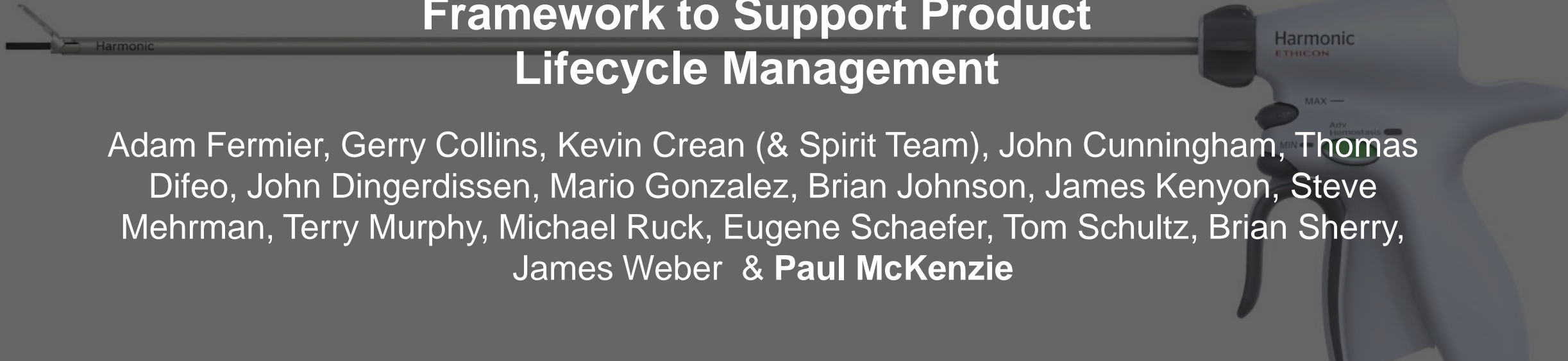




Shaping
the future
of surgery

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**

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

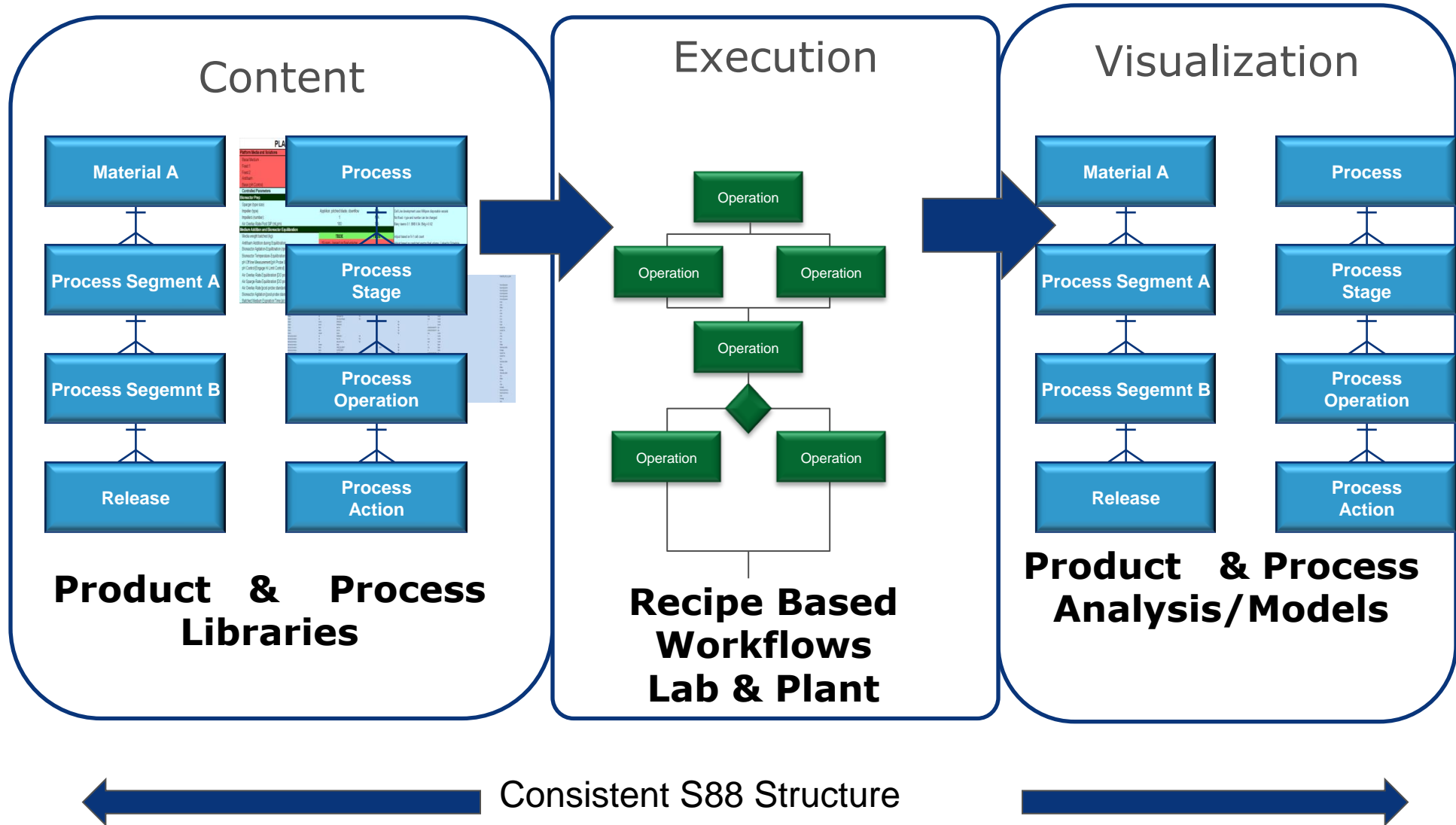
Internal Sites

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

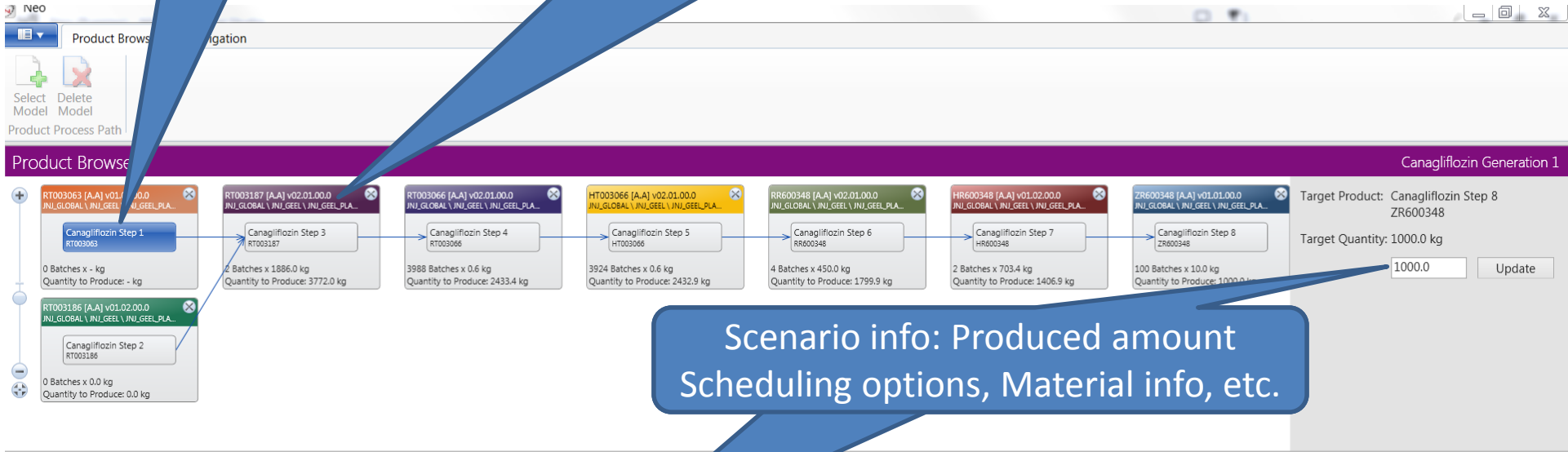
Recipe Framework



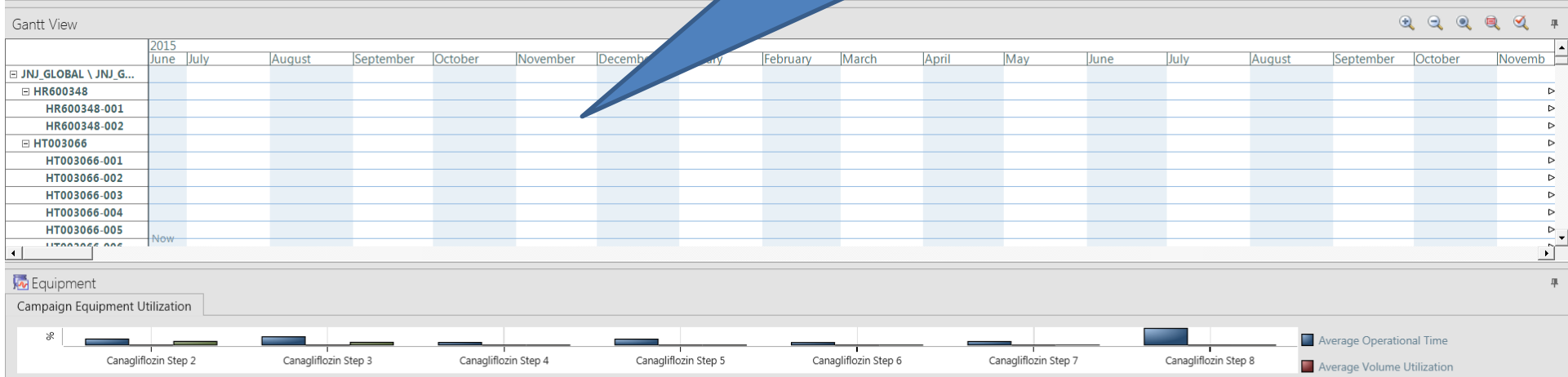
End to End View of Product

Inner box is synthesis step

Outer box is selected Design scope. A design could encompass multi-steps



Scenario info: Produced amount
Scheduling options, Material info, etc.



General Recipe – Process Definition with Quality Constraints

The screenshot displays the Neo software interface for process definition. The main design area shows 8 units (A-J) with their respective components and parameters. The instructions table at the bottom provides a detailed view of the process steps, including time, process actions, instruction text, and operating targets.

	Time (hrs)	Process Action	Instruction Text	Comm with	Operating Target	Process Range	Supplementary Note
A/1	0.00	CHG Liquid1	Charge the indicated amount of Isopropyl Acetate:		1.9 kg		
A/2	0.00	CHG Liquid2	Charge the indicated amount of Water:		0.0 kg		
A/3	0.07	AdjAgit1	Start agitation and agitate for the indicated amount of time:		30.00 min		
A/4	0.58	CHG Solid1	Charge the indicated amount of RR 600348:		0.7 kg		
A/5	1.08	AdjTemp1	Adjust vessel temperature to the indicated target:		65.0 °C		
A/6	1.09	AdjAgit2	Start agitation and agitate for the indicated amount of time:		30.00 min		
A/7	1.60	XFR Liquid1	Perform total transfer to Unit B.	B/1 B.Filter1			
B/1	1.60	Filter1	Receive slurry from Unit A.	A/7 A.XFR Liquid1			

CQA for Chiral Purity mapped to CPP for wash quantity

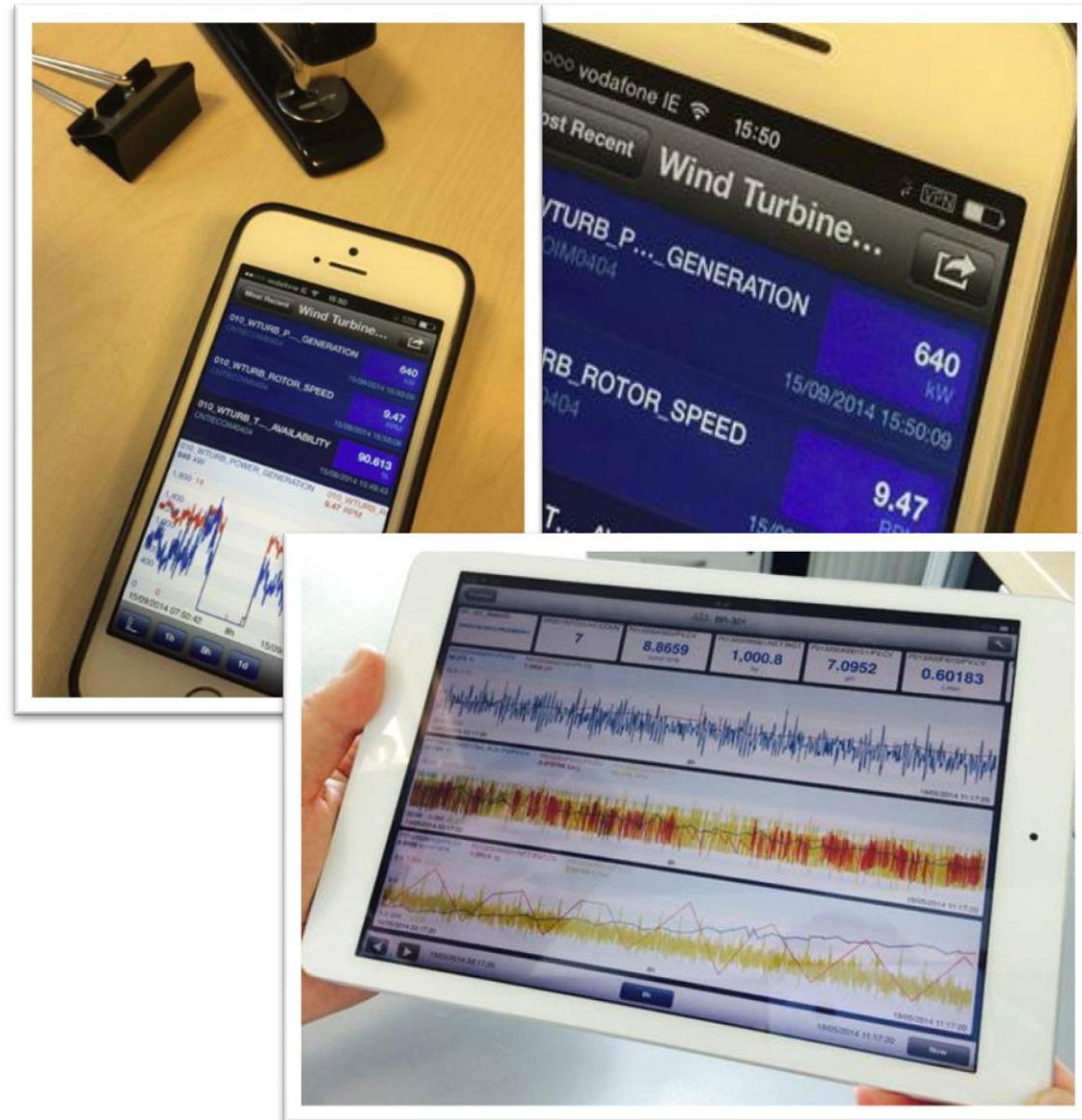
The screenshot displays the Neo software interface for process design. The top menu includes View, Edit, Lifecycle, Limits, PV Trend, Comments, Stages, and Navigation. The main workspace shows a 'General Design' view with eight units (A-H) and their associated parameters. A 'Limits' table is visible at the bottom, detailing various process limits and their classifications. Three callout boxes provide context for the mapping of CQA to CPP:

- Mapped parameter classification:** Points to the 'Criticality Classification' column in the Limits table, which shows 'FinalStepCritical' for the 'Purity - Chiral' limit.
- Mapped parameter name and step:** Points to the 'Parameter Name' column, showing 'F.CHG Liquid1.Mass' for the 'Purity - Chiral' limit.
- Mapped parameter source design:** Points to the 'Source Design' column, showing 'HT003066 v03.00.00' for the 'Purity - Chiral' limit.

LimitType	Name	Associated Tasks	Limit Category	Description	Classification	Source Design	Parameter Name	Criticality Classification	Critic...
Sample Limit	Purity - Chiral		Regulatory	HPLC test for chiral purity	CriticalQualityA...	HT003066 v03.00.00	F.CHG Liquid1.Mass	FinalStepCritical	0
Yield Limit	Yield Limit		Action	Expected Yield: 100.0% Standard Range: 0.0 %-100.0 %	None				
Temperature Limit	Cool to 34 to 42 DegC	E/03/VSLTMP-36C C/08/VSLTMP-40C	Regulatory	Mixture temperature between limits (inclusive) of 34.0 *...	None				
Temperature Limit	Cool Gradually to -5 to 15 DegC	F/04/VSLTMP-0C	Regulatory	Mixture temperature between limits (inclusive) of -5.0 *...	None				
Temperature Limit	Cool to 49 to 58 DegC	C/05/VSLTMP-52C	Regulatory	Mixture temperature between limits (inclusive) of 49.0 *...	None				
Duration Limit	Dry for 2hr to 68hr	J/02/DRY-70C	Regulatory	Duration of Unit J : Dry1 must be between limits (includ...	None				
Duration Limit	Stir for at least 1hr30min to 14hr3...	C/07/MONITOR-AGIT	Regulatory	Duration of Unit C : AdjAgit1 must be between limits (in...	None				
Duration Limit	Stir for at least 20min	A/06/MONITOR-AGIT	Regulatory	Duration of Unit A : AdjAgit2 must be between limits (in...	None				
Temperature Limit	Heat to Reflux	C/03/VSLTMP-80C	Regulatory	Mixture temperature between limits (inclusive) of 70.0 *...	None				

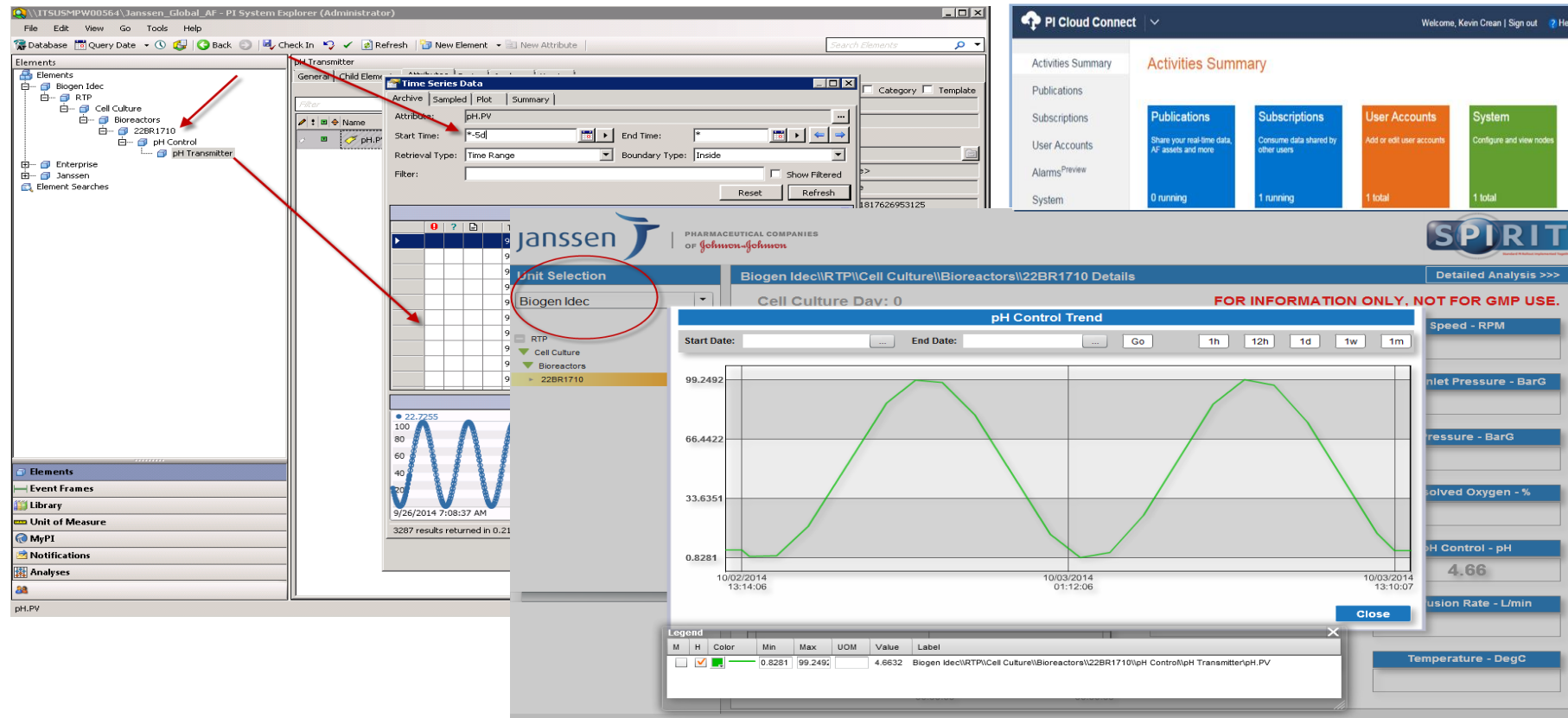
Mobility

- 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

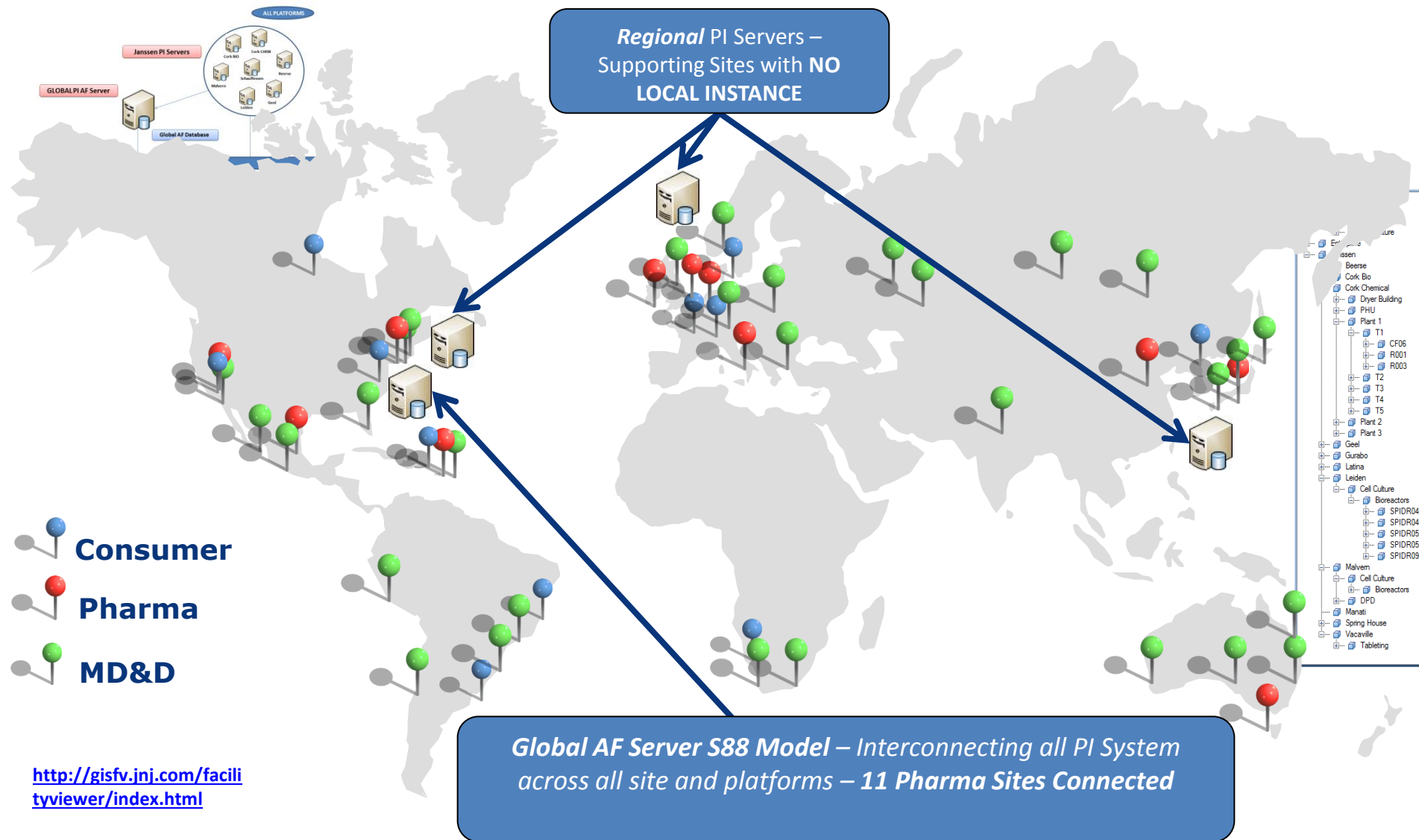


PI Cloud Connect

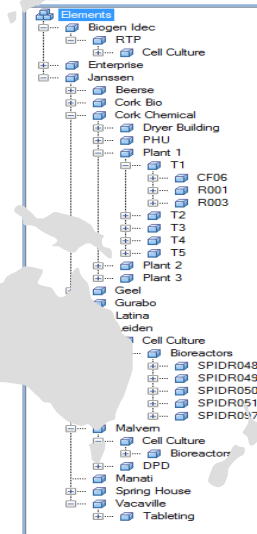
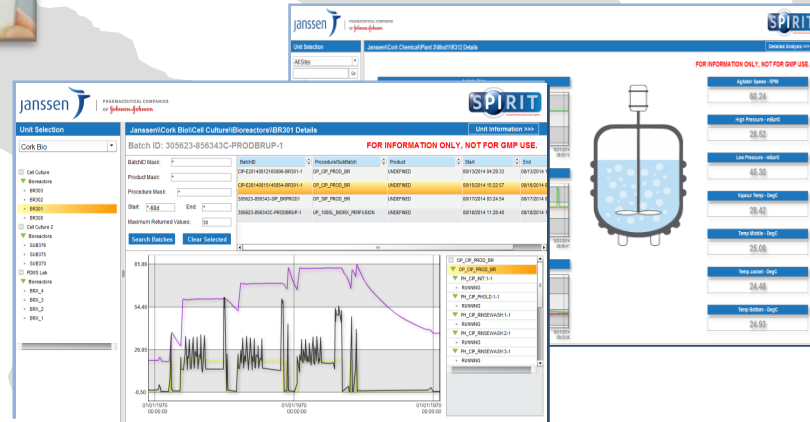
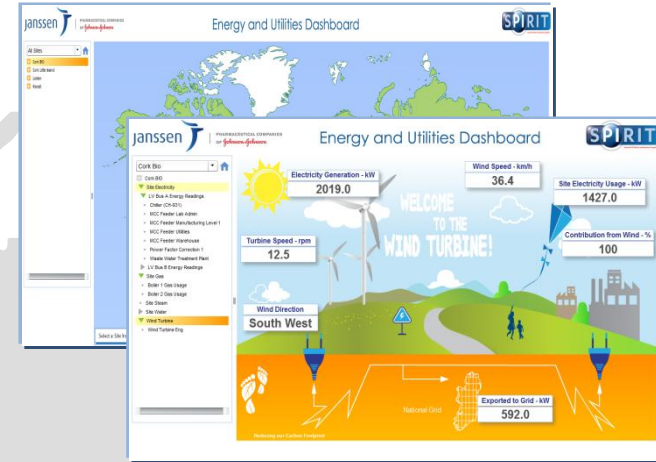
- External Partner AF Template and Elements to **SPIRIT Global Standard and** Integrated to **JNJ Global AF DB** - Automatically visualized on SPIRIT Process Visualization Module
- External Partner Team: SPIRIT, OSI Soft and Partner.
- Connecting with Global IT – Security Assessment on application approach,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



Global Content - Connecting PI Cross Platform/ Cross Sector Capability

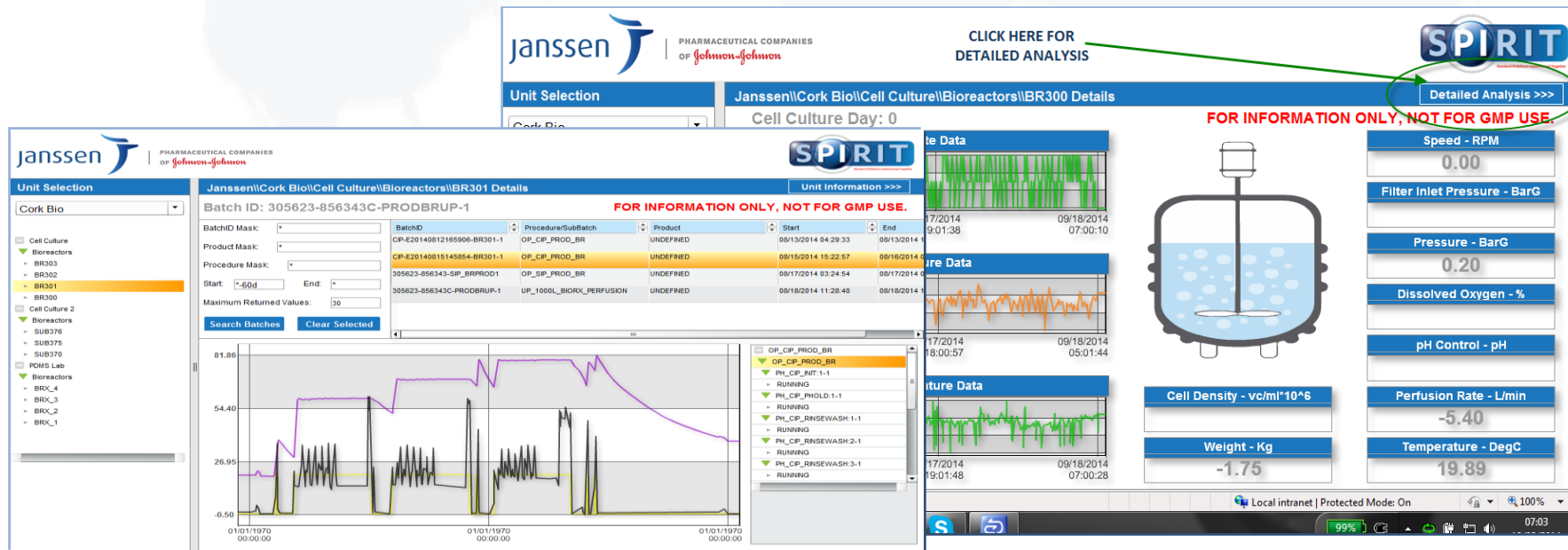


Global Interconnected Standard Visualization



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.



Unit Selection | Janssen\Cork Bio\Cell Culture\Bioreactors\BR300 Details

Batch ID: 305623-856343C-PRODBRUP-1

BatchID	Procedure/SubBatch	Product	Start	End
CP-E20140812165906-BR301-1	OP_CP_PROD_BR	UNDEFIN	08/13/2014 04:29:33	08/13/2014 07:00:10
CP-E20140815145854-BR301-1	OP_CP_PROD_BR	UNDEFIN	08/15/2014 15:22:57	08/16/2014 07:00:10
305623-856343-SIP_BRPROD1	OP_SIP_PROD_BR	UNDEFIN	08/17/2014 03:24:54	08/17/2014 07:00:10
305623-856343C-PRODBRUP-1	UP_1000L_BIORX_PERFUSION	UNDEFIN	08/18/2014 11:28:40	08/18/2014 07:00:10

FOR INFORMATION ONLY, NOT FOR GMP USE

Cell Density - vc/ml*10⁶: -1.75

Temperature - DegC: 19.89

Perfusion Rate - L/min: -5.40

pH Control - pH: 0.20

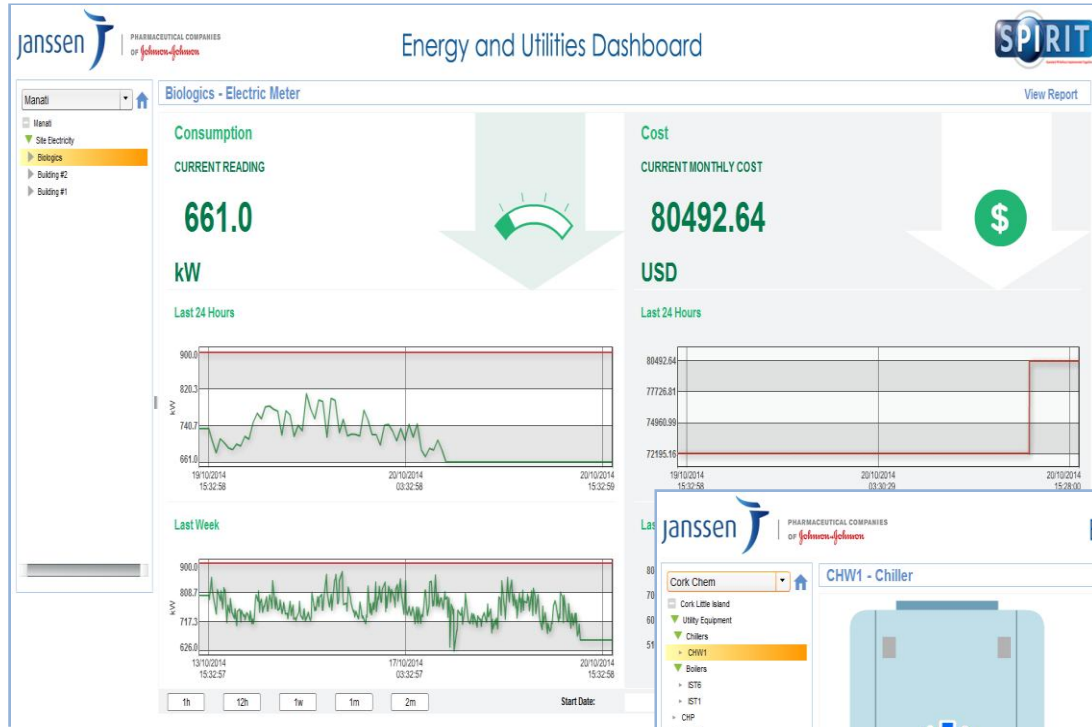
Pressure - BarG: 0.20

Filter Inlet Pressure - BarG: 0.00

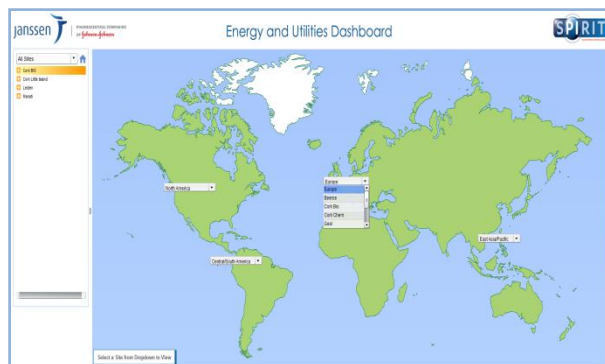
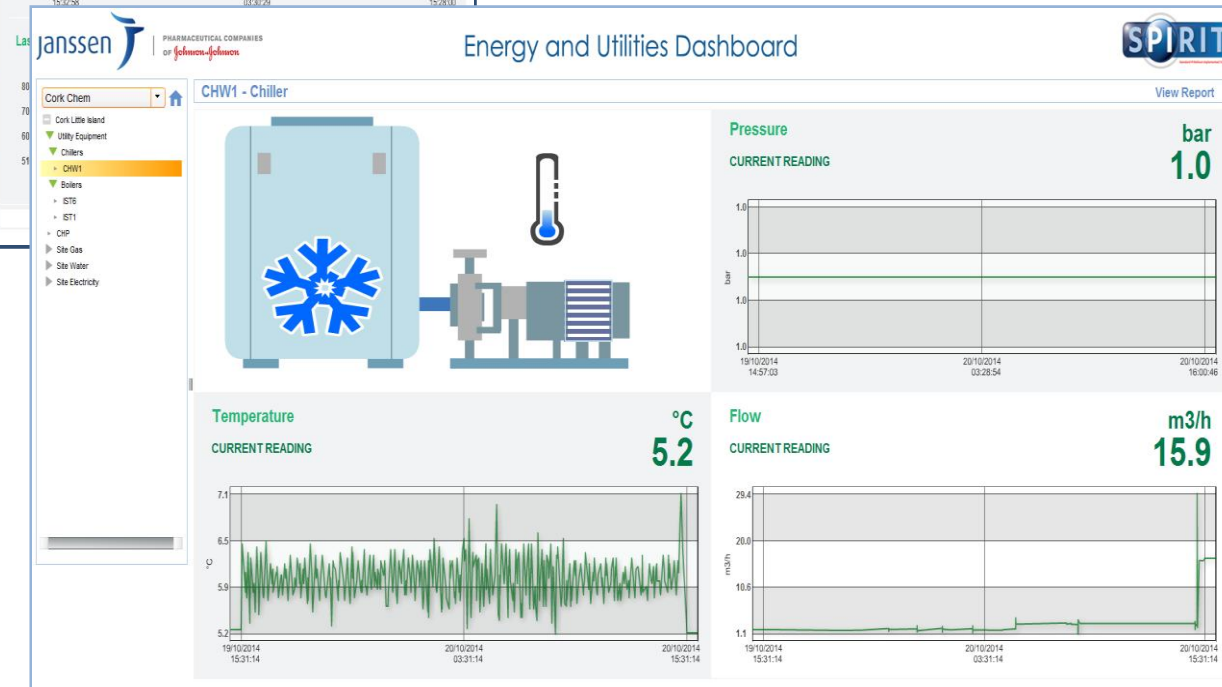
Speed - RPM: 0.00

<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

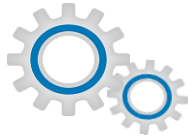


APPLICATION LINK

<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

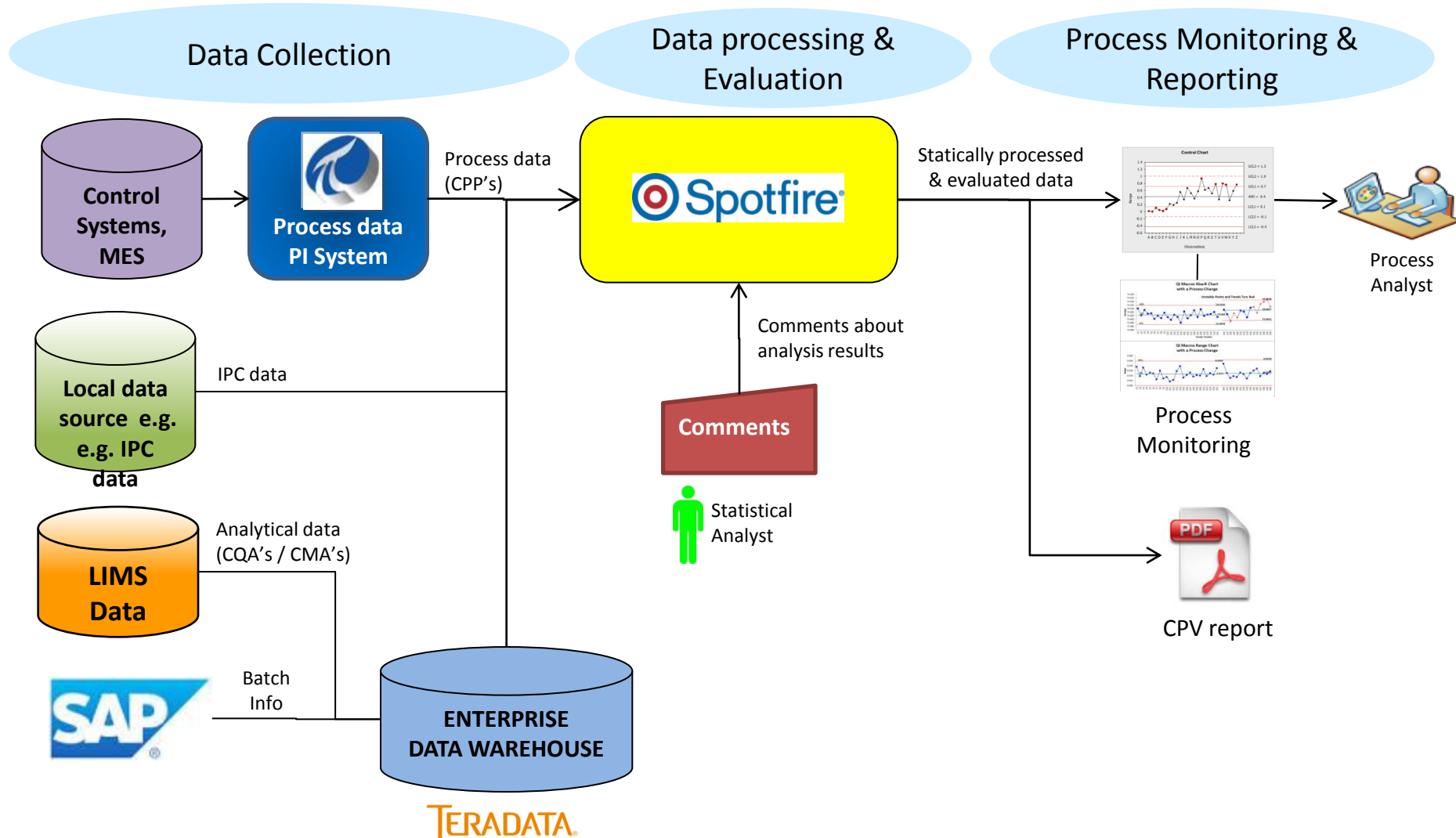
TEAM



- **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

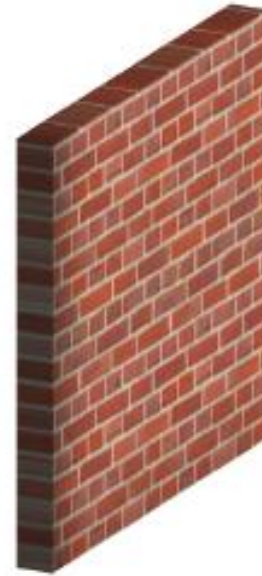
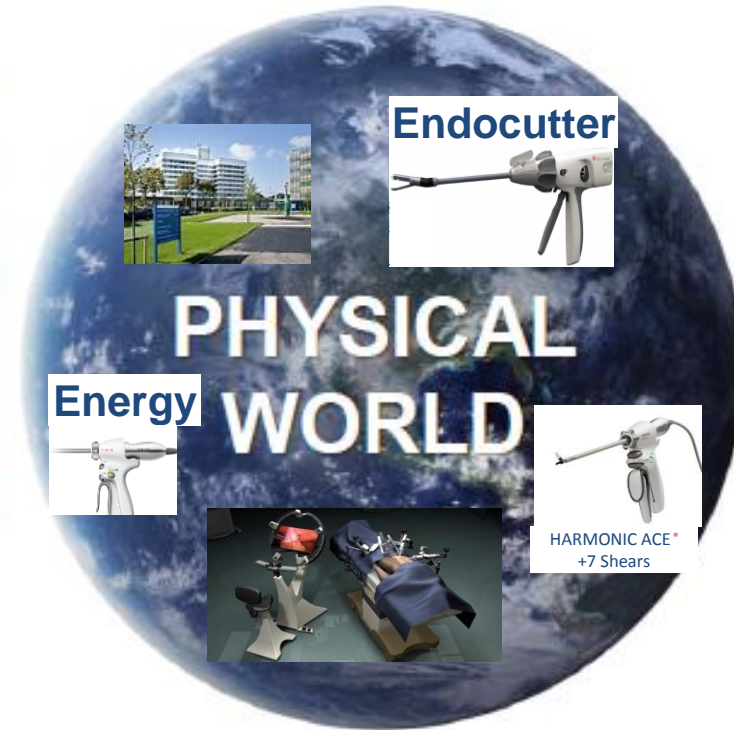


What I am realizing now that I am in Medical Device !!!

Digital World

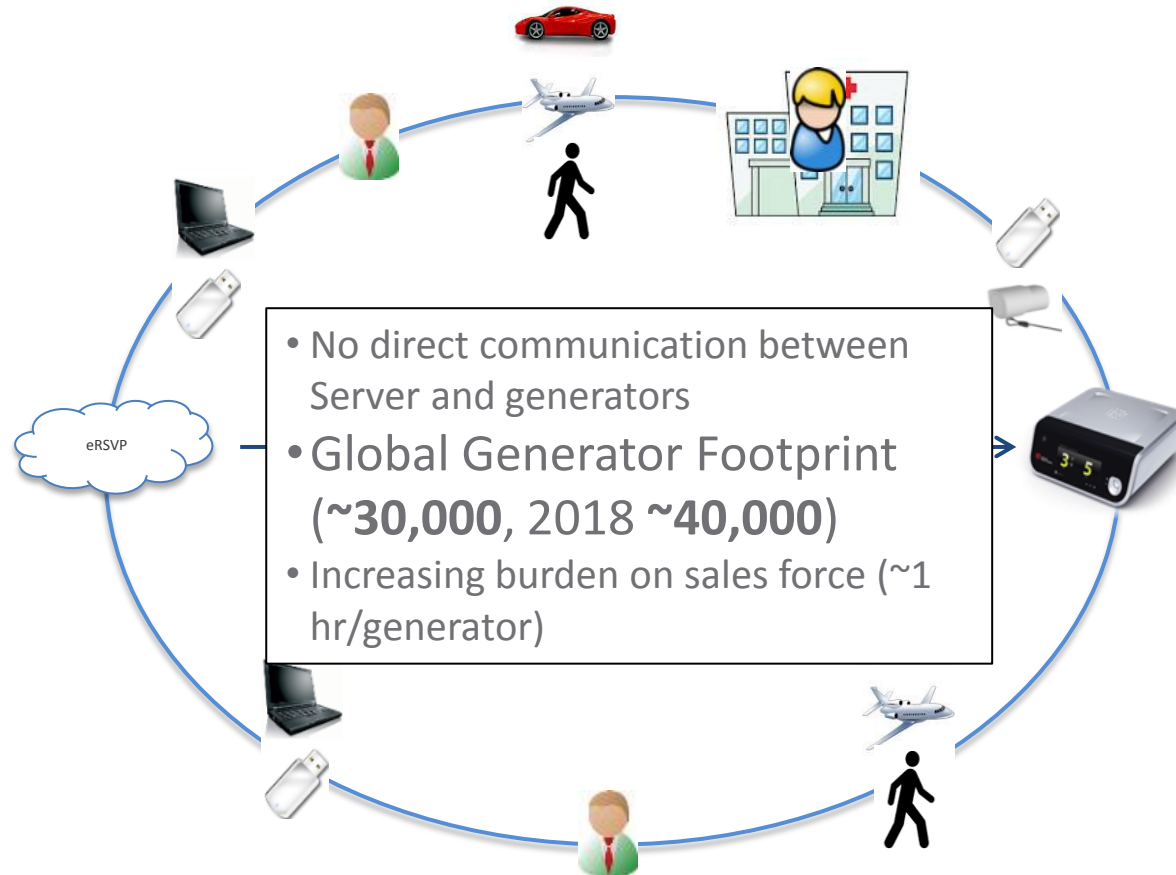


Physical World



??

Current Practice of Software Update for Ultrasonic Generators



Long and manual software updating process

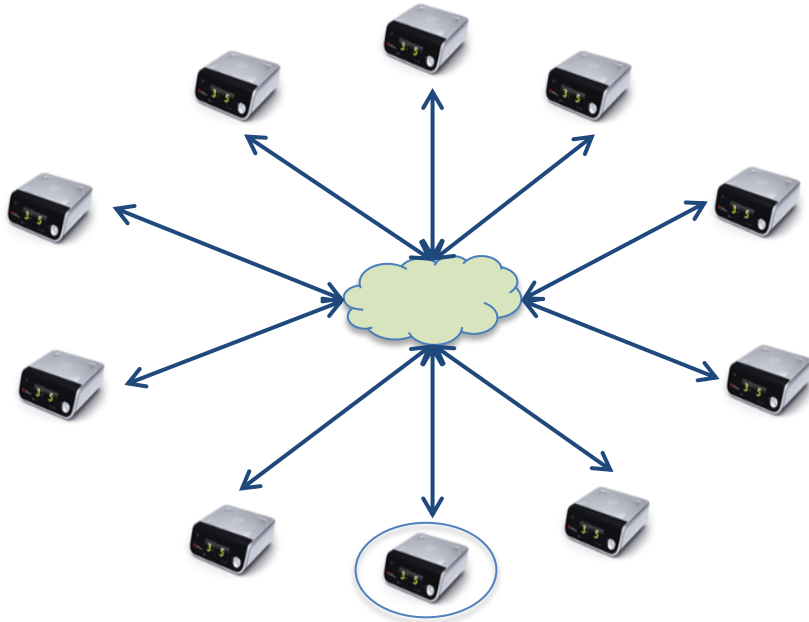
Slow response to generator functional failure

Lack of understanding about generator usage information

Key Challenges

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 !**