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

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**Genzyme/Sanofi**

# Introductions

- Jason Valenta
  - EA Program Manager
- Tim Alosi
  - APEX Program Manager
- Nick Alexiades
  - EA Program Lead & System Owner

# History of PI System at Genzyme

- 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

# Current EA Status at Genzyme

- EA became effective in August 2013
  - Currently includes 7 named sites (Includes Sanofi Sites)
  - The Framingham campus alone has over 10 distinct PI Systems
    - SDLC (Development, Test & Production Systems)
    - Business Process Separation (Production, Process Development & APEX)
- Role of the EA
  - Leverage the 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

# 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.
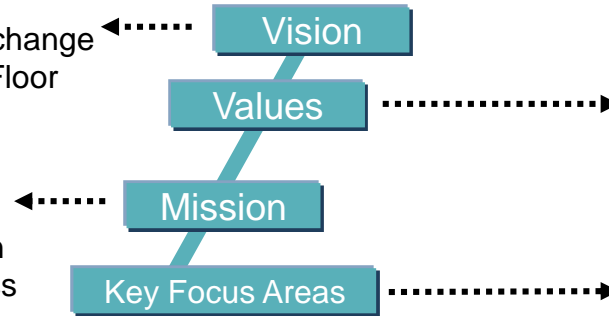
# "Shop Floor" Global Solution Center

## Vision

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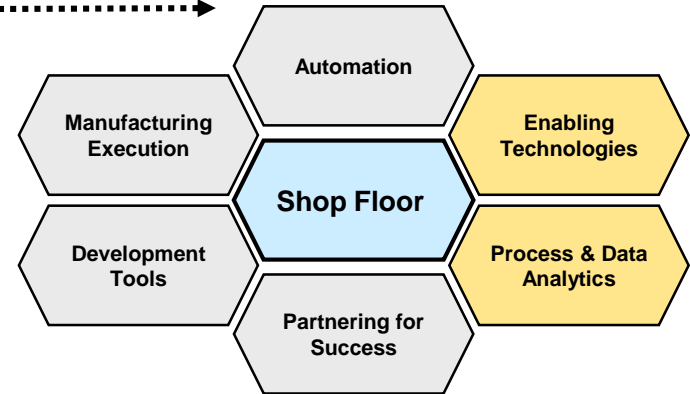
## Mission

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

# Apex Target Business Processes

**Average Business v.s. Compliance Impact**

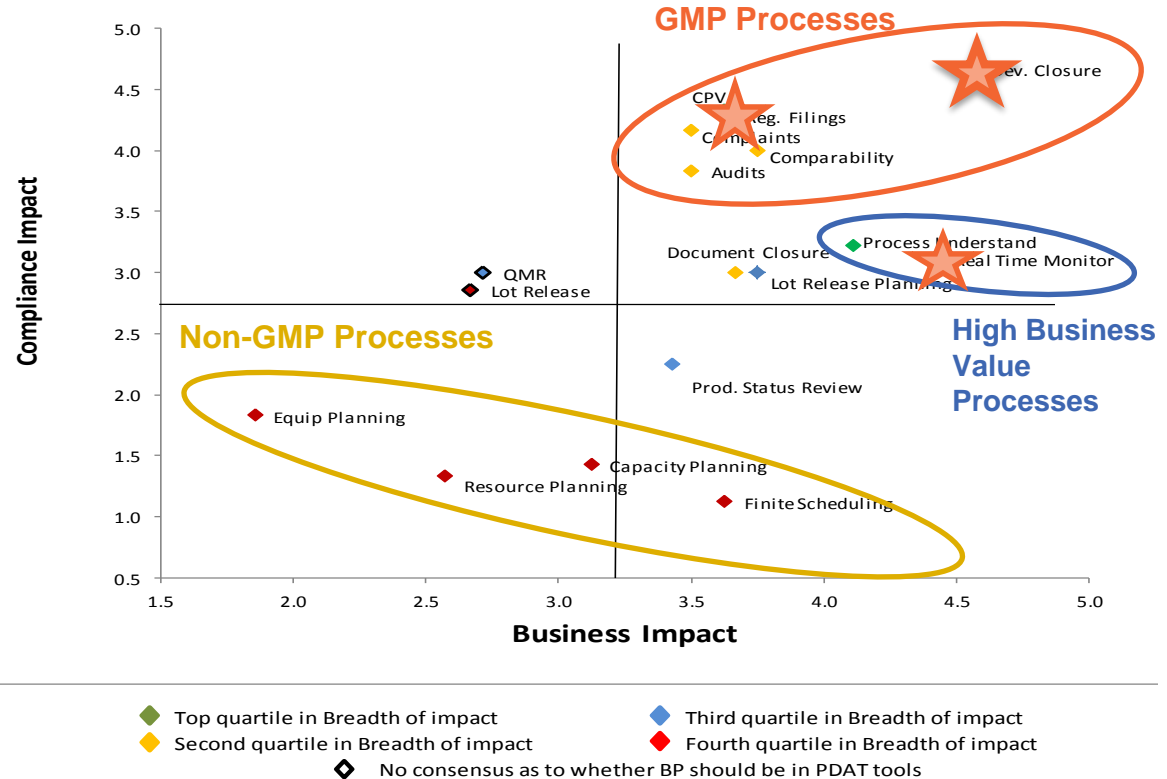## Top Business Processes

- **Deviation Closure**
Analyze batch data across process steps, with or without calculations and from different source systems (e.g. MDE, LIMS, MES, ERP, etc.)
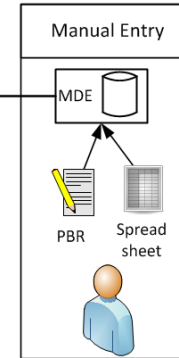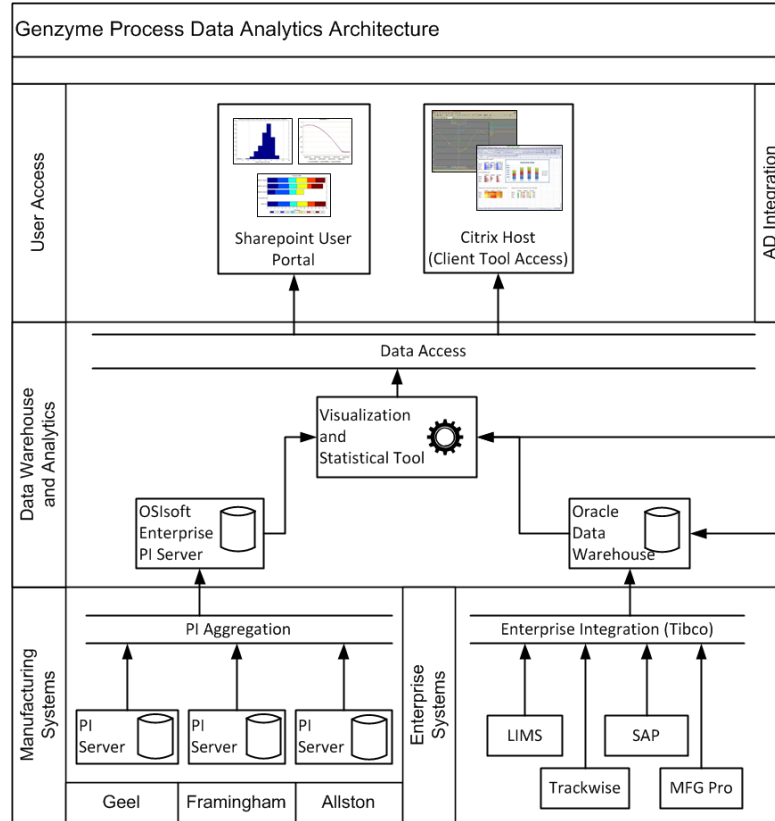
- **Continuous Process Verification**
SPC trending of CPPs and CQAs
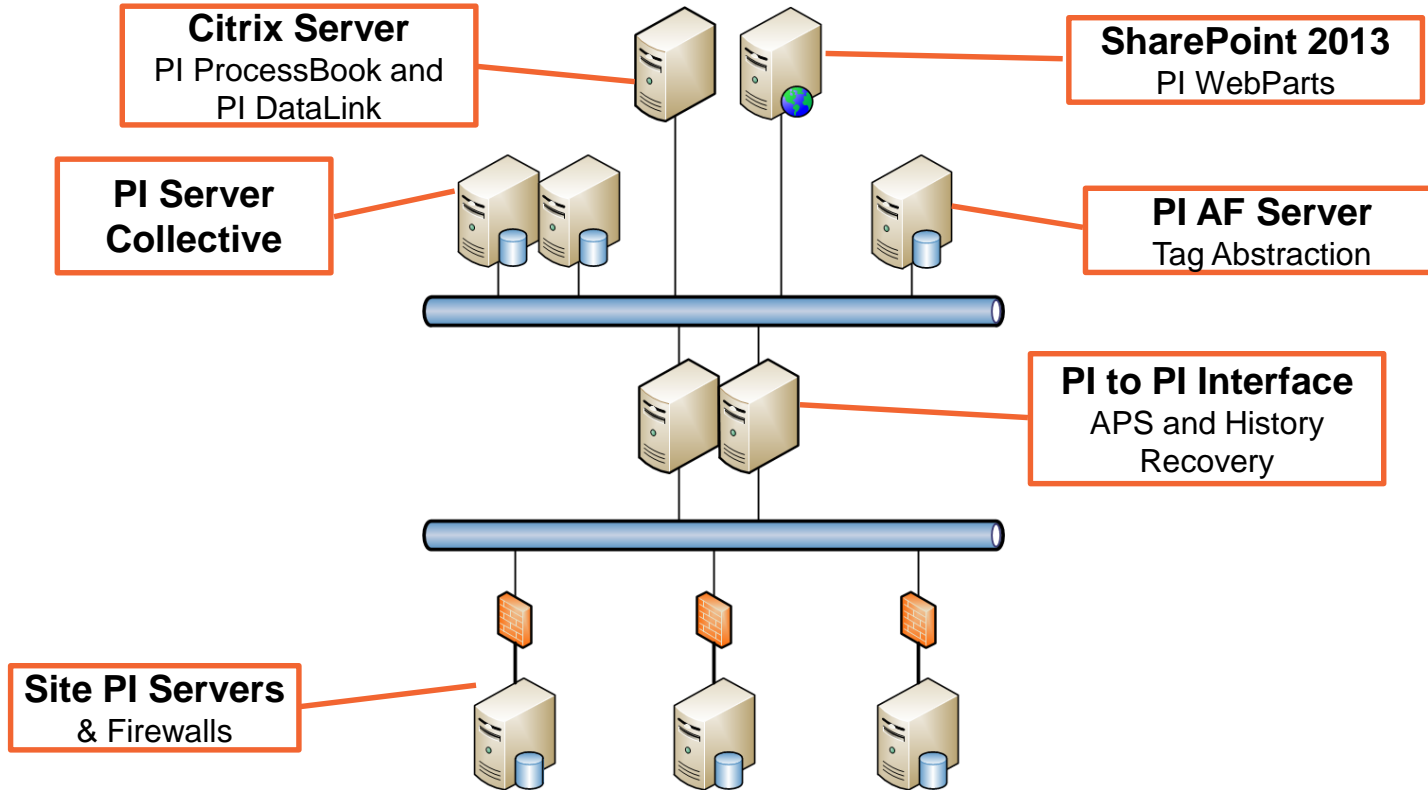
- **Real Time Monitoring**
Routine Monitoring of on-line parameters



Chart: Compliance Impact (y-axis, 0.5 to 5.0) vs Business Impact (x-axis, 1.5 to 5.0)

**GMP Processes** — Dev. Closure, CPV, Reg. Filings, Complaints, Comparability, Audits

**High Business Value Processes** — Process Understand, Real Time Monitor

Document Closure, QMR, Lot Release, Lot Release Planning

**Non-GMP Processes** — Equip Planning, Resource Planning, Capacity Planning, Finite Scheduling, Prod. Status Review

Legend:
- 🟢 Top quartile in Breadth of impact
- 🔵 Third quartile in Breadth of impact
- 🟡 Second 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 Components in Apex



**Citrix Server**
PI ProcessBook and
PI DataLink

**SharePoint 2013**
PI WebParts

**PI Server Collective**

**PI AF Server**
Tag Abstraction

**PI to PI Interface**
APS and History Recovery

**Site PI Servers**
& Firewalls
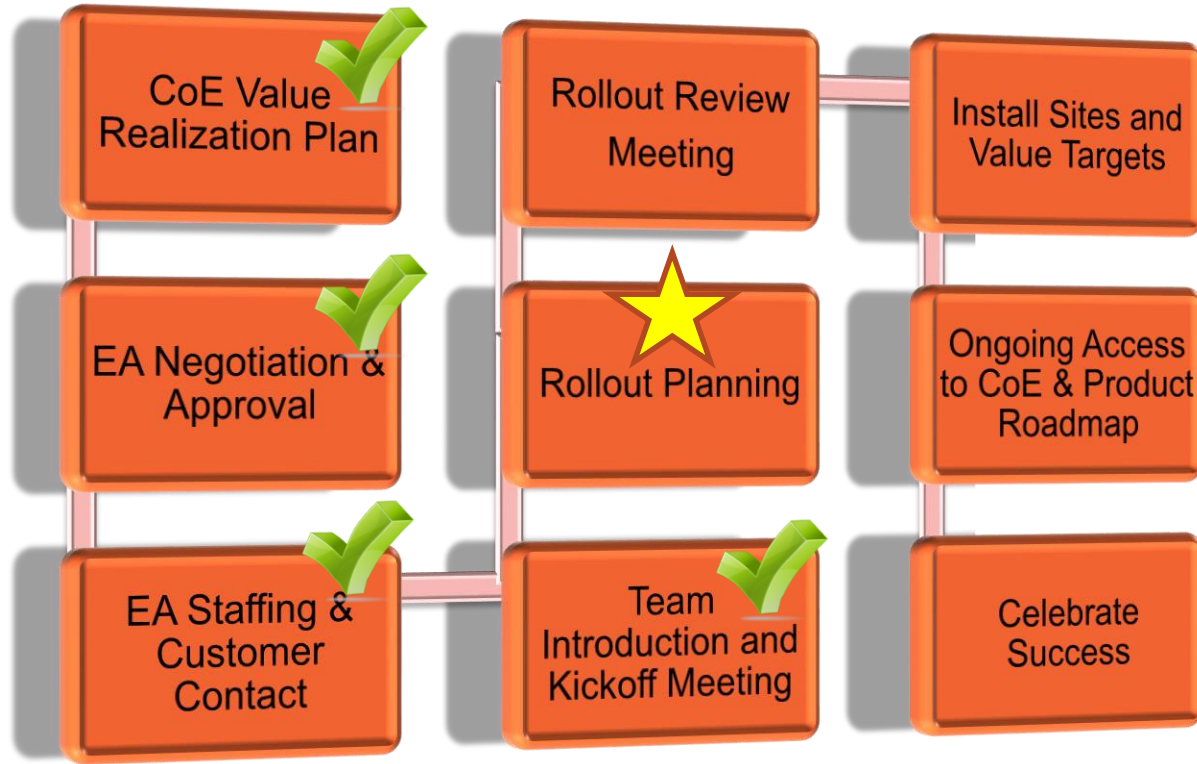
# PI System in the Apex Program

- 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
  - Event Frames for Events/Alarms
  - Batch Context

# Next Steps with EA

# 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 Client Tools
    - Redundant PI Interfaces to Core Systems (DeltaV, Factory Talk, EBI, PASX, etc.)
      - PI to PI interface
      - PI Interface for OPC DA
      - PI Interface for OPC HDA
      - PI Interface for RDBMS
      - EMDVB (PI Interface for Emerson DeltaV Batch)
      - etc.

# Incremental Functionality

- Managed PI
  - Augment existing system monitoring
  - Provide insight into issues common across multiple sites
- PI Coresight
  - Central, site based or both
- PI Notifications

THANK YOU

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