Enterprise PLM- A Global Competitive and Compliance Imperative

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Carestream

An independent company with a proven track record and $2+ billion in revenue

A world leader in:
- Medical imaging ... digital imaging solutions and traditional film
- Healthcare information solutions
- Dental ...media, digital imaging solutions and practice management software
- Non-destructive testing.. media, imaging solutions
“Globalization has added complexity to knowledge workers operational environments robbing their time to innovate.”

“Unmanaged application and process proliferation is an Achilles Heel (weakness) for a regulated company.”

“IoT data will further complicate business, disrupt markets and dramatically change time to market expectations for releasing innovative data enhanced services.”
Globalization was enabled by internet connectivity
  leverage world wide talent
  balances the cost structure
  allows presence in emerging markets

What to understand and manage
  Collaboration becomes more time consuming robbing innovation cycles
  Complexity in the organization increases as work groups decentralize
  Productivity can be negative if process, tools, and master data are not given proper consideration
  Regulatory risk footprint increases as business process and tool diversification occurs

“Business processes enabled IT applications are the circulatory system for your innovation engine,
  when clogged life moves slower and in a much more limited fashion, a silent killer in a data enabled world”
Challenges - Application and Process Proliferation

Mergers & Acquisitions and IT Neglect can lead to System Proliferation

- Organic and inorganic growth
- New market opportunities
- IT Cost focus not a strategic focus

What to understand and manage - IT is no longer just a cost center in today’s world

- Geographic and company proximity and culture will impact the willingness to change, discuss IT!
- Purchased companies have existing IT and business infrastructures, harmonize IT!
- Change is difficult, a natural resistance to harmonization, lead IT!
- Process and IT proliferation will occur if neglected, manage IT!

“Customers do not buy your engineering change control process or PLM system, they buy your products and innovation content that is maintained and controlled within PLM”
Challenges - Compliance

Regulations and compliance is our way of life, but compliance presents opportunities

- Internal and External Audit findings
- Universal Device Identification (UDI) and Registration
- China FDA
- FDA focus on sustained quality of outcomes vs pure compliance

What to understand and manage

- Internal Audits are a good source for assessment of your current risk footprint and process opportunities
- Design of a new process and tool set to meet regulations can create an opportunity to harmonize
- Verification and Validation of computer systems takes time, effort and attention, harmonization saves time

"PLM is a critical enterprise platform that must evolve to support a quality mindset of continuous business improvement, reduction of compliance risks and prepare the company for a data enabled fast paced future"
FDA is taking a new approach

• In recent years, a growing number of patients have suffered from adverse events due to medical devices. To better understand the reasons for these lapses in quality and safety, we conducted interviews with medical device industry thought leaders and FDA leadership and in parallel analyzed FDA adverse event reports and recall data.

• Our efforts revealed that there are systemic gaps within the medical device industry’s quality approach that result in these issues. Attempts to improve quality are hindered by challenges within the industry as well as specific aspects of the Agency's regulatory approach. Moving toward greater visibility into device quality and properly aligning FDA’s regulatory approach will be important to catalyzing industry movement towards improved device quality. **Investment by FDA now in a holistic quality infrastructure will support a next generation of medical devices that are as safe and well made as they are innovative.**

“Increasing complexity of medical devices and usage environments is straining the current quality system infrastructure. Companies report that they have not systematically upgraded their quality infrastructure due to the unclear economics and concerns about regulation.”
Accelerating Change – 3rd Wave of IT is birthing a 4th Wave of Industry Productivity

Here comes - Industry 4.0

- Powerful Connected Devices
- Connectivity - Internet
- Cloud Computing Infrastructure
- Ubiquitous Sensing
- Data Sharing, Social Networking

$30b+ investments
New Devices

NEST- will not only play in the $3 billion global thermostat sector;

NEST will shape the $6 trillion energy sector.
- HBR Nov 2014

Digital Enablement is here

“Over the next five years many business components will be digitized to enable a new range of products, services, and business models.”
- HBR Nov 2014

New Business Models -
CEO Travis Kalanick on Uber’s $40B Valuation

The taxi market in San Francisco is about $140 million per year Uber’s SF revenues at $500 million per year. (That’s over 3x!)

Uber and automated cars are reshaping the world wide automotive industry
So what does this all really mean?

“Tightly managing your information from cradle to grave is table stakes to maintain effectiveness and compliance in a digitally connected world”

“The ability to “hyper innovate” services around data and rapidly evolve hardware through software will become the competitive advantage as data shapes consumption patterns and market expectations”

“Enterprise PLM is core to compliance, process automation, flow of information and master data management across the lifecycle”
“A complete and integrated approach to the management of key baselines will become a core competency in the post IoT world that demands compliant “hyper-innovation” cycles “

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Consolidated macro process view is critical to communications and strategic planning.

Helps business to visualize IT solution architecture.

Process automation, data flow and IT system harmonization are enabled through clear communications.

Provides a basis for planning over a long period of time.

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Visualize an Integrated Lifecycle Management Ecosystem

**Goal:** Fast and efficient master data flow end to end across IT systems

Consolidate **ALL** product related (DHF, DMR) baseline data in the Enterprise PLM System. Use a PLM core to automate processes and flow data across the product lifecycle.

**Quality System Framework**

**Operational**
- Stage Gate Process
- Engineering Change Process
- Engineering Change Implementation Process
- Quality Testing

**Inspirational**
- IDE
- ALM
- Integrations
- Requirements
- CAx
- PDM

**Transaction**
- WIP - CAx/PDM/ALM

**PLM/Quality Engineering**
- Design Baseline - DHF
- Product Configuration Baseline - DMR

**Process Training**
- ERP - Purchasing Systems
- As Built Production Baseline - DHR
- Serviced Baseline - DHR Extend

**Process Documentation**
- Integrations

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DEFINE and CONSOLIDATE the Baseline of Configuration Items

Example- Product Configuration Baseline- Design Master Record (DMR)

- Engineering Change
- Composition - Drawings - Specs - Formulation
- Design Information SW/HW/SYS
- Bill Of Materials
- Process Specifications - equipment - methods - environment
- Device Identification - Submission - Labeling - Track
- Work Instructions - Methods - Training
- Quality Assurance Records - Inspection - Testing
- Non-conformance - Process - Parts
- Engineering Change Bill Of Materials (ECCs)
- Technical Pubs - Install - Service - Maintain
- Document Families

Look in Engineering Systems
Look in Manufacturing Systems
Look in Documentation Systems
Leverage the PLM Platform for Consolidation and Integration of Baselines

Design History Baseline – Example - DHF (Minerva/Aras Solution)

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**Name:**
8617 - Quality Center Upgrade

**Description:**

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<td>FDX Legacy Retirement Plan</td>
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<td>User Training Plan</td>
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<td>Procedure and Work Instructions</td>
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<td>FDX Data Design Plan</td>
<td>IT Tech Lead</td>
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Define a Common Change Control Process in PLM

Configured PLM Solution in ARAS Innovator
Impact of the IoT and Machine Connectivity

...more frequent and faster product software updates to harness market opportunities

IoT data is already showing up across the lifecycle enhancing design, quality, and service information. IoT data will drive more frequent product updates to expose data and add services based on data.
Critical Takeaways

REALIZE IT – 3 IT Technology waves have already drastically changed the working environment and are combining to bring about exponential change in markets. IT is becoming a strategic function.

HARMONIZE IT – So that you have the focus to be successful and remain compliant and efficient in the data enabled IoT world

LEAD IT – provide a solid IT strategy that aligns with business vision and work together with the business and functions on solutions to business problems

INTEGRATE IT – across functional teams form an Integrated Lifecycle Management (ILM) Ecosystem consisting of QMS, PLM, ALM, PDM, ERP, SLM…

Enterprise PLM is a CORE Platform - Product Lifecycle Management enables automation and is core to controlling all PRODUCT related configuration items through automated processes

• Define – critical baselines (DHF, DMR) and configuration items clearly
• Consolidate- product records into a single PLM system
• Create Information Flow - enable “Hyper Innovation” cycles with fast and efficient “lean” automated business processes
Join me in conversation!

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### IoT RESULT – A Shift from Selling Things to Selling Services

**Increasing Business Process and Selling Process Changes**

- **Sell Thing**
  - Sales Transactional
  - IoT Connect to internet

- **Sell Improved Services & Product Servitization**
  - Sales Flow
  - Data and Remote Access Availability

- **Sell Customer Partnership (Consulting, Customer Benefit)**
  - Predictive Device Modeling & Customer Efficiency and Customer Cost Out
  - Knowledge/Trending
  - Information availability

- **Sell Customer Side Efficiency and Innovation**
  - Information Sharing, Eco-System Efficiency, Customer side processes improvements
  - Selling Eco-System Services
  - Business Intelligence

- **Proactive Service & Consumption Models Internal Cost Out**

- **Services Selling Diversification**

**Internal Focus** ➔ **Customer Focus**

- **Revenue Opportunity**
  - 7x Revenue opportunity over selling a “Thing”

**SOURCE:** D. Sherburne 5/2016

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