From Compliance to Competitive Advantage

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OSIsoft's Role in Compliance

- What is the role of OSIsoft's RtPM in Compliance?
- What is a Compliance Architecture?
- What should our customers do now for SO?

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Compliance Areas Matrix 1 - Mandates

Mandate	Description	Business Requirement	Industry
EPA Clean Air Act (1990)	**Sets limits on air pollutants.**	Sets limits on how much of a pollutant can be in the air anywhere in the United States. The law allows individual states to have stronger pollution controls than those set for the whole country.	**All**
EPA Clean Water Act (1972)	**Set limits on water discharged to waterways.**	Employs regulatory and non-regulatory tools to reduce direct pollutant discharges into waterways, finance municipal wastewater treatment facilities, and manage polluted runoff.	**All**
EPA Title V	**Regulation of chemical substances whose manufacture may present risk to health or the environment**	Various acts requiring registration, reporting, and conformance.	**Oil & Gas** **Chemicals** **Pulp & Paper**
FDA 21 CFR Part 11	**Electronic records and signature**	Technical and procedural requirements for electronically maintained records and electronic signature used in manufacturing transactions.	**Pharmaceutical** **Food**
FDA – GMP	**Finished Drugs or Medical Devices**	Requires manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States.	**Pharmaceutical**
Sarbanes Oxley	**New laws for companies to really show that they are committed to solid corporate governance practices.**	**Section 409: Real Time Disclosure.** Issuers must disclose information on material changes in the financial condition or operations on a rapid and current basis.	**All**
NERC Critical Infrastructure Protection	**Cyber security standards**	Reduces risks to the reliability of the bulk electric systems from any compromise of critical cyber assets (computers, software and communication networks) that support those systems.	**Power Generation** **Transmission & Distribution**

Compliance Area Matrix 2 - Standards

Standard	Description	Business Requirement	Industry
QS 9000	**Quality Management**	Provides requirements that, if they are effectively implemented, will provide confidence that a supplier can consistently provide goods and services that: •Meet your needs and expectations and •Comply with applicable regulations	**All**
ISA-SP95	**Enterprise – Control System Integration**	Defines the interface between control functions and other enterprise functions.	**All**
ISA-SP99	**Manufacturing and Control Systems Security**	Define procedures for implementing electronically secure manufacturing and control systems and security practices and assessing electronic security performance.	**All**
ISA-SP88	**Batch Control System Standards**	Recommends practices for the design and specification of batch control systems as used in the process control industries.	**Pharmaceutical** **Chemical**
NERC GADS	**Generating Availability Data System (GADS)**	Manages the collection of operating information for improving the performance of electric generating equipment. The information is used to support equipment reliability and availability analyses and decision-making by GADS data users.	**Power Generation**
HACCP	**Hazard Analysis and Critical Control Point Principles**	Establishes critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping to assure that potentially hazardous products do not reach the consumer.	**Food**

Compliance Area Matrix 3 – Best Practices

Best Practice	Description	Business Requirement	Industry
KPI	**Key Performance Indicators**	Establish and continuously monitor key manufacturing metrics against targets.	**All**
CBM	**Condition Based Maintenance**	Proactive maintenance approach, which requires monitoring of critical equipment periodically. CBM is just-in-time maintenance that ensures "the right work, at the right time."	**All**
FDA - PAT	**Ensure Final Product Quality**	Controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes.	**Pharmaceutical**
OEE	**Overall Equipment Effectiveness**	Evaluate performance of a single piece of equipment or even an entire factory, as governed by the cumulative impact of the three OEE factors: Availability, Performance Rate and Quality Rate.	**Chemicals** **Food** **Metals & Mining**
Six Sigma	**Continuous Quality Improvement**	Methodology for eliminating defects (driving towards six standard deviations between the mean and the nearest specification limit) in any process -- from manufacturing to transactional and from product to service.	**Metals & Mining**

Customer Challenges

- **Our customers are all facing some regulatory requirements and have to report on them**
  - Manufacturing, quality, environmental, etc.
- **Data must be pulled together from many sources:**
  - Multiple PI Servers across the Enterprise
  - External relational databases
  - Web services

The Bottom Line:

As business and IT recognize the overlapping requirements of individual compliance mandates, leaders are taking steps to build out a sustainable architecture that minimizes time and cost while maximizing future reuse.

John Hagerty, AMR Research Staff

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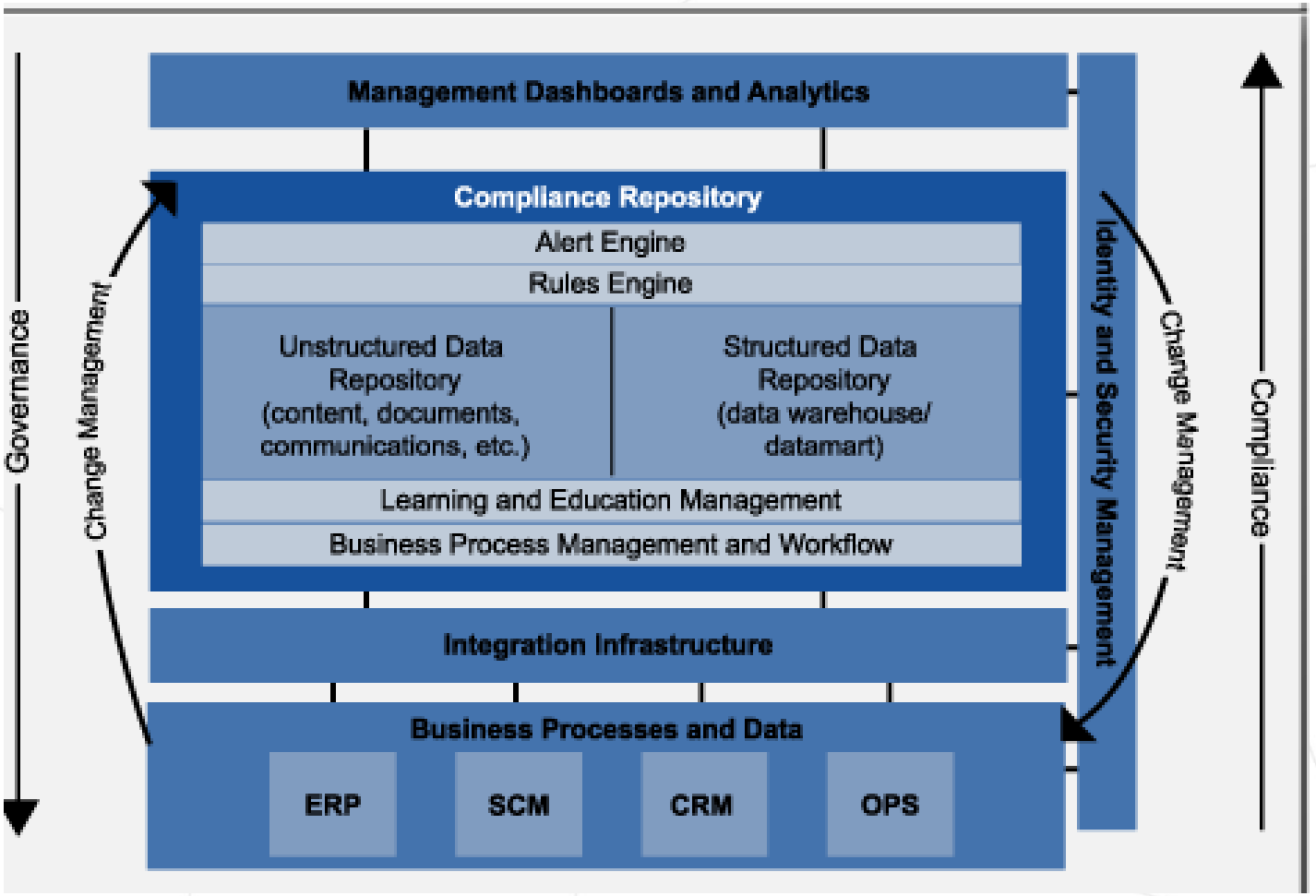
Active Compliance Architecture



Source: AMR Research 2004

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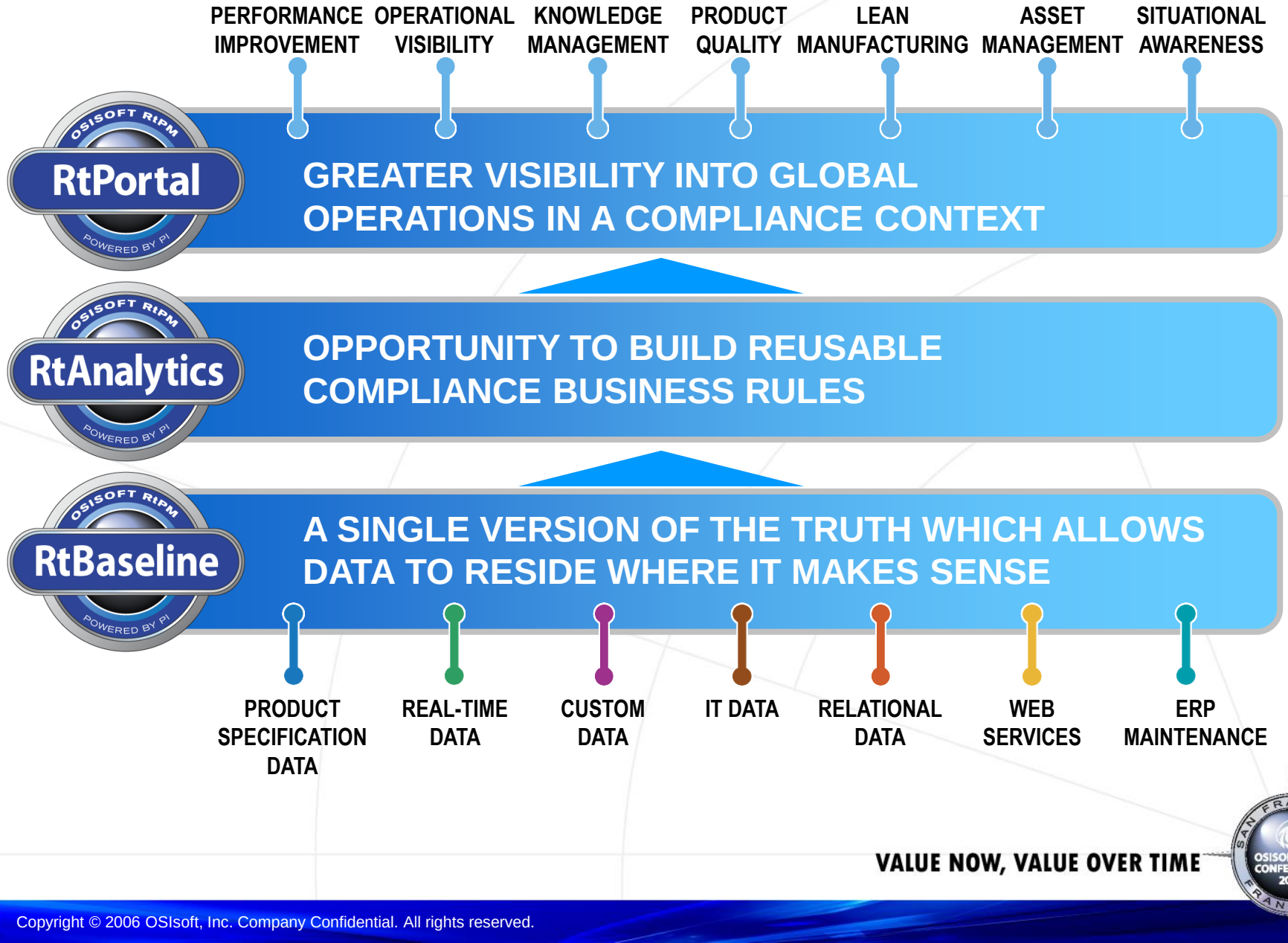
RtPM – A Corporate Infrastructure for Compliance



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Compliance Requirements and RtPM

- **Data integrity and trusted data is fundamental**

  RtPM - Validation Ready Products PI Audit Trail

- **Security and privacy are key constructs**

  Security to the tag level Use of WinOS security IT Monitor

- **Archiving for a retention period is expected**

  Fundamental to all PI Servers

- **Documentation and reporting considerations are paramount**

  Configurable Compliant Reporting – RtReports

- **Most areas require sophisticated analytical capabilities**

  ACE Sigmafine RLink RtReports RtWebParts

- **Virtually all compliance mandates are driven by rules, policies and procedures – either internally generated or formally dictated**

  ACE Sigmafine RtAlerts RtReports

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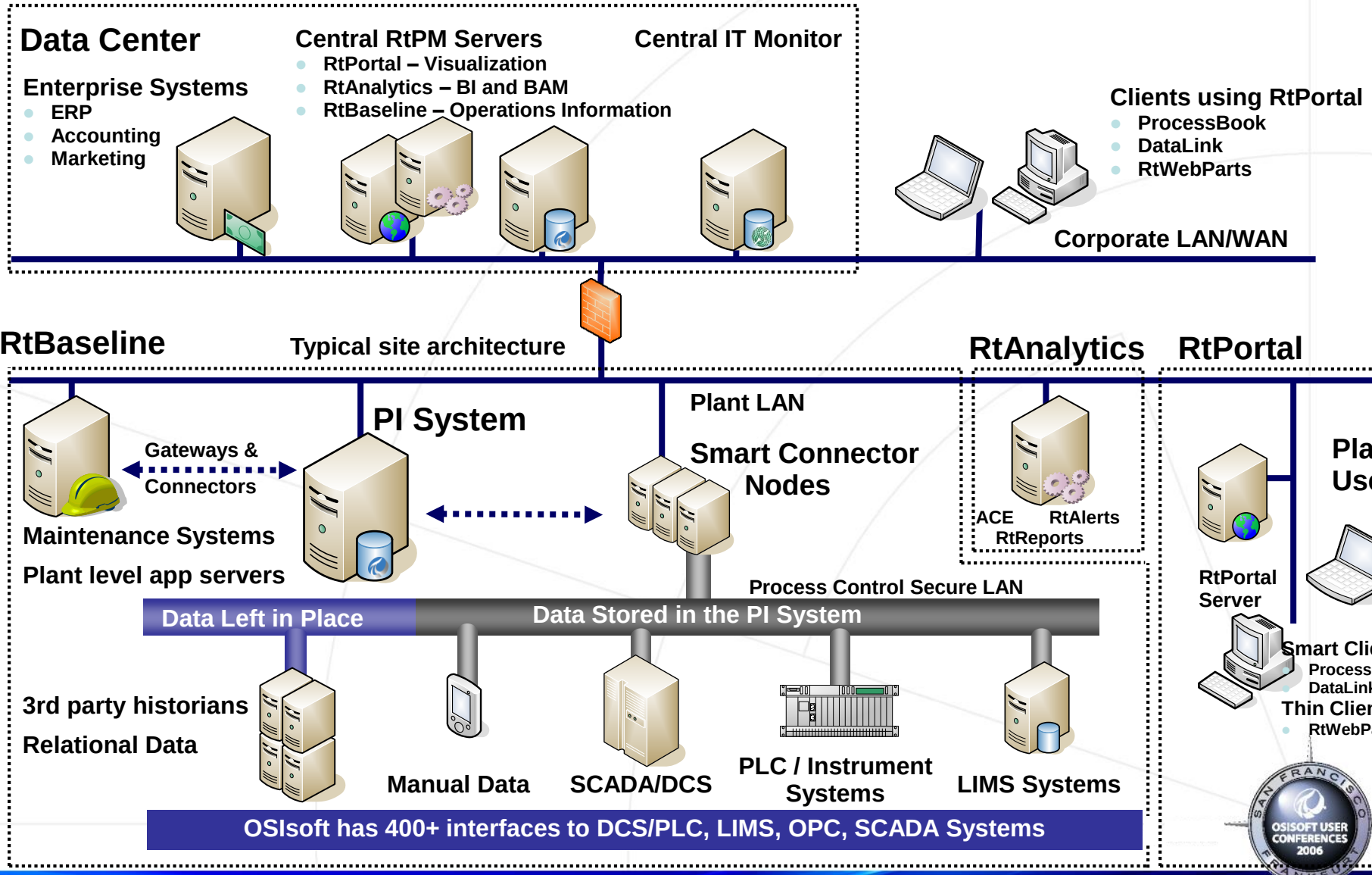
Detailed Enterprise Compliance Architecture



What you can do now

- Turn on the PI Audit trail
- Establish security procedures for user logins and passwords
- Set tag security both data access and configuration and review PI Trust relationships
- Implement management of change policy on PE's and ACE equations and use a source control system
- Implement management of change policies on critical Process Book displays and Datalink spreadsheets

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