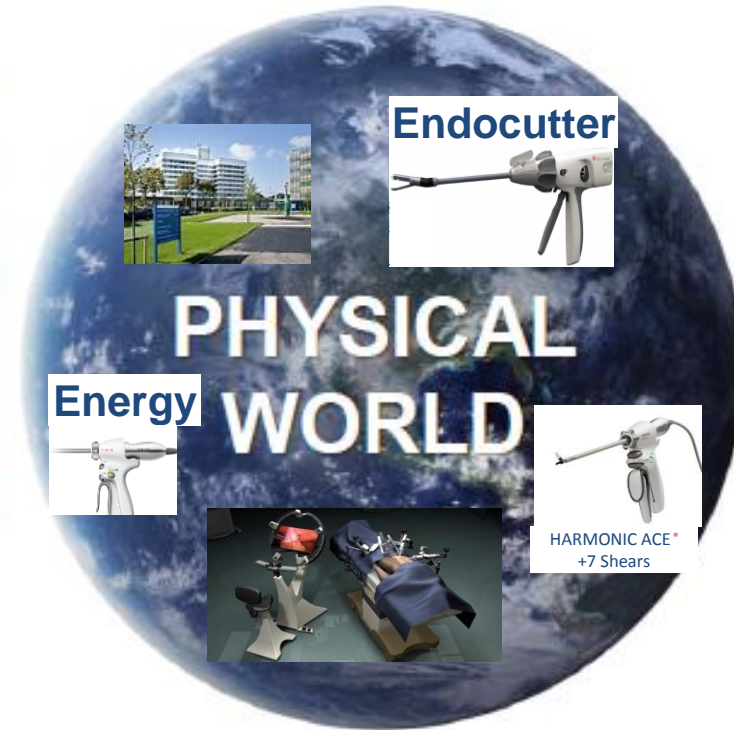
Current Practice of Software Update for Ultrasonic Generators

- No direct communication between Server and generators
- Global Generator Footprint (**~30,000**, 2018 **~40,000**)
- Increasing burden on sales force (~1 hr/generator)

eRSVP
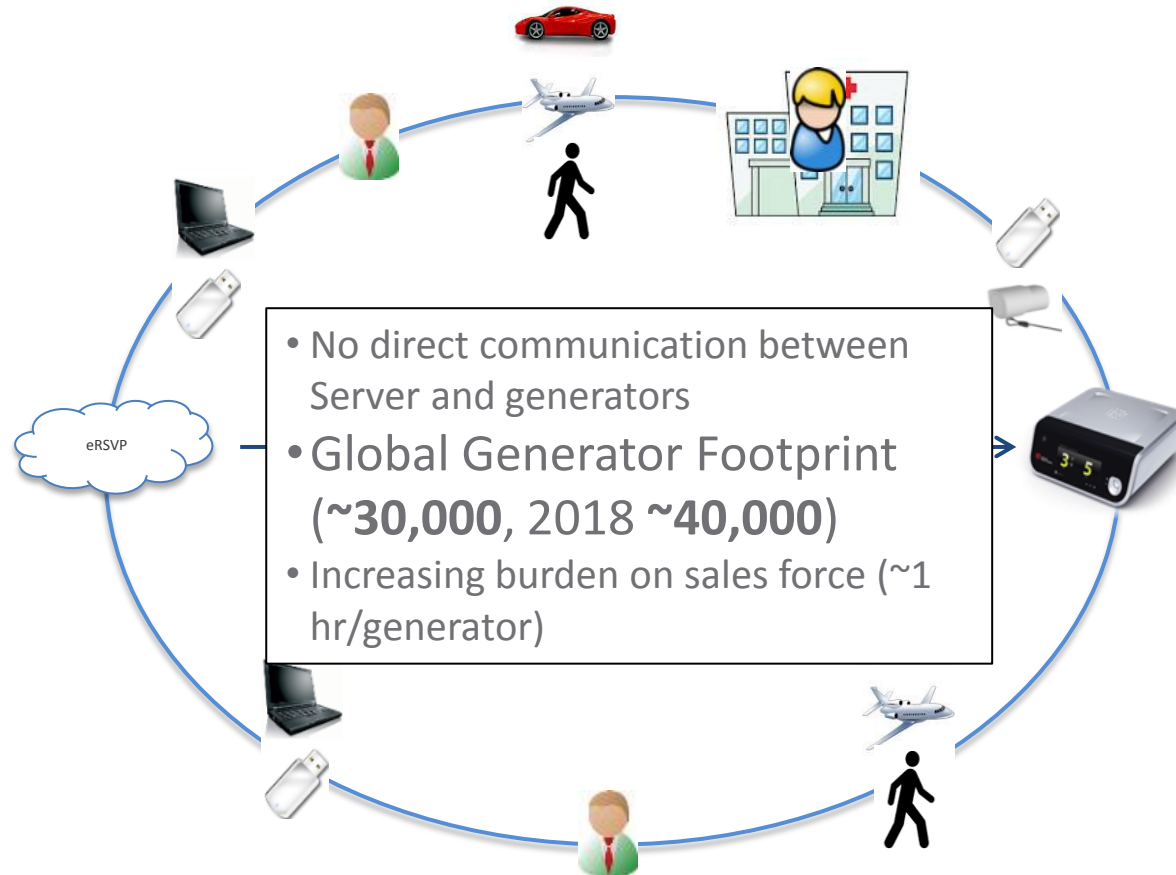
Key Challenges

Long and manual software updating process

Slow response to generator functional failure

Lack of understanding about generator usage information

Establishing an Automated Two-way Communication Network

Future State

Solution Benefits

Fast and automated software update process

minimizes human involvement and provides greater flexibility for software deployment

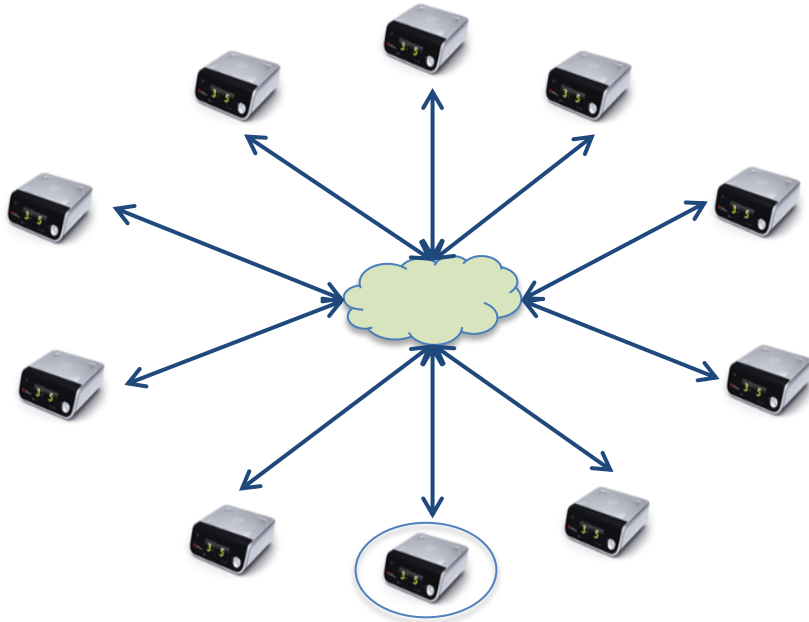**Generator operating status monitoring and diagnosis**

minimizes the likelihood of generator service interruption and leads to higher customer satisfaction

Generator Data Collection

instant and reliable data collection and analysis, enabling commercial option deployment, new business models, and improved strategic planning

Conclusions:

- To establish a sustainable approach to quality by design a long term strategy is being implemented for CONTENT/EXECUTION/Visualization
  - Data centric = data based versus document based

- Leveraging the S88/S95 standards has proven applicable to all process and lab segments

- Making Progress across the board!

- We still have more to do to connect to field !

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