Enablement and Standardization of Advanced Process Data Technologies with an Enterprise Agreement

Presented by **Nick Alexiades - Sanofi**

About Sanofi

- Sanofi, a diversified global healthcare leader, discovers, develops, and distributes therapeutic solutions to improve the lives of everyone.

- €34.9 billion in Global Sales (2012)

- 100,000 Global Employees

Copenhagen, Denmark

Waterford, Ireland   Haverhill, UK

Massachusetts, US   Geel, Belgium

Lynnwood, WA   New Jersey, US   Marcy l'Etoile, France

Lyon-Gerland France

Perth, Australia

About Sanofi

- **Key Therapeutic Areas**
  - Animal Health
  - Cardiovascular Disease
  - Degenerative Diseases
  - Diabetes
  - Immune-Mediated Diseases
  - Infectious Diseases
  - Multiple Sclerosis
  - Oncology
  - Ophthalmology
  - Rare Diseases
  - Vaccines

- **Subsidiaries**
  - **Sanofi Pasteur**
  - **Genzyme**
  - Shantha Biotechnics
  - Chattem
  - Zentiva
  - Medley
  - Nichi-Iko
  - Merial

About the Presenter

- BS in BME
- MBA in Pharmaceutical Technology Management
- 10 years Biotech/Pharma/ cGxP experience
- 5 years of total PI Experience
- 1 year w/ Genzyme

- Past:
  - Managed EA & supported PI Rollout to 9 Global sites
- Current:
  - Site System Owner
  - EA Lead
  - Enterprise (APEX ePI) System Owner
  - Solution Center IS Project Lead

History of PI System at Sanofi

- Legacy Historian: RAPID
  - Migration of legacy data complete at 1 site (2 others are "in flight")
- Standalone PI System implemented at 5 sites & 2 sites with a Factory Talk embedded PI System
  - 6 different architectures, security models & administration procedures
  - The Framingham campus alone has over 10 distinct PI Systems
    - SDLC Environments (Development, Test & Production Systems)
    - Business Process Separation (Production, Process Development & APEX)

Sanofi ONE-IS Strategic Direction

Current Situation

- Siloes, multiple sources of information.
- Federated processes, data, and systems.
- Complex and fragmented landscape.
- Same or similar applications sourced from multiple vendors.

A new global shop floor architecture will be designed to:

- Consolidate legacy enterprise and common plant solutions by driving towards Sanofi standard enterprise platforms.

- Improve integration across solution pillars & standardize process design across business units.

- Drive sustainable compliance into all solutions.
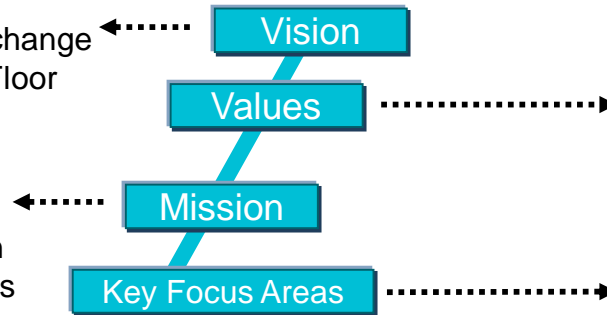
"Shop Floor" Global Solution Center

Vision

To be recognized as a strategic partner of change and business transformation for the Shop Floor systems & processes.
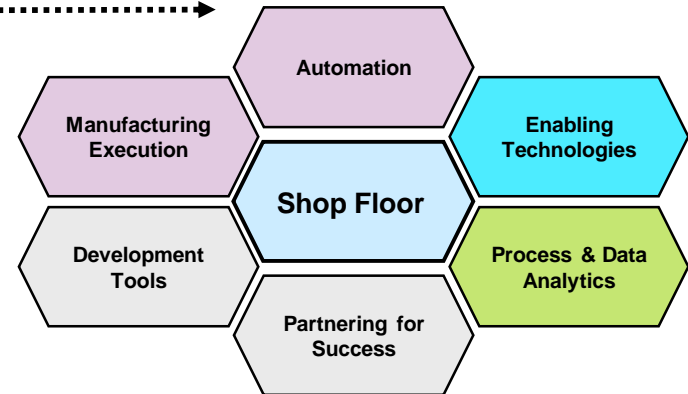
Mission

Architect a comprehensive Global Shop Floor system design that fosters integration across solution pillars, standardizes process design across business units, and drives sustainable compliance.

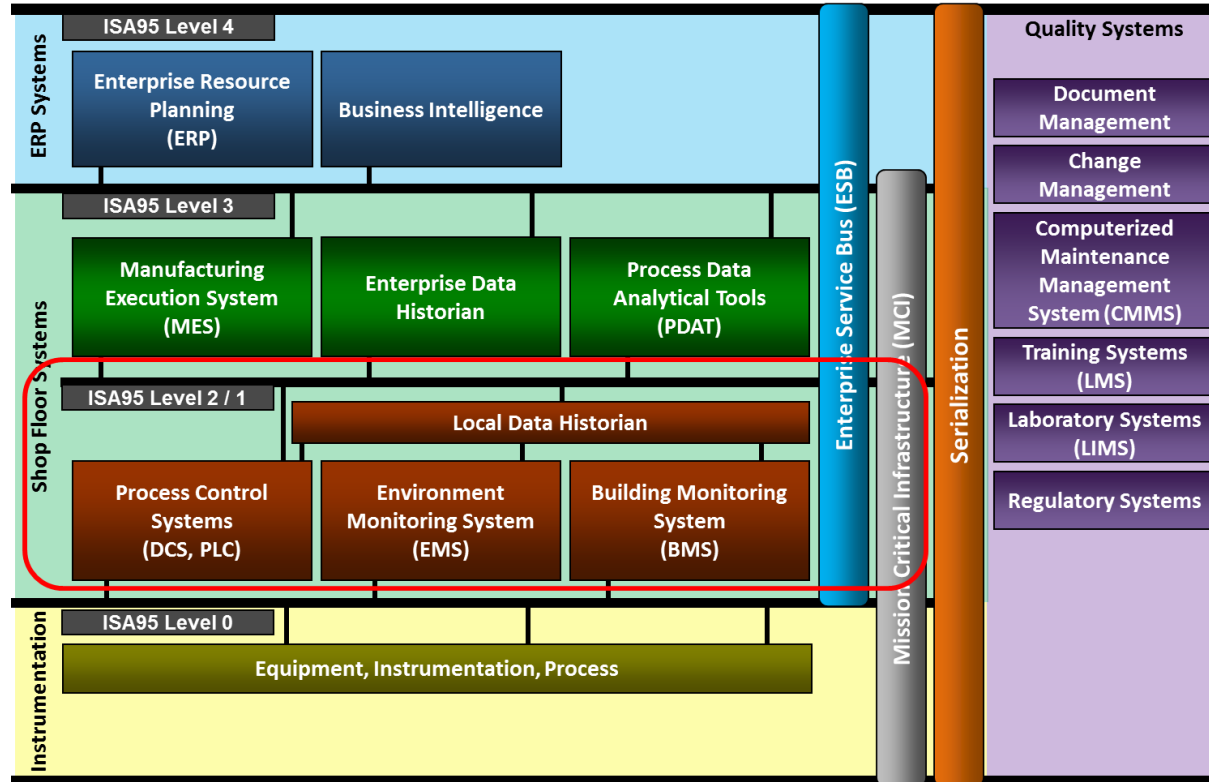|	
1	**Implement Standard Shop Floor Systems across Sanofi.**
2	**Orchestrate, Transform & Harmonize Shop Floor business processes.**
3	**Improve Product Quality and Operational Efficiencies.**
4	**Consolidate and Simplify the Shop Floor IT Landscape.**

Vision → Values → Mission → Key Focus Areas

Values

Innovation
Confidence
Solidarity
Respect
Integrity

Automation
Manufacturing Execution
Enabling Technologies
Shop Floor
Development Tools
Process & Data Analytics
Partnering for Success

Global Solution Center

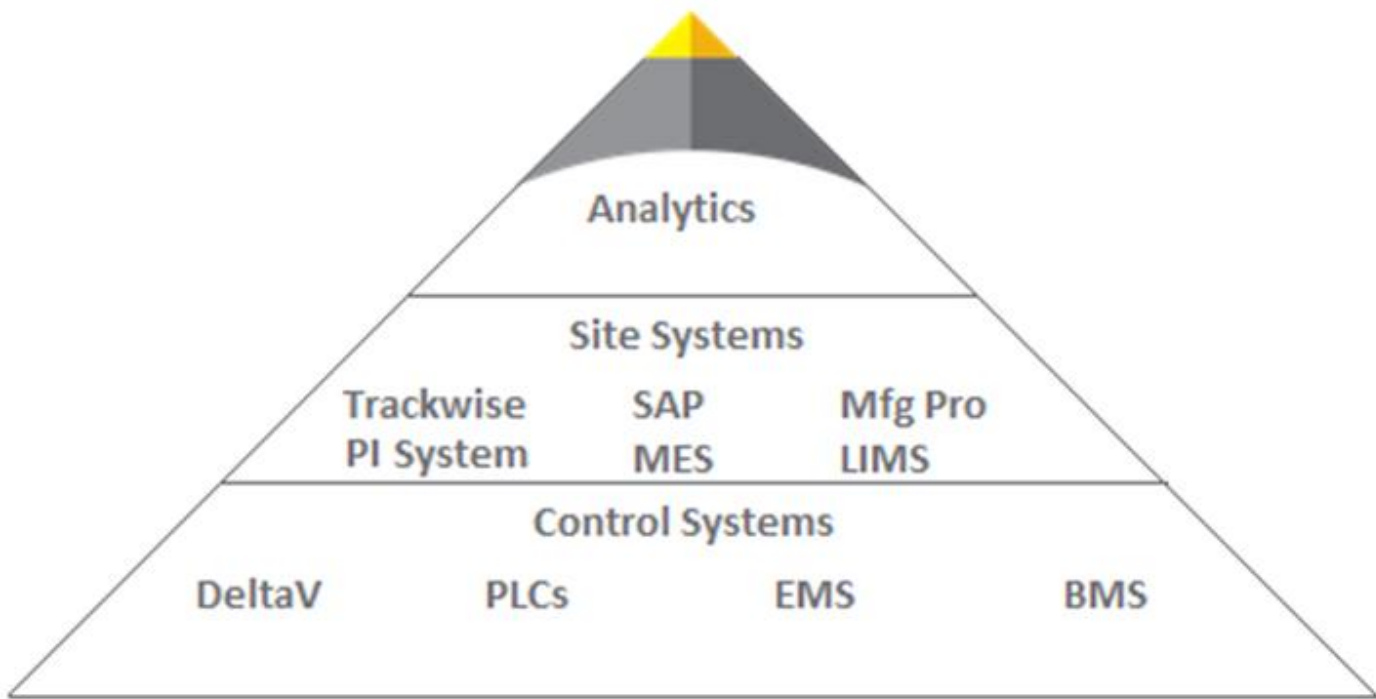Integrated Production Management System Domains

Enterprise Agreement (EA) Status at Sanofi

- EA became effective in August 2013
  - Currently includes 7 named sites
- Role of the EA
  - Leverage the Center of Excelence (CoE) to establish best practices and a core centralized solution reducing the implementation and validation burden at the sites
  - Simplify the licensing structure at existing and future sites
  - Leverage the licensing benefits and CoE knowledge to provide a centralized PI System aggregating data from multiple sites
  - Provide additional functionality through the availability of software that was not previously purchased or available

Process Data Analytics Tools (PDAT)

Apex Target Business Processes

Top Business Processes
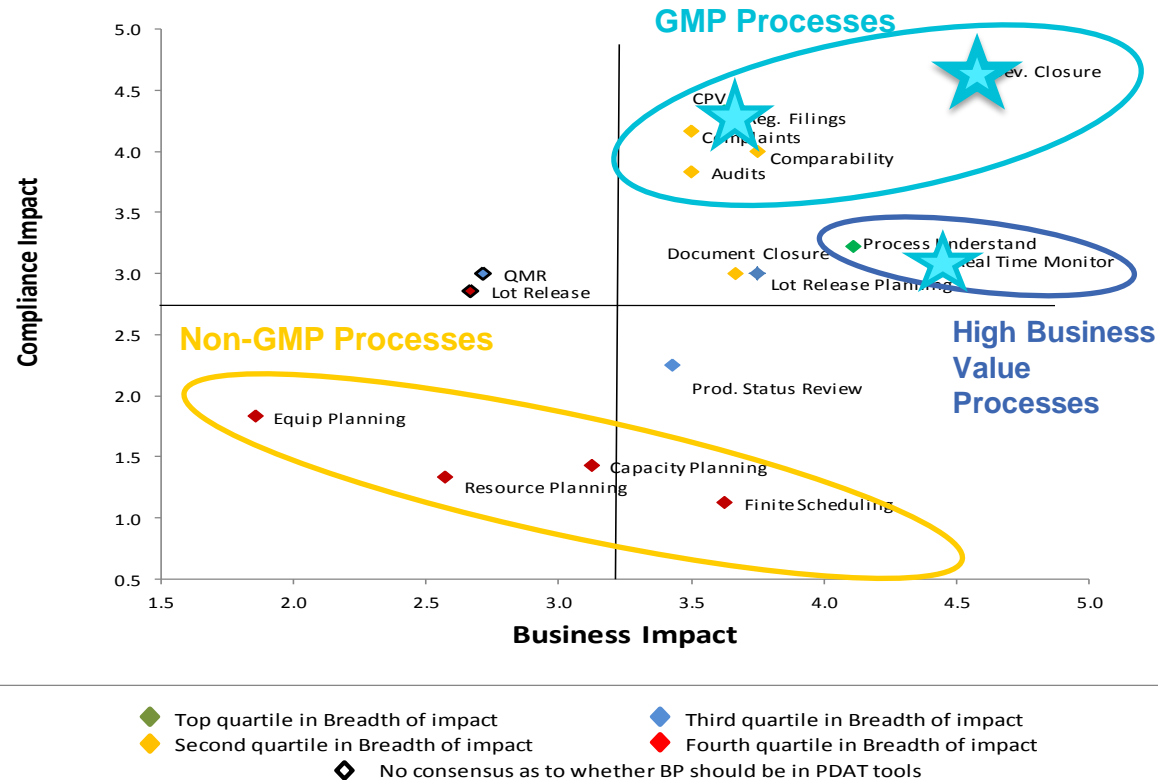
- **Deviation Closure**
Analyze batch data across process steps, with or without calculations and from different source systems (e.g. MDE, LIMS, MES, ERP, etc.)
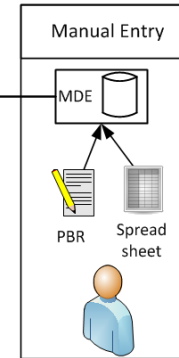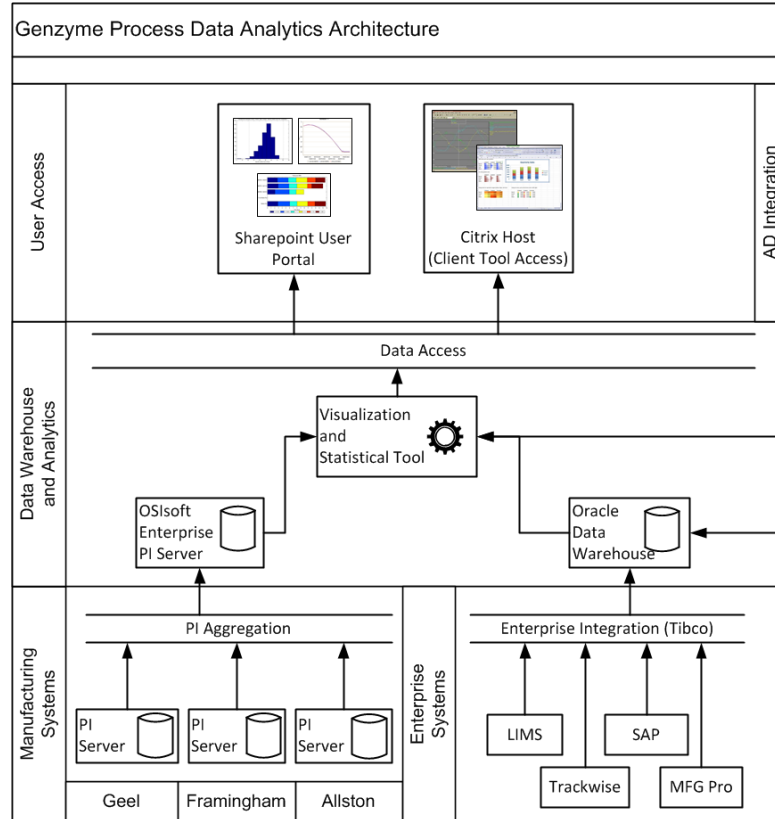
- **Continuous Process Verification**
SPC trending of CPPs and CQAs

- **Real Time Monitoring**
Routine Monitoring of on-line parameters

Average Business v.s. Compliance Impact

Scatter plot with axes "Compliance Impact" (y-axis, 0.5 to 5.0) and "Business Impact" (x-axis, 1.5 to 5.0).

- **GMP Processes** region includes: CPV, Reg. Filings, Complaints, Comparability, Audits, Dev. Closure
- **High Business Value Processes** region includes: Process Understand, Real Time Monitor, Lot Release Planning
- **Non-GMP Processes** region includes: Equip Planning, Resource Planning, Capacity Planning, Finite Scheduling
- Other points: QMR, Lot Release, Document Closure, Prod. Status Review

Legend:
- Top quartile in Breadth of impact
- Second quartile in Breadth of impact
- Third quartile in Breadth of impact
- Fourth quartile in Breadth of impact
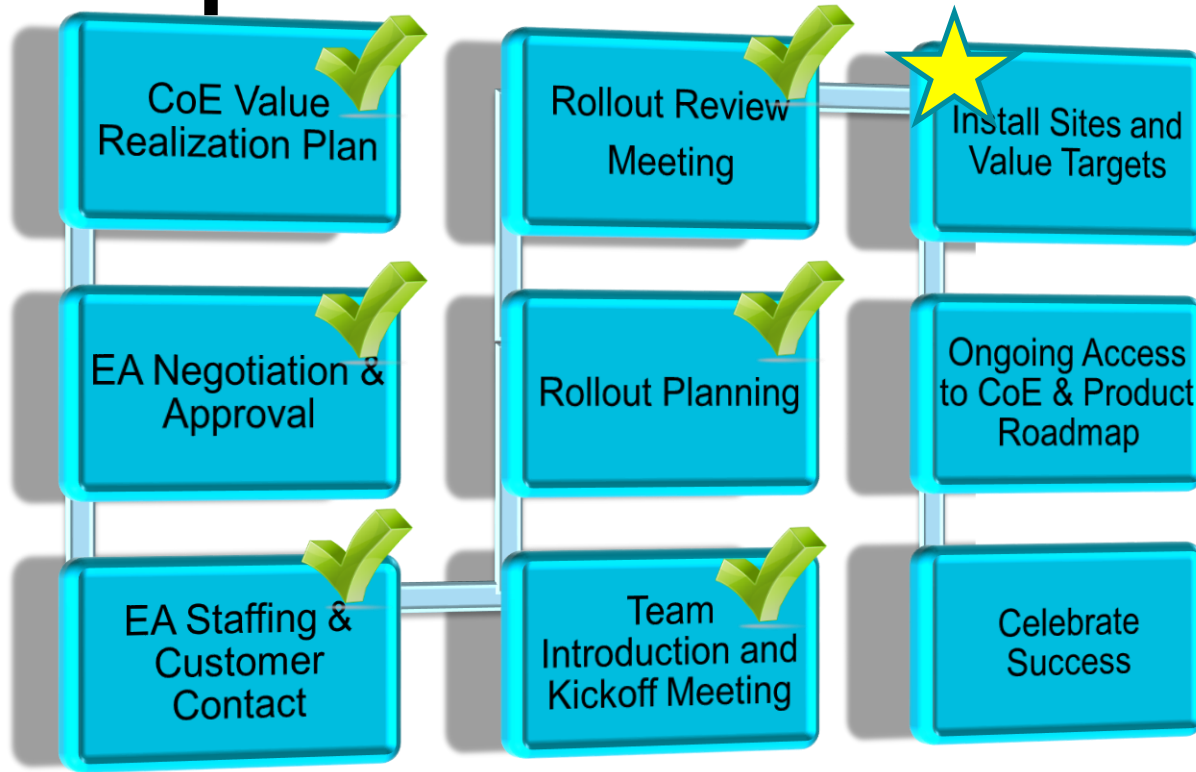- No consensus as to whether BP should be in PDAT tools

Apex Solution Architecture

PI System in the Apex Program

- What are we doing today
  - Connection to Statistical Tools (Statistica)
  - Real time process monitoring and alerting
  - SPC for Critical Process Parameters
  - Process and Equipment Modeling / aliases in PI AF
  - User Tools (PI WebParts, PI DataLink, PI ProcessBook)
- Items to work on
  - PI Event Frames for Events/Alarms
  - PI Batch Context

Next Steps with EA

CoE Value Realization Plan ✓

Rollout Review Meeting ✓

Install Sites and Value Targets ★

EA Negotiation & Approval ✓

Rollout Planning ✓

Ongoing Access to CoE & Product Roadmap

EA Staffing & Customer Contact ✓

Team Introduction and Kickoff Meeting ✓

Celebrate Success

Establishing the Rollout Plan

- Identifying the current state of site PI Systems
  - Current architecture and versions
  - Source Systems
  - Successes and Pain Points
- Identifying Short, Medium & Long term milestones
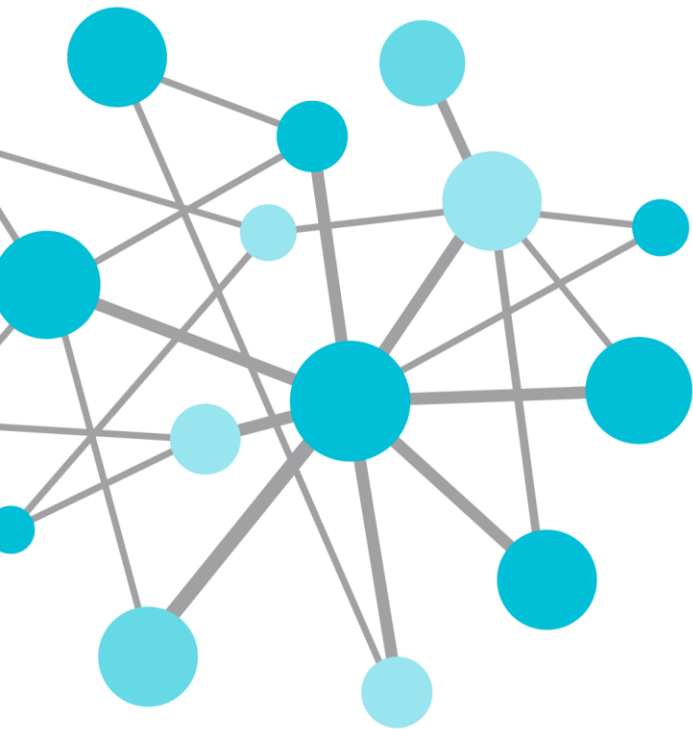- Identifying the standard future state

Core Solution Development

- Establish a certification lab to develop & test a core system
  - Reduce the amount of testing and environments a site needs to maintain
  - Provide improved support and knowledge sharing
  - Core System Components
    - PI Collective
    - PI AF Server
    - PI Notifications & PI ACE
    - PI Client Tools
    - Redundant PI Interfaces to Core Systems (DeltaV, Factory Talk, EBI, PASX, etc.)
    - Managed PI

Deployment Kits

- Documentation
  - Requirement and Design Specifications
  - Validation and Install Protocols
  - SOPs
  - Training Curriculum
  - Best Practice Guidance

- Installation
  - Standard Software
  - Validated Automated Configuration
    - Piconfig, .bat & .ini files
- Canned Modules
  - PI AF Templates
  - Report Templates
  - APEX Prerequisites

THANK YOU

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