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Turning **insight** into **action**.



Leveraging PI ACE as Enabler in a Plant Manufacturing Execution System

Presented by **Roberto Gubellini, Mauro Misuri – Eli Lilly Italia**
Pierre Menard – Global Automation Partners

Agenda

- *Lilly* and  *Global Automation Partners* At-A-Glance
- The story of the project
- The background
- Challenges & the solution
 - Architecture
 - Data flow
 - Client Tools
- Results & Benefits

About *Lilly*

- Large Pharmaceutical Manufacturer
- Founded 1876 (135 year heritage)
- ~23 B\$ Net Sales (2010)
- ~38,000 employees worldwide with ~ 7,500 in R&D
- Manufacturing plants located in 13 countries
- Clinical research conducted in more than 50 countries
- Research and development facilities located in 9 countries
- Products marketed in 143 countries
- Products treat depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, osteoporosis, cancer, and many other conditions

Source: www.lilly.com

About *Lilly* Italy - Sesto Fiorentino (Florence)

- 50 years long story
- 1990: Global manufacturer for antibiotic products
 - FDA approved for antibiotic supply from 1996 until 2003
- 2003: Plant new mission, largest biotechnology center in Italy for Insulin production
- Now:
 - ~1000 employees (~650 in the manufacturing)
 - Productive capacity: ~ 100 million insulin cartridges for injectible pens and blister packaging
 - High level of automation and paperless production

Source: www.lilly.it

Story of the project

- **The needs**
 - How could we better integrate MES with real-time data infrastructure?
- **The idea**
 - Can we achieve this using PI System components?
- **The feasibility study**
 - Let's investigate!
- **The implementation**
 - Let's do it!

The idea – Roberto Gubellini

- Master's degree in Computer Science Engineering
- Joined Lilly in 2003, Manufacturing IT Platform & Infrastructure role during the first Insulin production project
- Since 2008
 - Process Automation Engineer for Data Historian,
 - Building Management System and Water Treatment control systems.
- Since 2009, second Insulin production project
 - Responsible for the rollout of the PI System
 - Process Monitoring solutions and the formulation process control system



The feasibility study – Mauro Misuri

- Mauro Misuri is a Process Automation Specialist that joined Eli Lilly in 2000.
- Has more than 20 years of experience in automation and control systems.
- Extensive knowledge of
 - Formulation, Filling, and Component Processing machine automation
 - MES system
- Since 2009, joined second Insulin production project

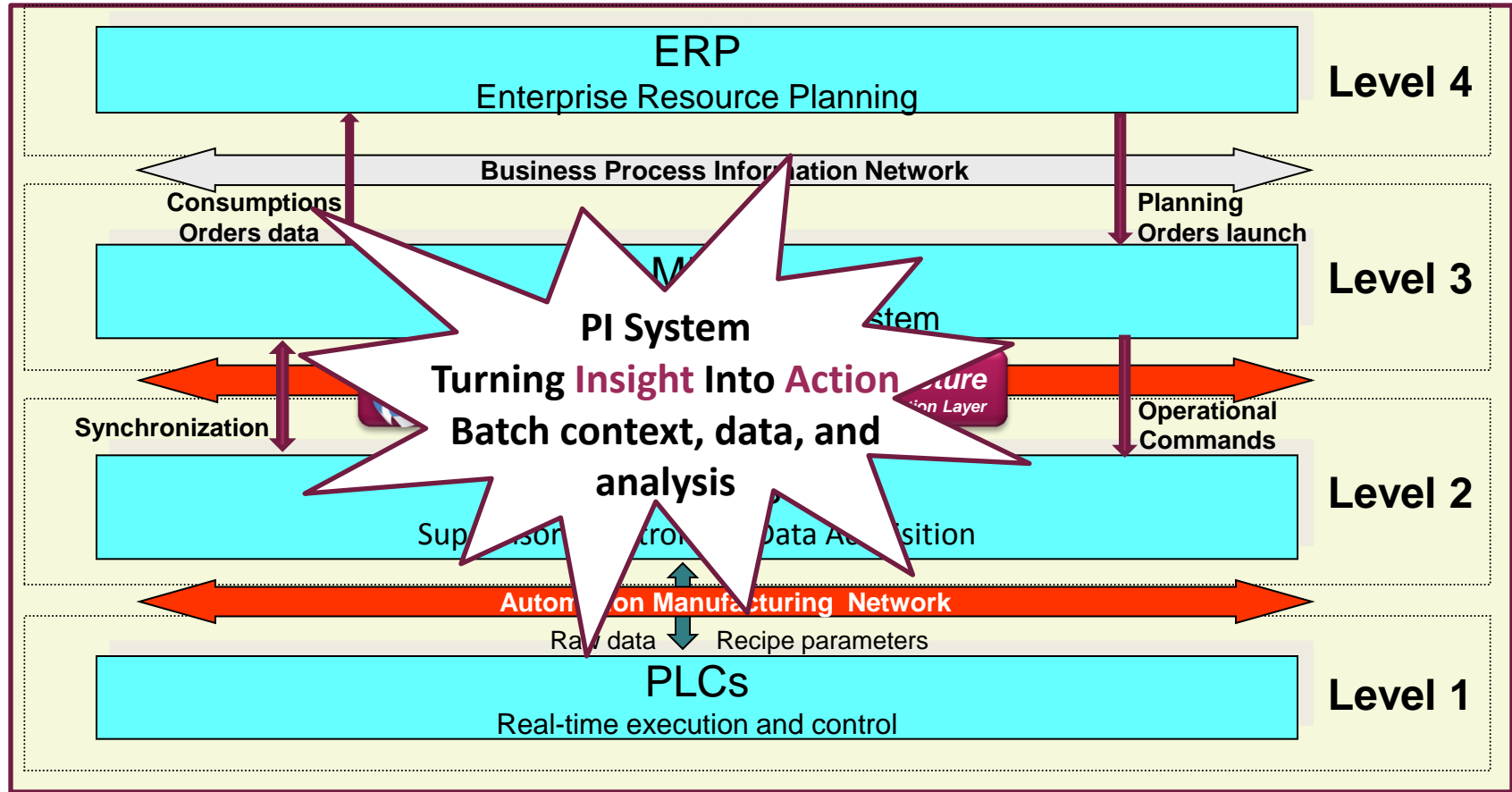


About *Global Automation Partners*

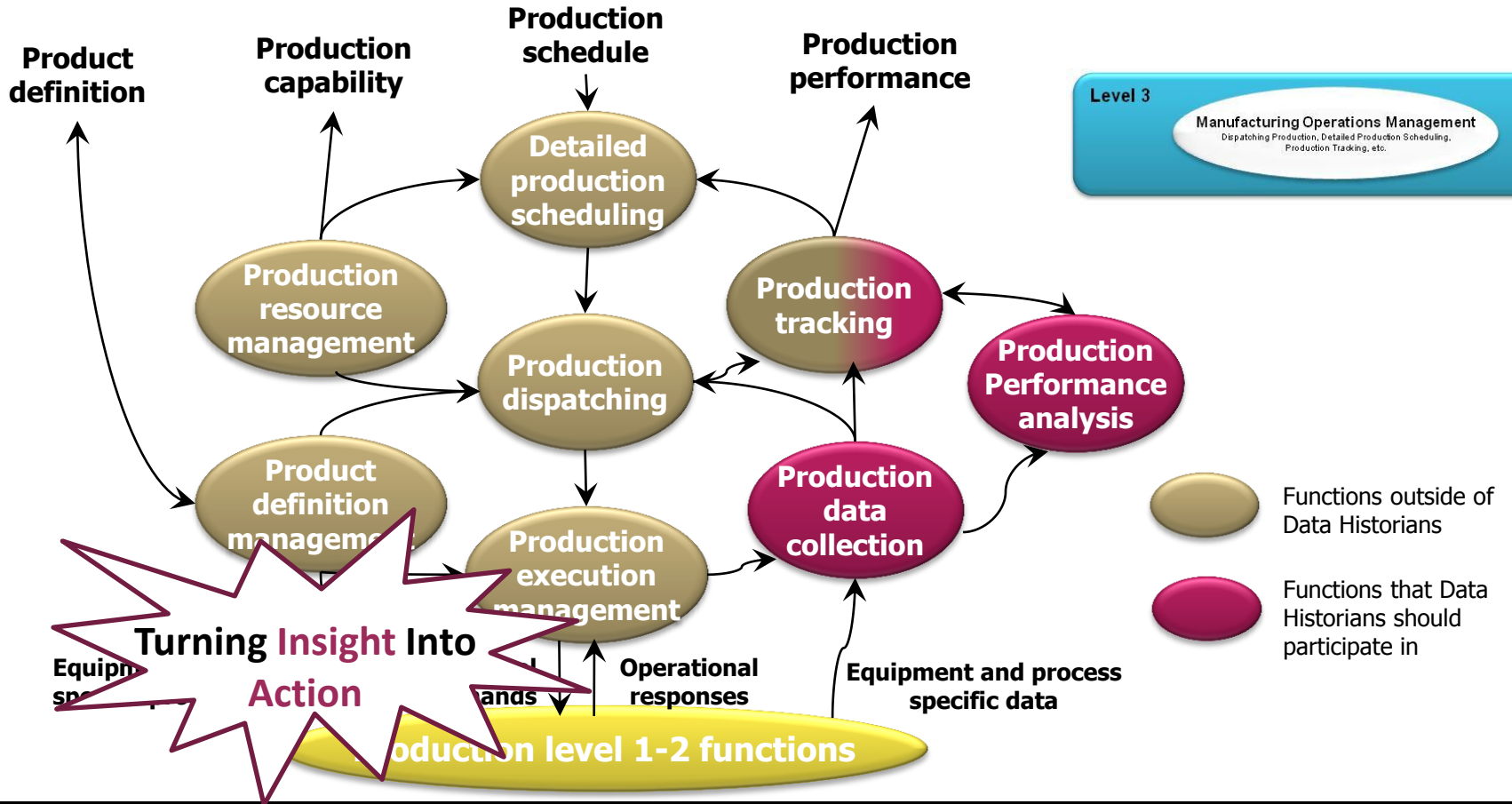
- Engineering firm specialized in delivering Automation and Manufacturing IT solutions and services for manufacturing industries (www.gap5.com)
- Leader in applying OSIsoft's technologies to integrate data and provide business intelligence for better decision making
- Offices in Canada (Montreal) and the US (Danbury, CT – San Francisco, CA - Greenville, SC - Indianapolis, IN – San Juan, Puerto Rico)
- Expertise in Pharma/Biotech, Food and Beverage, Chemical, Specialty Chemical, Petrochemical, and other industries
- Part of M+W Group since 2010
- Sister company M+W PA with global presence in Europe and Asia



Logical System Architecture – S95 & S88



S95 Level 3: Manufacturing Operations Management Functions



Scope of the project

Washers



Autoclaves



Processors



Formulation



Filling Line

The implementation – Pierre Menard

- Joined Global Automation Partners in 2004 as a senior application engineer.
- Bachelor degree in Electrical Engineering.
- Over 23 years of experience in automation and industrial computing.
 - Involved for the past 12 years solely on PI System projects for aluminum and biotech industries.

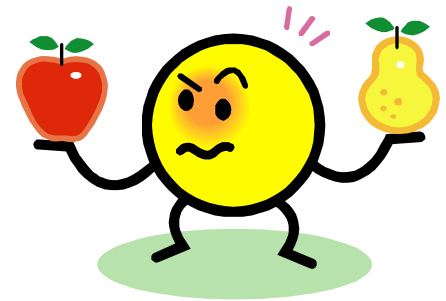


Requirements

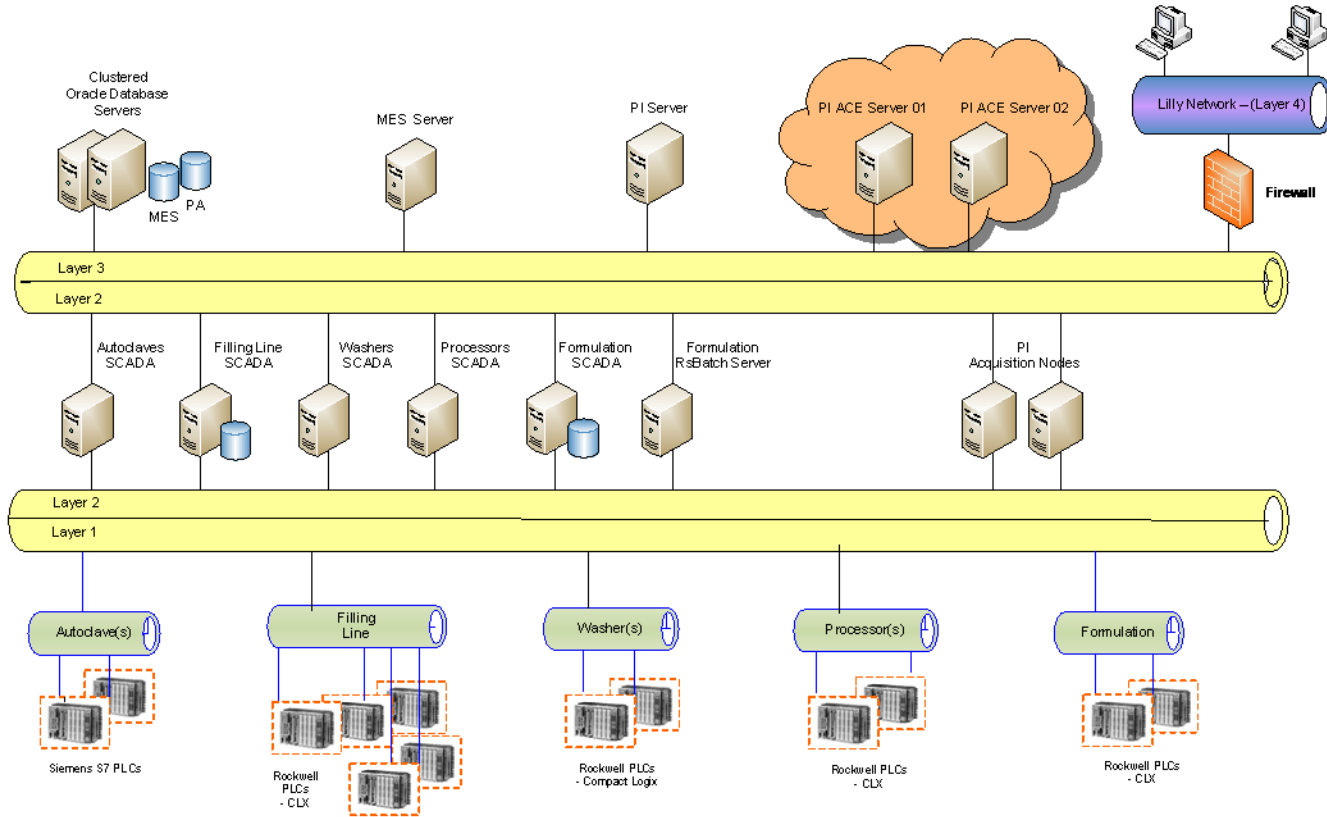
- Use PI System to enable integration between SCADA and MES
 - Core component of the solution
 - Automates transaction between SCADA systems and MES
 - Based on Scheduled algorithms
- Develop a Recipe Manager application
- Develop a Report Manager application

Constraints / Particularities

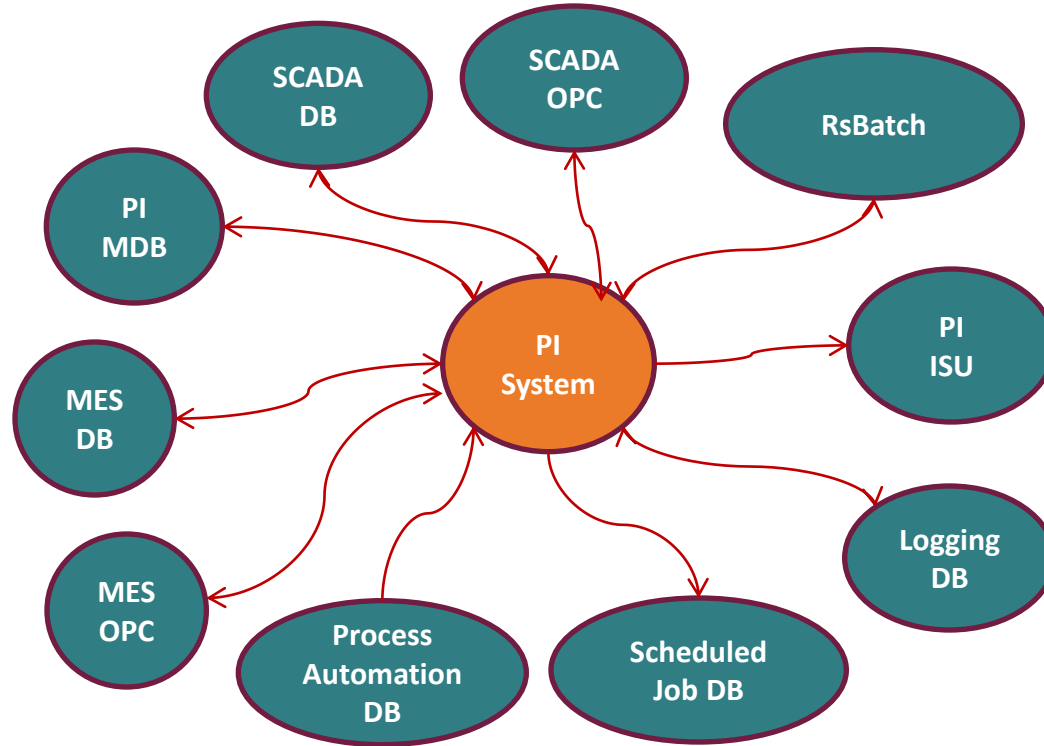
- Compatible with existing system architecture
 - Existing data in Relational databases
 - Rockwell, Siemens, RsBatch, etc...
- Fast Track / RAD
 - Must simplify and minimize coding (.NET libraries)
- Reliable, Scalable, Modular
 - One Design – Multi Vendor
 - Self-Healing / Immune to failure / Low maintenance cost
- Regulated environments (21 CFR Part 11)
 - Maximize COTS usage



SCADA/MES Integrator - System Architecture

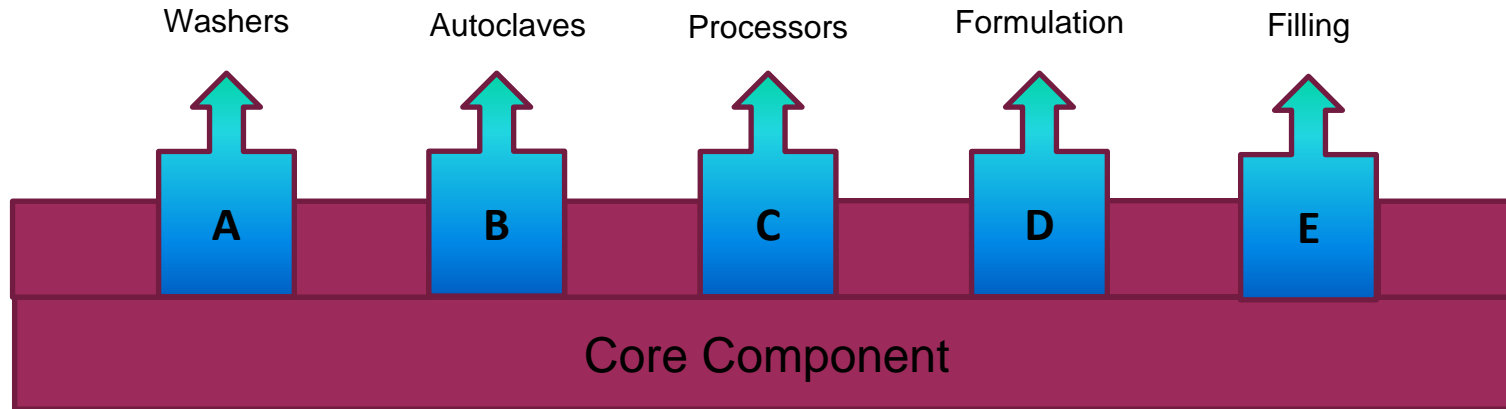


SCADA/MES Integrator – Data Flow



SCADA/MES Integrator - Modularity

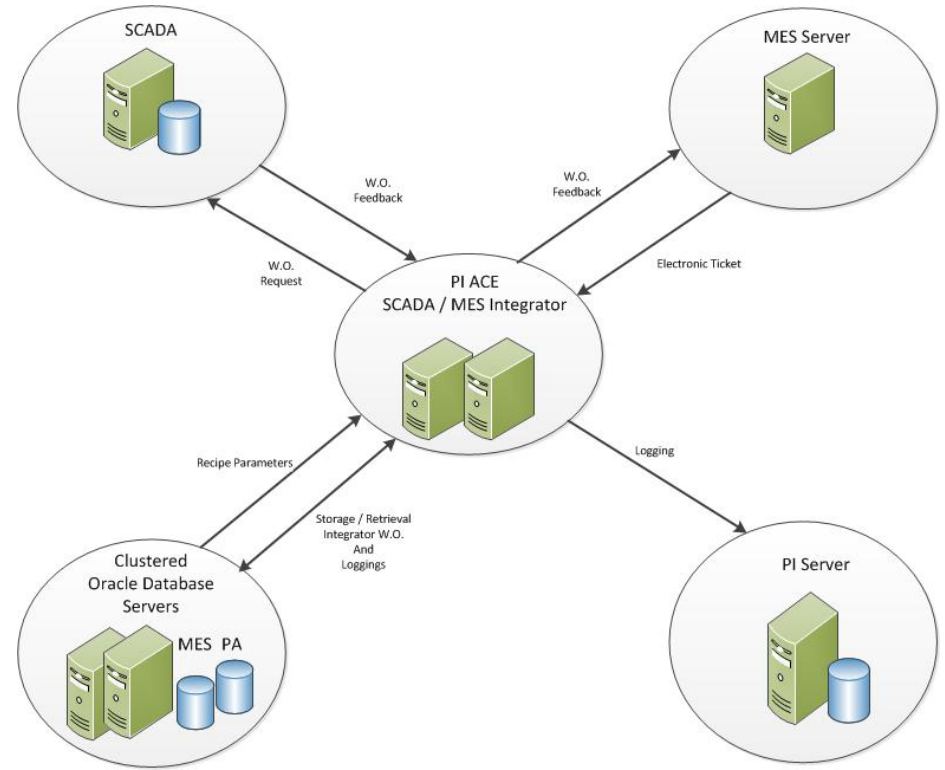
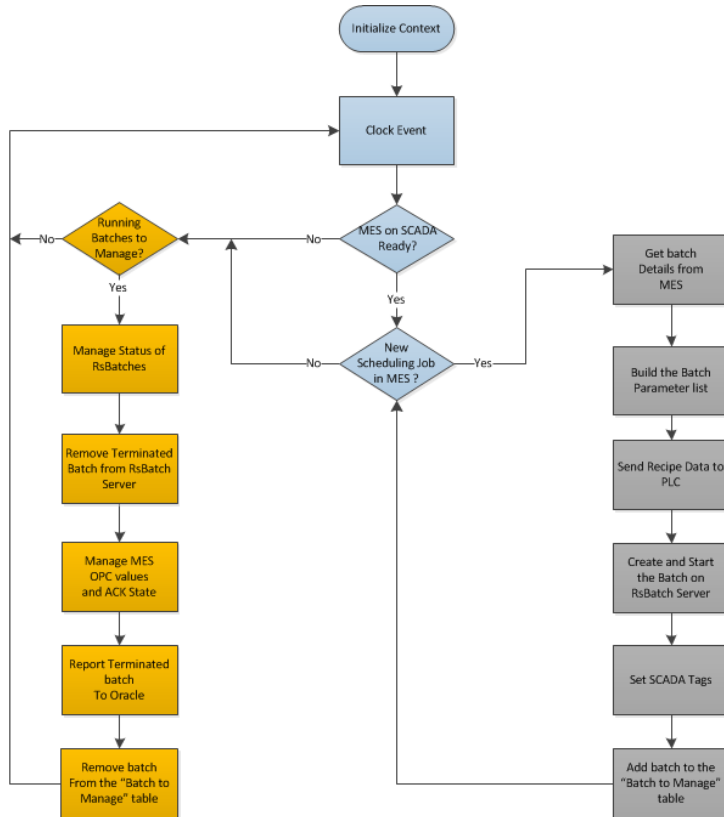
- One Design – Multi Vendor
- Modular and Scalable application
- Maintenance on a “per equipment” basis



SCADA/MES Integrator - Modularity

- “Core Component” composed of:
 - Redundant PI ACE schedulers
 - Interface with SCADA stations
 - Interface with PI Server
 - Interface with Clustered Oracle databases (Logging, Recipes, Reports)
- “Cartridges” composed of:
 - Standalone SCADA / MES synchronization contexts
 - Developed on a vendors / equipment's basis.

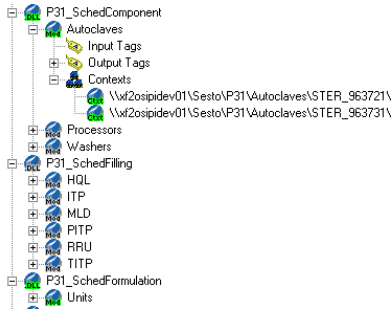
SCADA/MES Integrator – Process Flow



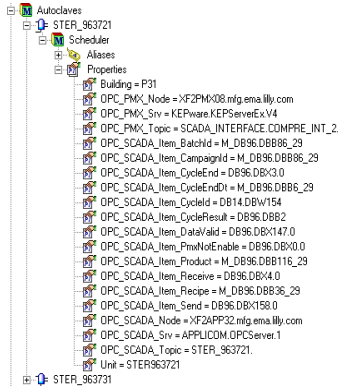
SCADA/MES Integrator - Reliability

- Extensive logging
 - Oracle tables (Detailed info, max 1 month duration)
 - PI Server (Initialisation info, Major Faults, life duration)
- ISU to monitor each SCADA/MES context

SCADA/MES Integrator - Configuration

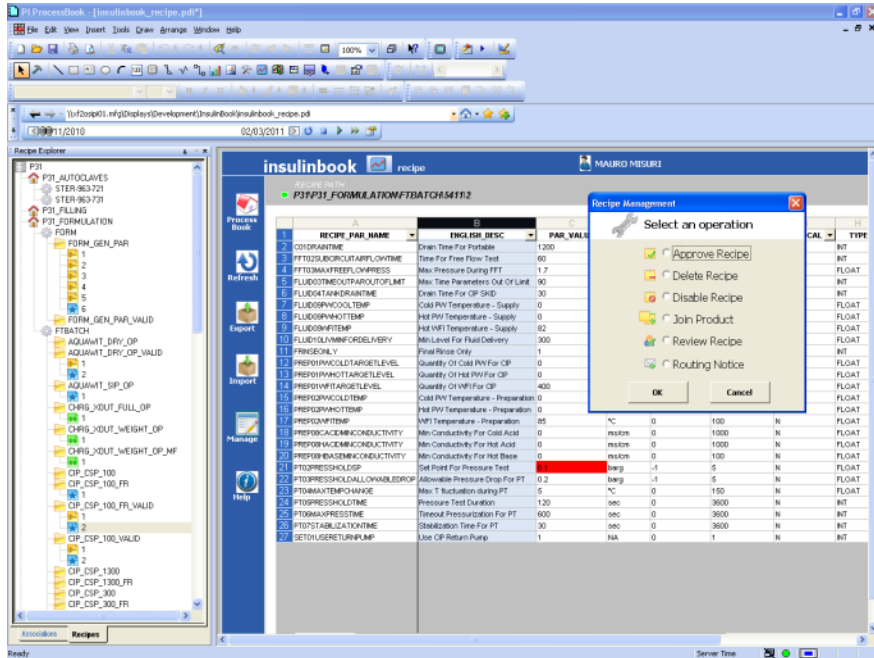


- Through PI ACE Manager
 - Equipment's can be start/stop individually



- Through PI Module Database
 - Equipment OPC parameters are defined

Recipe Management Tool



- Tree view recipe selection
- View Recipe parameters
- Excel Import/Export
- Review and Approve
- Email notification
- Recipe comparison
- Versioning management

Report Management Tool

The screenshot displays the 'insulinbook' report management tool. On the left is a tree view of the system hierarchy, including categories like 'P31', 'Alarms', 'Critical Changes', 'Recipe Download', 'Use Logone', 'Autoclaves', 'Clean Utilities', 'MS705_1', 'MS705_2', 'PSS', 'PV', 'VFI', and 'Formulation'. The main window shows a report for 'P31 Washers' with a table of cycle data. Below the table is a 'Cycle Trend' graph showing various parameters over time.

| ID | LINE | ID | MACHINE | CYCLE ID | CYCLE TYPE | CYCLE RESULT | BATCH ID | PRODUCT ID | STATOCCLO | CODSTJ |
|-----|---------|------|---------|----------|------------|----------------------|--------------------|-------------------------|-----------|--------|
| P31 | WASHERS | WASH | 981-721 | 31179 | Local | Completed OK | LOC_2011222_134659 | LOC_PROD_2011222_134659 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31196 | Local | Completed OK | LOC_2011222_164140 | LOC_PROD_2011222_164140 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31225 | Local | Completed OK | LOC_2011223_126010 | LOC_PROD_2011223_126010 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31240 | Local | Completed With Alarm | LOC_2011224_356542 | LOC_PROD_2011224_356542 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31279 | Local | Completed OK | LOC_2011226_105157 | LOC_PROD_2011226_105157 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-731 | 31307 | Local | Completed With Alarm | LOC_2011228_31261 | LOC_PROD_2011228_31261 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31338 | Local | Completed OK | LOC_2011228_105618 | LOC_PROD_2011228_105618 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31310 | Local | Completed OK | LOC_2011228_144559 | LOC_PROD_2011228_144559 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-721 | 31327 | Local | Completed With Alarm | LOC_201131_30550 | LOC_PROD_201131_30550 | TERMINATO | 110 |
| P31 | WASHERS | WASH | 981-731 | 31332 | Local | Completed With Alarm | LOC_201131_130022 | LOC_PROD_201131_130022 | TERMINATO | 110 |

- PI Module DB Configuration
- Tree view Report selection
- Cycle Report Review
- Alarms Report Review
- Critical Changes Review
- Unit & Cycle based trends
- Report Approval Process



Results & Benefits

- Reduction of deviation due to human errors
 - Automatic data entry of batch information
 - Automatic selection of according machine recipe parameters
- Reduction of Batch disposition time (from 80 down to 40 man hours)
- Real time control and traceability of production operations
- Enhanced paperless approach
- Low maintenance costs

Future Plans and Next Steps

- Integrate the other Insulin production line
- Migration to PI Server 2010
- Leverage PI High Availability
- Leverage PI AF and coming PI Event Frames

Turning **insight**
into **action.**

Questions

- Roberto Gubellini

Email: gubellini_roberto@lilly.com

- Mauro Misuri

Email: misuri_mauro@lilly.com

- Pierre Ménard

Email: pmenard@gap5.com



Thank you

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