Case Study: Achieving World-Class Manufacturing

Rama Katragadda
Enterprise Architect
Genentech

SUPPLY CHAIN OPTIMIZATION FORUM

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Agenda

- About Genentech
- Case Studies
  - Product Operations – World Class Manufacturing
- Lessons learned
- Vision
- Q&A

About Genentech

- Genentech is a leading bio-technology company
- Develops, manufactures drugs for significant unmet medical needs,
  - Oncology,
  - Immunology,
  - Tissue growth & repair

- Annual revenue of more than $12B with roughly 30% annual revenue growth in the past few years.
- More than 12,000 employees, with headquarters in S. San Francisco, CA
- Fortune "100 Best Companies to Work For" for the ninth consecutive year.

Genentech Organization

- Research
  - Drug Discovery
- Product Development
  - Clinical Trials
- Product Operations (PROP)*
  - Manufacturing
- Commercial
  - Sales & Marketing
- CFO Organization
  - CIT
  - HR, Finance, Facilities

Challenges in Product Operations

- Rapid growth - Annual revenue growth @ ~ 30%
- Large number of business software applications in place to support business growth.
- Need to integrate multiple sites
- Ad hoc and point-to-point application integrations were implemented to meet short term requirements
- No single system of record

IT Goals

- Develop an enterprise-wide integration strategy.
- Build infrastructure that supports decoupling of different business applications
  - Must be scalable and flexible to deploy upgraded systems independently of other systems
  - Rationalize the systems without impacting business

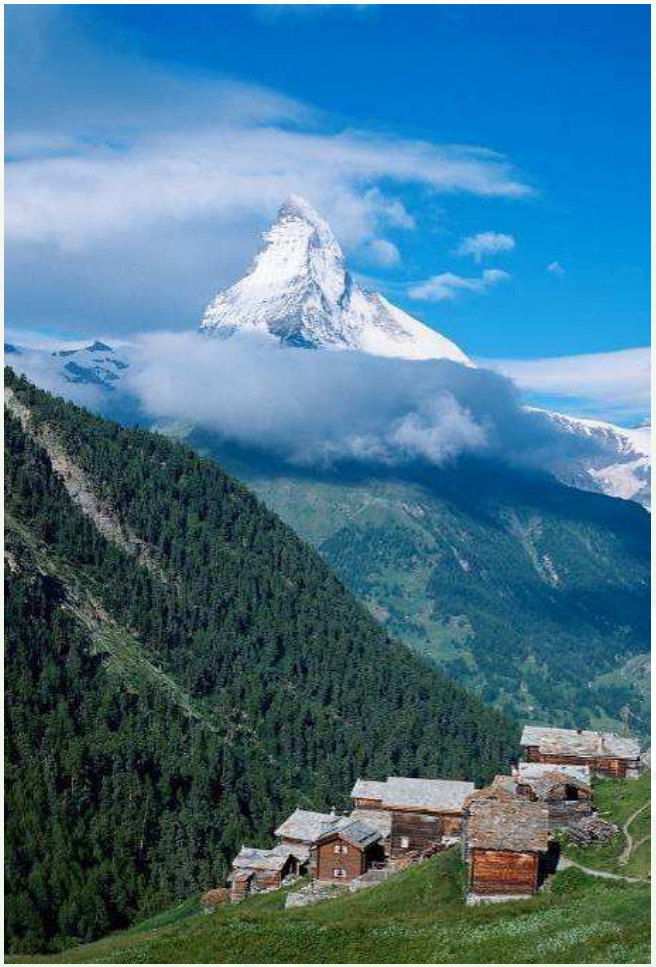
Top Business Goal – Class A

- Objective benchmark of world class manufacturing measuring planned, predictable, performance
- Published standard of excellence
- Recognized worldwide (3,000+ companies)
- Proven best practices, in use for 30+ years

The Approach

- Selected industry-standard SCOR (Supply Chain Operations Reference) model as future-state for PROP application portfolio
- A Common Information Model (CIM) based ISA-95 (international standard for the integration of enterprise and control systems)
- Create an Enterprise Service Bus to connect disparate systems together in near real-time.
  - Standards based (e.g. JMS, SOAP) platform
  - Reusable service-based architecture
  - Integrate various proprietary backend systems
- Establish an Integration Competency Center to drive adoption and reuse across Genentech.

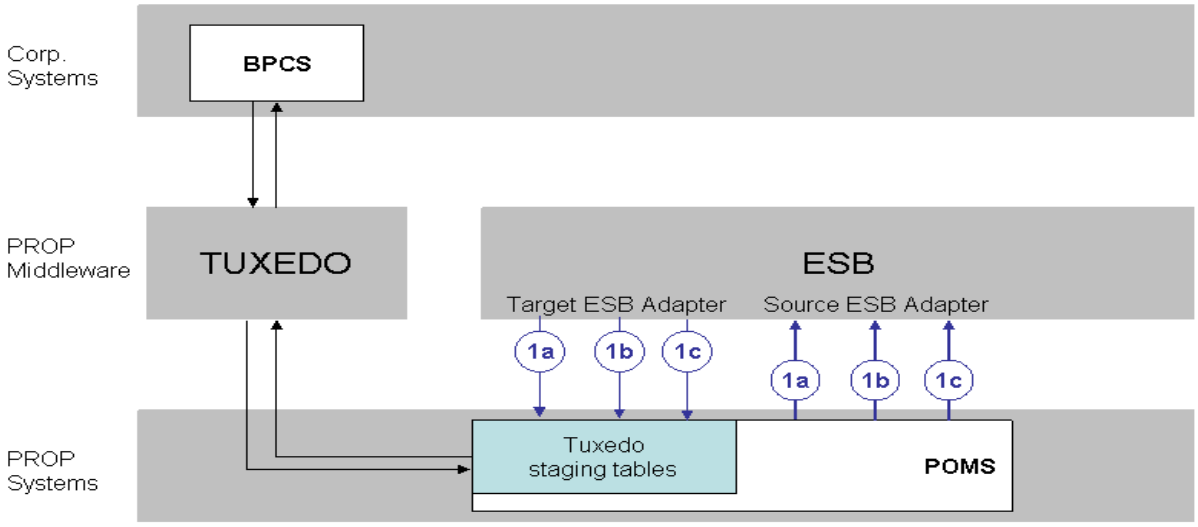
PROP “Summit” Program



- Genentech’s PROP group established the “Summit” program
  - World Class Manufacturing
  - Rationalize the business applications
  - Automate Supply chain operations
  - minimize compliance risk.
- Summit Facets:
  - ERP rollout – Replace BPCS with SAP
  - Roll out MES systems (POMSnet) in Vacaville, SSF, Oceanside, Singapore manufacturing facility
  - Implement ESB to support ERP and MES rollout

PROP(SUMMIT) ESB Phase 1

- Foundation for PROP ESB
- 2 Systems (POMS, BPCS), 3 Use cases, No changes for BPCS



Flow Legend

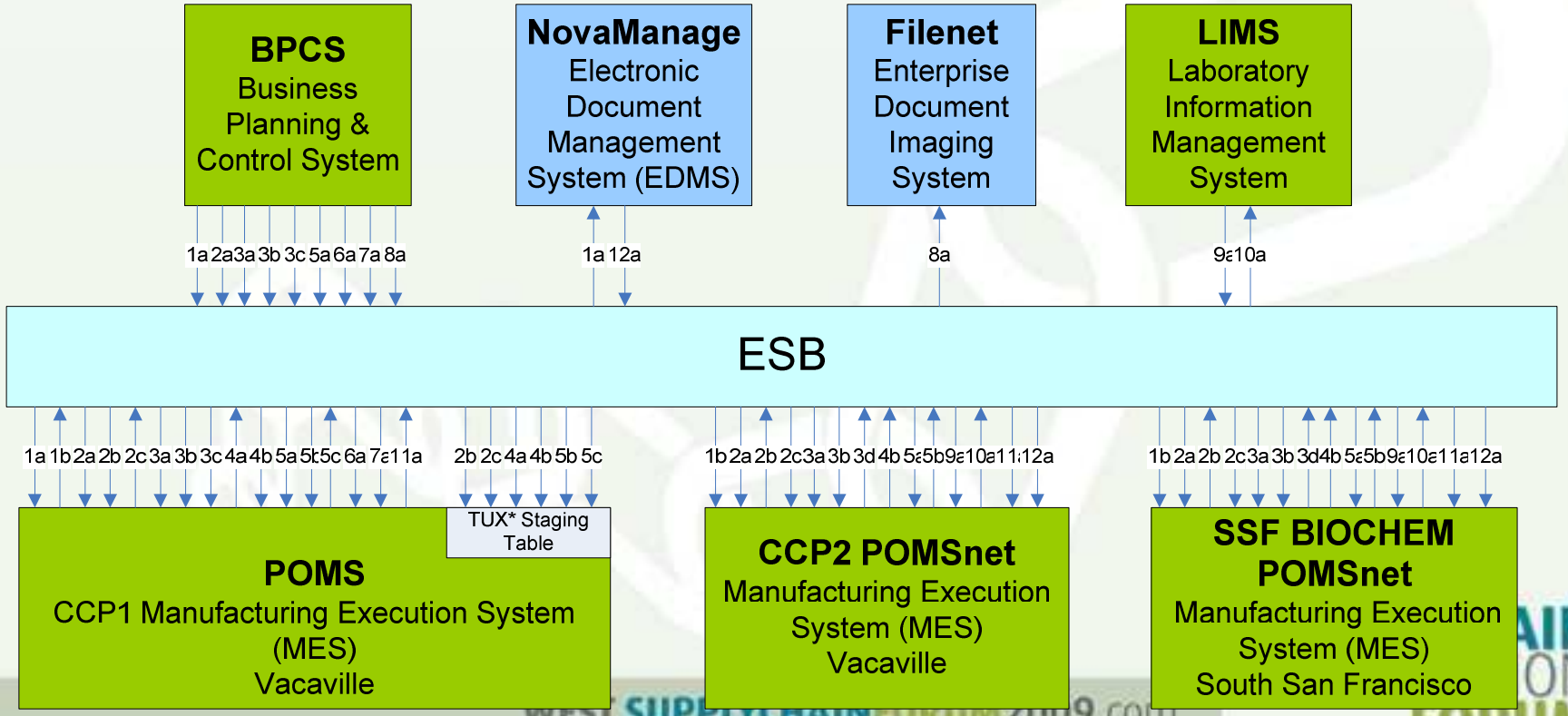
1a: Material Lot: New Lot created, updated

1b: Production Response: Consumption, Production

1c: Material Usage:
A: Scrap- Type, Quantity, Reason Code, Cost Center
B: :Adjust- Quantity Change, Reason Code

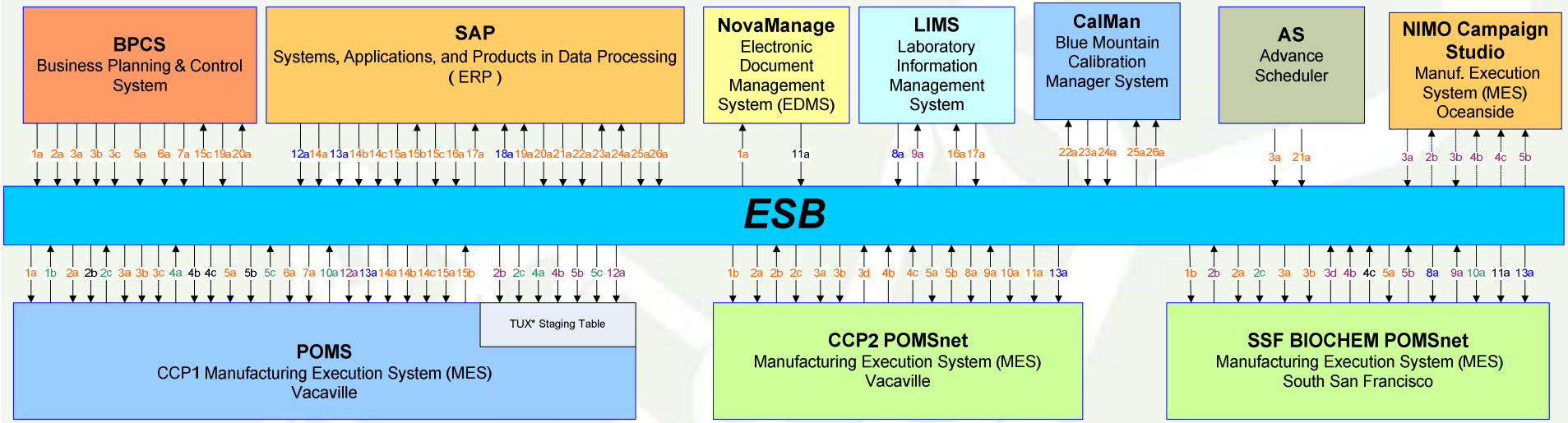
PROP(SUMMIT) ESB Phase 2

- Support 2 sites - CCP2 and SSF MES BioChem
- 7 Systems, 13 use cases



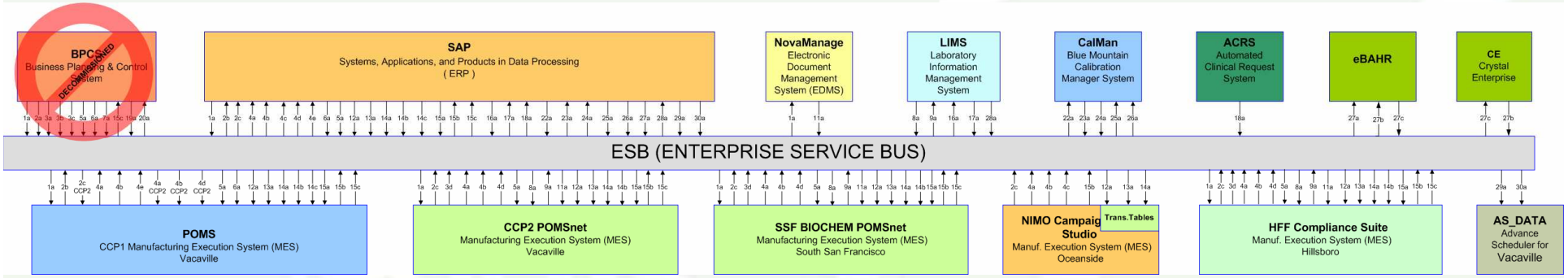
PROP(SUMMIT) ESB Phase 3

- Support 3 sites - CCP2 and SSF MES BioChem, NIMO Oceanside
- 10 Systems, 18 use cases

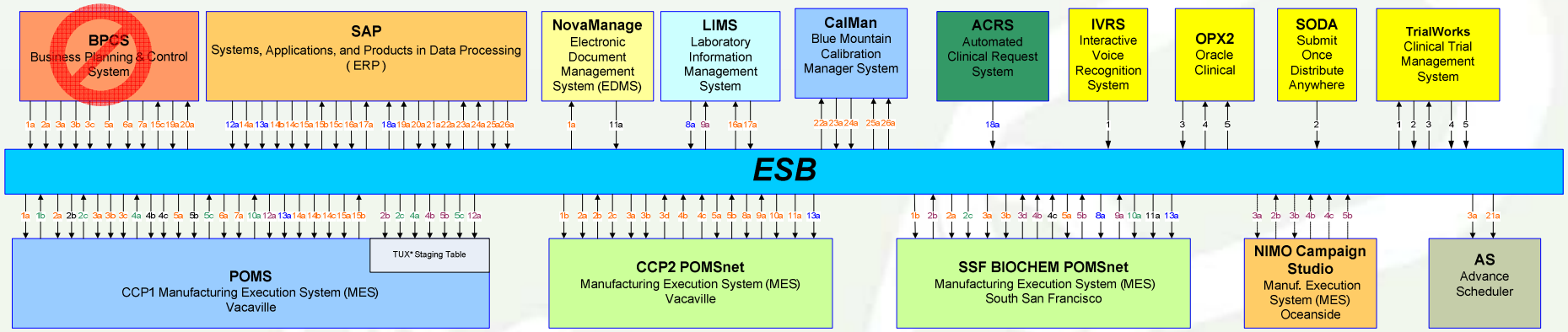


PROP(SUMMIT) ESB Phase 4

- Support 5 sites - CCP2 and SSF MES BioChem, NIMO Oceanside, Singapore, HFF
- 13 Systems, 40 use cases



Validated Integration Landscape (GxP)



Material Master:
1a. Material Master- Create, Update
1b. Material Master- Create, Update

Material Lot Master:
2a. Material Lot Master- Create, Update
2b. Material Lot Master- Create, Update
2c. Material Lot Master- Create, Update
12a. Material Lot Master (SAP) – Create, Update
13a. Material Lot master (SAP) - Create

Production Request:
3a. Production Request- Create, Update
3b. Material Allocation- Create, Update
3c. Operation Details- Create, Update
3d. Production Request- Create
14a. Production Request (SAP) - Create, Update
14b. Material Allocation (SAP) – Create, Update
14c. Operation Details (SAP) – Create, Update

Production Response:
4a. Material Consumption or Batch Consumption- Update
4b. Material Production, Batch Consumption,
4c. Unit Procedure Status or Control Recipe Status- Update

Material Inventory:
5a. Material Inventory- Create, Update
5b. Inventory Adjustment- Waste Material, Material Transfer
5c. Inventory Adjustment- Waste Material
15a. Inventory Adjustment (SAP) - Material Transfer
15b. Inventory Adjustment (SAP) - Material Consumption
15c. Material Inventory (SAP) - Inventory Transfer

Unit of Measure
6a. Unit of Measure- Create, Update

Reason Code:
7a. Reason Code- Create, Update

LIMS Results:
8a. LIMS Test Results- Create, Update
17a. LIMS Raw material Results – Create, Update

LIMS Sample Logging:
9a. LIMS Sample Logging- Create
16a. LIMS Sample Logging (SAP) – Create, Update, Purge

Lot Flag:
10a. Lot Flag- Create, Update

EDMS (NovaManage) Documents:
11a. EDMS Document Data- Create, Update

Clinical Inventory
18a. Clinical Inventory – Create, Update

Inventory Request:
19a. Material Staging Request (Inventory)- Create, Update

Depleted Batch Reconciliation:
20a. Raw material Inventory snapshot (SAP)- Create, Update

Maintenance Order:
21a. Maintenance Order- Create, Release

Equipment Master:
22a. Equipment Master - Create, Update

Measurement Data Template:
23a. Measurement Data Template - Create, Update, Delete

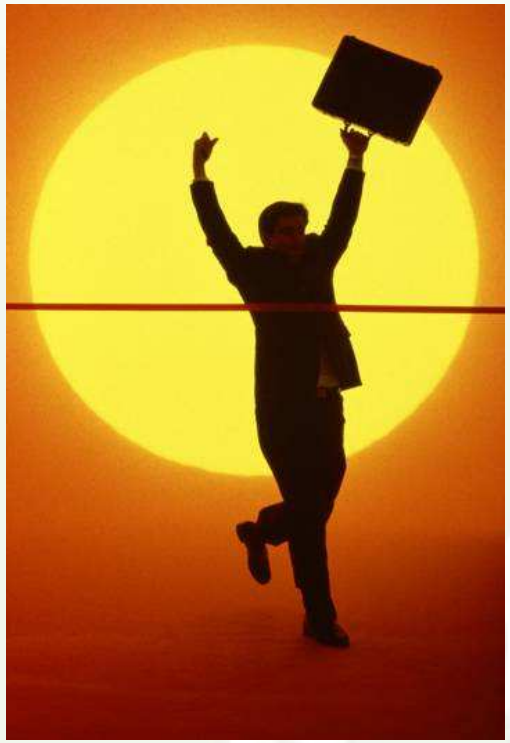
Work Order Confirmation:
24a. Work Order Confirmation - Create

Work Order:
25a. Work Order - Create

Maintenance Plan:
26a. Maintenance Plan - Create, Update, Delete

1. Patient Visit
2. StudyInfo
3. Planned Milestone
4. Actual Milestone
5. Synchronize Studies

PROP ESB Benefits



- On track for World Class manufacturing
- Reduced development and support costs by eliminating ad-hoc, point-to-point interfaces.
- Scalable and extensible application integration without impacting system performance.
- Improved quality of data by enforcing data integrity and consistency across applications through common information model compliance and with guaranteed delivery of messages.
- Improved productivity of implementing multiple projects by decoupling source and target systems.
- Eliminated paper statements by automating data exchanges with manufacturing sites.

Saved over $4M in cost when integrating two additional manufacturing sites to production line.

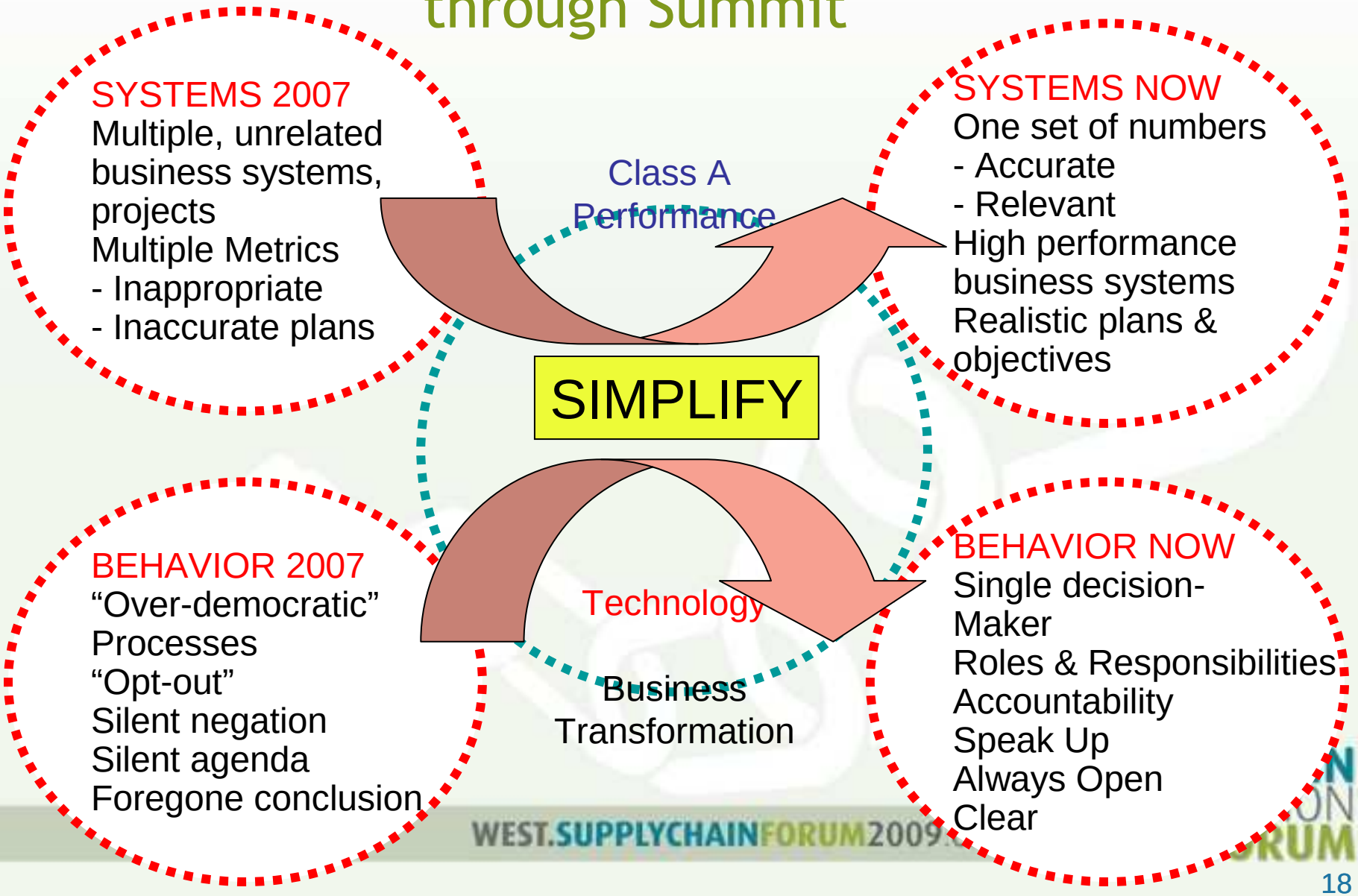
Lessons Learned: Overall Approach

- Strong business sponsorship
- Started slowly with a low-risk Pilot project
- Integration Competency Center
  - Better adoption
  - Direction and Vision
  - In-house POC
  - Educating the business and developer community

The Nine Class A Behaviors to be delivered through Integration

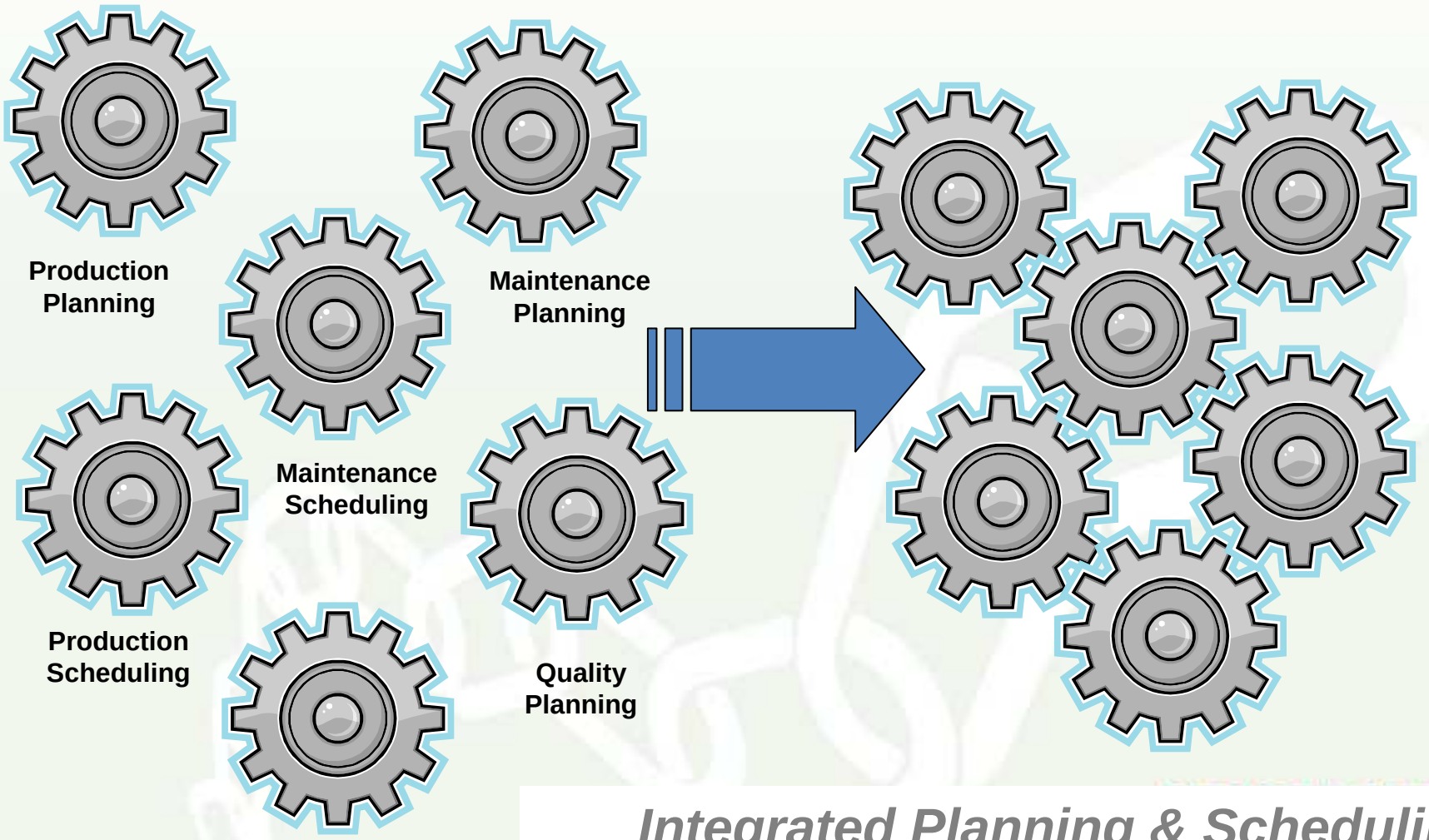
1. One Set of Numbers to Run the Business
2. Shared, Aligned and Realistic Plans
3. A Passion for Accuracy
4. A Passion for Simplification
5. Business Process Performance Measurements
6. “Democracy” in Planning, “Autocracy” in Execution
7. Never uncertain—Always open
8. Embracing Accountability and Speaking Up
9. Knowledgeable Workforce with Clear Roles and Responsibilities

Business Transformation through Summit



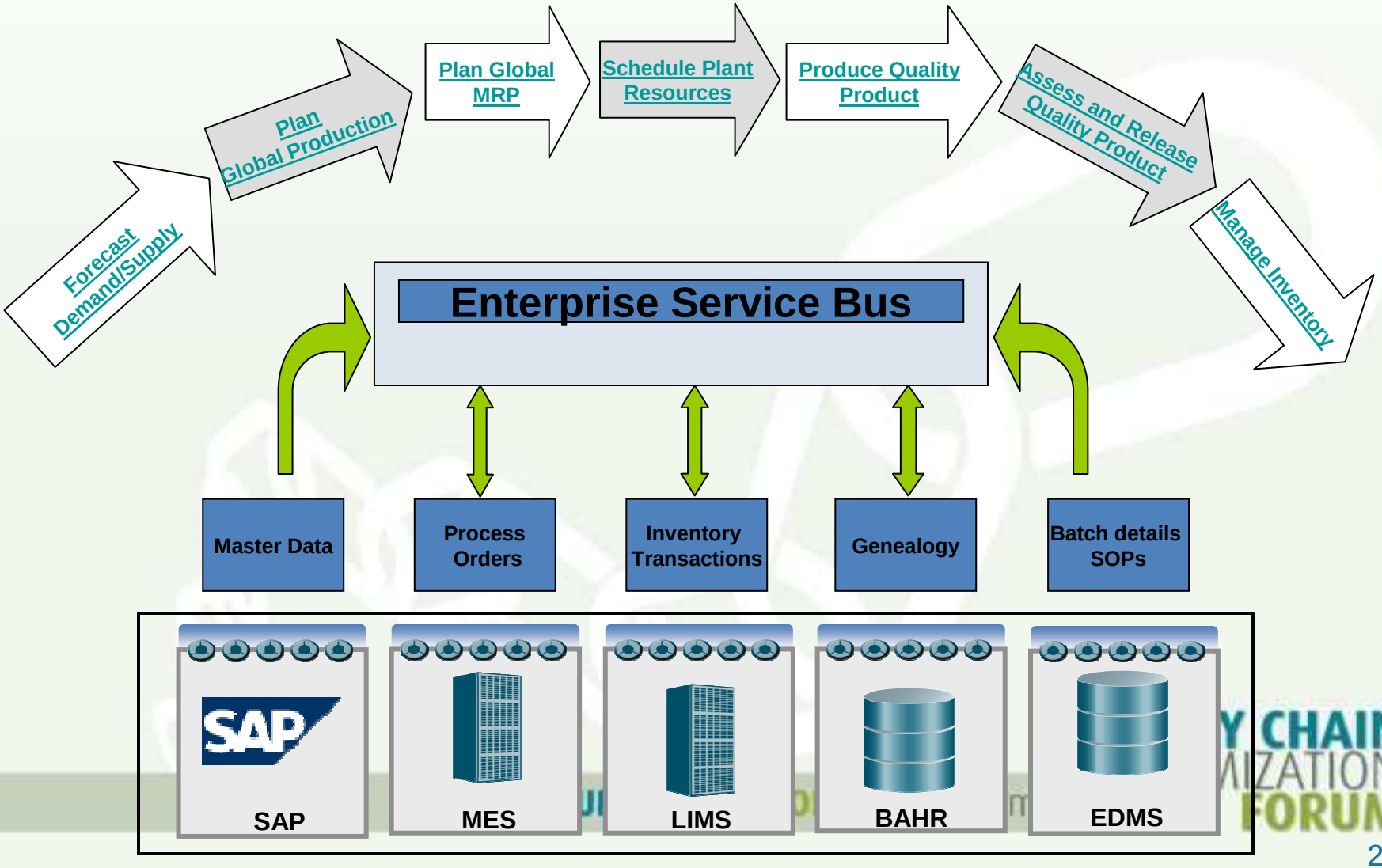
Class B

Class A



Integrated Planning & Scheduling Business Process

Supply chain interactions optimized



Bottom Line…

Integration across MES, ERP and Legacy applications helped Genentech discover its manufacturing problems *earlier* which in turn helped in ensuring:

…**higher product quality**

…**shorter product development cycles** due to enhanced communication

…**faster ramp up** of the production of new products

…**easier compliance** with government regulations through track and trace mechanisms.