PLM Roadmap at Bayer Medical Care
Navigating PLM Strategy & Success Post Merger

Science For A Better Life
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Navigating PLM Strategy & Success Post Merger

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Product Supply and R&D Medical Care Business Partner
Medical Care, a Bayer HealthCare Company
Agenda

- Company Overview
- Business Challenges addressed by Enovia PLM
- Next Steps in PLM Strategy
- Q&A
Company Overview

Bayer AG
Bayer HealthCare
Bayer Medical Care
Bayer HealthCare
Full Year 2013

Employees* 56,000
Sales € 18,924 billion
EBITDA before special items € 5,334 billion
R&D expenditure € 2.0 billion
CEO of Bayer HealthCare AG Olivier Brandicourt
Bayer HealthCare
Divisions

**Pharmaceuticals**
- General Medicine
- Specialty Medicine

**Animal Health**
- Companion Animal Products (CAP)
- Farm Animal Products (FAP)

**Consumer Care**
- Non-prescription drugs
- Vitamin and Mineral Supplements
- Rx dermatology

**Medical Care**
- Diabetes Care
- Radiology
Global Leader in Specialty Pharmaceuticals and Consumer Health

<table>
<thead>
<tr>
<th>Division</th>
<th>Sales 2013</th>
<th>Employees 2013: 56,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer Health</td>
<td>€ 1,306 million</td>
<td>Pharma</td>
</tr>
<tr>
<td>Animal Health Division</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumer Care Division</td>
<td>€ 3,904 million</td>
<td>Pharma</td>
</tr>
<tr>
<td>Medical Care Division</td>
<td>€ 2,526 million</td>
<td>Pharma</td>
</tr>
<tr>
<td>Pharmaceuticals Division</td>
<td>€ 11,188 million</td>
<td>Pharma</td>
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</table>

Bayer HealthCare Sales 2013

€ 18,924 million
# Bayer HealthCare
## Top Products

<table>
<thead>
<tr>
<th>Pharmaceuticals</th>
<th>Animal Health</th>
<th>Consumer Care</th>
<th>Medical Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalat™</td>
<td>Kogenate™</td>
<td>Advantage™ product line</td>
<td>Contour™</td>
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<tr>
<td>Aspirin™ Cardio</td>
<td>Levitra™</td>
<td>Baycox™</td>
<td>Gadovist™</td>
</tr>
<tr>
<td>Avalox™ / Avelox™</td>
<td>Mirena™</td>
<td>Baytril™</td>
<td>Magnevist™</td>
</tr>
<tr>
<td>Betaferon™ / Betaseron™</td>
<td>Nexavar™</td>
<td>Drontal™ product line</td>
<td>Mark 7 Arterion™ Injection system</td>
</tr>
<tr>
<td>Cipro™ / Ciprobay™</td>
<td>Qlaira™</td>
<td>Seresto™</td>
<td>Radimetrics Enterprise Platform</td>
</tr>
<tr>
<td>Diane™</td>
<td>Stivarga™</td>
<td></td>
<td>Stellant™ DT Injection system</td>
</tr>
<tr>
<td>Eylea™</td>
<td>Xarelto™</td>
<td></td>
<td>Ultravist™</td>
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<tr>
<td>Fosrenol™</td>
<td>YAZ™ / Yasmin™ / Yasminelle™</td>
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ENOVIA PLM at Bayer

• Challenges of Mergers & Acquisitions
• ENOVIA PLM Landscape at Bayer
• Business Requirements
  • Electronic Change Management
  • Document Management - Controlled Documents (PDF Stamps) (Cowasys) & Exalead Search
  • CAD Management
MEDRAD PLM Strategy vs. Bayer HealthCare PLM (Product Data Management) Strategy

• MEDRAD was working toward completing Enovia PLM environment that included eBOM/Product Structures with full integration to ERP system (SAP)
  • One source of the truth
• Bayer HealthCare working towards full standardization of Product Data Management using SAP as backbone
  • IT Governance fragmented along functional lines (R&D, Product Supply, Commercial, and CAO)
  • PLM cuts across R&D and Product Supply
• PLM at Bayer HealthCare
  • R&D = Document Management
    • No standard application
  • Product Supply = Product Data Management (Primarily product labeling and content management)
    • Moving toward harmonizing BHC using customized SAP model

Challenges of Mergers & Acquisitions
Current PLM Implementation at Medical Care Divisions

Phases of Implementation:
- Portfolio & Project Management
- Rollout plan
- Launch plan
- Data Collection
- Review, Approve
- Implement
- Post-implementation

R&D Governance: Product Supply Governance

DC:
- Multiple Systems
- ERP Systems
  - APO-P2R-P4S
  - PDM/PTMS/DOC41

RAD:
- Radiology
- Enovia V6 R2011
- ERP Systems
  - SAP PRD

PS:
- Keep current systems in place
- BASICS SAP
- ERP Systems
  - APO-P2R-P4S
  - PDM/PTMS/DOC41
- BASICS SAP
Mid-Term PLM Implementation at Medical Care Divisions

First Phase (2015) to PLM Standardization for PLM

*Note:
- Utilize BASICS for Labeling requests and approval workflow. Will allow for standard application across the country platforms.
Current ENOVIA V6 Landscape
ENOVIA at MEDRAD R2011

<table>
<thead>
<tr>
<th>Application Vendor</th>
<th>Dassault Systèmes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Versions</strong></td>
<td></td>
</tr>
<tr>
<td>Live Collaboration Server</td>
<td>V6R2011.HF13</td>
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<tr>
<td>AutoVueIntegration</td>
<td>20.0.7421</td>
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<tr>
<td>Live Collaboration Services</td>
<td>V6R2011.HF5</td>
</tr>
<tr>
<td>Designer Central</td>
<td>V6R2011.HF3</td>
</tr>
<tr>
<td>ENOVIA Collaborative Design for Pro/ENGINEER</td>
<td>V6R2011</td>
</tr>
<tr>
<td>ENOVIA Microsoft Project Integration</td>
<td>V6R2011</td>
</tr>
<tr>
<td>IntegrationFramework</td>
<td>V6R2011.HF3</td>
</tr>
<tr>
<td>Library Central</td>
<td>V6R2011.HF1</td>
</tr>
<tr>
<td>Program Central</td>
<td>V6R2011.HF2</td>
</tr>
<tr>
<td>Service Management</td>
<td>V6R2011.HF5</td>
</tr>
<tr>
<td>Engineering Central</td>
<td>V6R2011.HF2</td>
</tr>
<tr>
<td>X-BOMForSAP_MxS-ERP</td>
<td>V6R2011</td>
</tr>
</tbody>
</table>
Implementation of Electronic EC

Enovia Engineering Central implemented in October 2008

- Customized OOTB
  - Business desire to fit current process
    - Included lifecycle changes and check triggers
  - Added efficiencies around routing
  - Released Parts management in 2009
    - Included integration into ERP (SAP)
      - Currently integrating into global BHC ERP (SAP) instance
Benefits of Electronic Engineering Change

- Were able to quickly start collaborating with acquired companies
- Average turnaround time for Engineering Change approval has almost cut in half
- Were able to bring on new plants and engineering groups with minimal disruptions to the business
- Visibility to where a particular Engineering Change is in the process
- Users able to work remotely
- Approval process now locked down and meets Part 11 requirements
- Much less scrap and rework due to upfront change notification to Procurement and Vendors
- Less design rework because of collaboration and upfront idea approval
- All audits since implementation have resulted in no significant findings
- Able to report on Engineering Change statistics
CoWaSys
PDF Stamp Rendering implementation at Bayer Medical Care

• CoWaSys integrated with Enovia
  • Current Implementation includes
    • PDF Conversion
    • Approval page with all viable signatures and time stamps
    • Highly configurable with the following functions
      • Watermarking
      • Advanced Stamping

• Not many options for PDF Stamping with the configuration level needed.
• CoWaSys no longer exists and product is not supported
Requirements for Exalead implementation at MEDRAD

• Basically replace all of the IDOL search related functions. This included but was not limited to the following
  • Replace configurable Commands and Menus that utilized Autonomy in the following Application areas
    • Framework
    • Common
    • Components
    • Engineering Central
    • Library Central
    • Program Central
    • Designer Central
CAD Management

Primary CAD tool Wildfire 5 with integration into Enovia PLM

- Benefits of CAD integration
  - Windows-based local workspace management
  - Local Design Management using local workspaces
  - Access Enovia using RMB within ProE
  - Auto-Recognition of files
  - Capture structure snapshot and store as ‘Baseline’
  - Interactive Update/Notification of in-session design
  - Create derived output – Automatic creation of PDF
  - Share design within ProE to team workspaces
  - Configurable user interface
  - Recently accessed designs

SolidWorks used for collaboration with vendors/partners
## Next Steps in PLM Strategy

<table>
<thead>
<tr>
<th>2015</th>
<th>2016</th>
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</thead>
<tbody>
<tr>
<td>Upgrade to V6R2014x, EBOM Management</td>
<td>Program Management, CAD Assessment, Material Compliance, eDMR</td>
</tr>
<tr>
<td>PDF Adlib Solution</td>
<td></td>
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<tr>
<td>Standalone UDI Solution</td>
<td></td>
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<tr>
<td>If ENOVIA selected, potential merger to the current ENOVIA environment</td>
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</table>
UDI Database and integration into FDA GUDID Database

Need to accommodate FDA requirements for reporting UDI to FDA’s GUDID Database

• Current activity
  • Gathering Data Elements for all identified UDIs
  • Determining which materials need UDI
  • Assessing impact to current business processes
  • Implementing Enterprise Printing solutions to accommodate UDI labeling requirements

• Next Steps
  • Vendor Evaluation
    • Enovia a top contender because of where current product data held

Timelines

• Requirements finalization and Vendor selection complete by end of 2014
• Start database implementation Q2 2015
• Start sending test data Q1 2016 for Class 2 devices
• Go live with full FDA GUDID integration by beginning of Q3 2016
PLM Upgrade 2015

Business Case for upgrade of Enovia to V6 2014x

• Current version out of support
• User interface enhancements
• Implement eBOM/Product Structures
• Need to replace current PDF Stamp solution (out of support)
• Build a solid base for future PLM Expansion Roadmap
  • Expanded use of Program Central with addition of Specification Central
  • Material Compliance Central
  • SolidWorks CAD integration
  • eDMR
Background & Objectives

Background
Bayer currently uses CoWaSys as their PDF rendition tool integrated with their ENOVIA PLM environment.
CoWaSys software is out of application support/maintenance mode.
While the PDF rendition solution is stable enough, in order to maintain compliance with a fully supported software environment, Bayer is looking for alternate PDF rendition solution options.

Objectives
Propose a solution and approach to replace the existing setup by leveraging ENOVIA–Adlib integration capabilities.

Enovia – Adlib Integration

- Centralized document transformation – from within the ENOVIA environment.
- Enables Life Sciences business processes with Submission-ready PDF to regulatory bodies for approval.
- Lower costs - licensing, administration, training.
- Combine multiple files of various file types into a single document with navigation tools such as table of contents, PDF bookmarks, index and intelligent hyperlinking.
- Enhances documents by exposing attributes such as document status, author, etc. through watermarking, cover pages, headers and footers.
- Strong existing partnership with Persistent to deliver the Adlib integration.
Forward-Looking Statements

This presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management.

Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here.

These factors include those discussed in Bayer’s public reports which are available on the Bayer website at www.bayer.com.

The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.
Thank you!
Stephen Matolcsy

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