Enterprise PLM- A 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
Challenges facing companies in the Digital World

“Globalization has added complexity to knowledge worker environments, robbing their time to innovate”

“Unmanaged application and process proliferation has become a major risk for regulated companies and an impediment to speed for all companies”

“Digital transformation brought about by the IoT will further complicate business by disrupting markets and dramatically changing time to market expectations”
Challenge - Globalization

Internet Connectivity brought about Globalization

- leverage to world wide talent
- balanced cost structure
- presence in emerging markets

What to manage to improve productivity

- reduce the complexity in the organization caused by decentralization
- give proper consideration to process, tools, and master data issues to reduce complexity
- minimize business process and tool proliferation due to preferences

“Processes are the circulatory system for your innovation engine, when clogged everything moves slower and in a much more limited fashion, a silent killer in a digitally enabled world”
Challenge - Proliferation of non-standard point solutions

System Proliferation is caused by a Leadership vacuum
- local preferences prevail
- M&A activity is not assimilated
- new market opportunities justify “fast and loose” decisions
- cost focused IT causes localized shadow IT
- lack of alignment causes infighting

What to lead to be successful
- culture and the willingness to change, **discuss IT**!
- duplication in business infrastructures, **harmonize IT**!
- people will resist change, **lead IT**!
- proliferation will occur if neglected, **manage IT**!

“Customers do not buy your engineering change control process, they buy your products and innovative content”
Challenge - Compliance Risk Mitigation

**Regulations and compliance is a way of life**
Universal Device Identification (UDI) and Registration mandates
Global mandates – China FDA, etc
FDA focus on sustained quality of outcomes vs pure compliance

**What to understand and manage**
internal and external audit findings can help to prioritize risk areas
harmonization reduces risk dramatically
compliance issues present opportunities to harmonize
common IT saves time and money because Verification and Validation takes time, effort and attention

“PLM is a critical enterprise platform that should evolve in support of a quality and compliance mindset. PLM enables harmonization and prepares the company for Digital Transformation”
FDA is taking a new approach- Quality Outcomes

• 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.”
Challenge – Digital is Fast and Disruptive

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

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

New Business Models - CEO Travis Kalanick on Uber’s $40B Valuation (now $63B)
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
“The 3rd Wave of IT is birthing a 4th Wave of Industrial Productivity”

Here comes - Industry 4.0

- Connectivity – Internet as a Utility
- Cloud Computing Infrastructure
- Ubiquitous Low Cost Sensing
- Social Networking-Data Sharing
- Artificial Intelligence-Analytics
- New Interfaces

Cloud Computing
$30b+ investments

AN EXPLOSION IN CONNECTED DEVICES
NUMBER OF DEVICES IN USE (IN MILLIONS)

Between now and 2018 we’ll see the number of smartphones, tablets, and other connected devices skyrocket.
Digital Transformation – A Shift from Selling Things to Selling Services

- Reactive
  - Sell Thing
- Proactive
  - Sell Improved Services & Product Servitization
  - Sell Customer Consulting, cost out, efficiencies
- Predictive
  - Sell Customer Side Efficiency and Innovation through matrixed offerings that combine data from internal and external sources
- Matrixed
  - Revenue Opportunity

Company Focus

Age of the Customer

Faster more frequent changes to products to rapidly enable new functionality and services will be the norm

SOURCE: D. Sherburne 5/2017
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So what does Digital Transformation really mean?

“The Age of hyper innovation”

The ability to rapidly build and deploy services around data and evolve functionality through software will become the competitive advantage as data reshapes markets

“The Age of the Customer”

Customers will be the focal point and rapid innovation will be the norm

Integrated Lifecycle Management (ILM) thinking

PLM will be core to compliance and coordination at the product level

Integration of systems will operationally enable “hyper innovation cycles”

Consistently managing product baselines from cradle to grave will be table stakes
PLM Core to Operational Flow

Common Baseline of Information in a Common Repository Controlled by Common Processes

Common Baseline = Single Source of Information

Request → Notify → Implement

SW → ME → EE → MFG

Are you ready to change?
Visualize an Integrated Lifecycle Management (ILM) IT Ecosystem

Philosophy – Integrate solutions for fast and efficient master data flow end to end

Quality Framework

Process Documentation
- Inspirational
  - IDE
  - ALM
  - Requirements
  - CAx
  - PDM
- WIP - CAx/ PDM/ALM

Operational
- Stage Gate Process
  - Project – Design – DHF – Baseline
- Engineering Change Process
  - Product Configuration Baseline – DMR
- Quality Testing

PLM/ Quality

Transaction
- Integrations
  - ERP – Purchasing Systems
  - As Built Production Baseline – DHR
  - Serviced Baseline – DHR
  - Extended to Customer

Process Training

SOURCE: David G. Sherburne
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“A complete and integrated approach to the management of key baselines conception to customer will become the core competency in the digital world”

SOURCE: David G. Sherburne
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Baseline = A Collection of Configuration Items @ Time Point

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

Engineering Change

Bill Of Materials

Composition - Drawings - Specs - Formulation

Design Information SW/HW/SYS

Look in Engineering Systems

Process Specifications - Equipment - Methods - Environment

Device Identification - Submission - Labeling - Track

Work Instructions - Methods - Training

Quality Assurance Records - Inspection - Testing

Non-conformance - Process - Parts

Look in Manufacturing Systems

Product Labeling - Specs - Process

Technical Pubs - Install - Service - Maintain

Look in Documentation Systems
Consolidate Baselines in PLM and Integrate Enterprise Systems

Footprint

RISK
Digital Transformation-frequent and faster product software updates

IoT data is enhancing design, quality, and service information today.

IoT data will drive more frequent product updates to expose data and add new services based on data.
Continuous increased usage and harmonization

PLI Users Per Month

90% Penetration

5 years
**Leverage the PLM Platform for Consolidation of Baselines**

**Project:** Design History Document Baseline – Example - DHF

*(Minerva/Aras Solution)*

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## Deliverable Matrix

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**Description:**
Implementation of Pilgrim Document Management and Training Attestation and effectiveness modules

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## Deliverable Matrix Line

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Interface for document approvals

PLI DCN

DCN Number: DCN06339
Status: In Work

Owned By:
Product 1672 Tahoma

Created By:
Clydes Davies 30106715
Created On: 2017-01-09 15:10:40

Modified By:
David Streitman 1249484
Modified On: 2017-02-13 21:19:08

Locked By:

Release Date:

## Affected Items

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Document: A883504
Title: P1672-Agile system decommission APPROVAL

Document: P1672-Agile system decommission APPROVAL
Title: P1672 - Process to retire Agile 110x17.docx
Common Change Control Process

Configured PLM Solution in ARAS Innovator
Common Change Control Process in PLM
Common Change Control Process in PLM

PLI - ECN's Released Per Year

- 2012
- 2013
- 2014
- 2015
- 2016
Implementation Time

Create -> Implementation Cycle Time

ECI Changes and Enhancements

3 years
PLM Gives the Power to Perform

Control the onslaught of work

Eliminate Redundancy

Instill Confidence

Speed up Implementation

Reduce Duplicate Information and Effort

Reduce Compliance Risk
Digital Transformation is HERE
ILM/PLM can Transform your Operations

Uninformed

Adhoc

Mistake Driven

TO

In Control

and Rapidly Innovative

FAST
Critical Takeaways

Enterprise Product Lifecycle Management is CORE

PLM enables operational flow at the product level through integrations (ILM)

PLM standardizes and integrates cross functional process work flows

PLM provides the harmonized framework to move change fast

PLM controls the PRODUCT configuration master data baselines critical to compliance

- Define – critical baselines (DHF, DMR) and configuration items clearly
- Consolidate – product records into PLM
- Create Flow - enable “Hyper Innovation” cycles with fast and efficient “lean” automated business processes functionally and geographically
- ILM- Integrated Lifecycle Management integrate to PLM core to the ILM eco-system
IT Must Lead and Be Strategic

DISCUSS IT

IT Technology waves have already drastically changed the working environment and are combining to bring about the next wave! **IT is a strategic function, not a cost center!**

HARMONIZE IT

have the focus to be fast, effective and compliant in the competitive digital world, **get control of master data baselines with PLM!**

LEAD IT

drive an integrated ILM strategy and philosophy that aligns with the business vision to focus on the customer and transform!

MANAGE IT

form a **Integrated Lifecycle Management (ILM)** plan consisting of QMS, PLM, ALM, PDM, ERP, SLM and execute!
Join me in conversation!

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david.g.sherburne@carestream.com
PLM is an important part of the Quality System Process and Solutions Architecture

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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