Managing Engineering Analysis and Simulation in Combination Product Development

Modern Supply Chain Experience, January 27, 2016

Naser Hineiti, PhD, Engineering Advisor, Delivery and Device R&D, Eli Lilly and Co.
Shantanu Dhar, Director, Advisory, PwC.
Todd Hein, Senior Director, Medical Devices, Oracle Corp.
Agenda

• Introduction - Framework for success at Lilly
• Leveraging PLM for Engineering Analysis, Simulation, and Regulatory Review
• Q & A
Best Practices Deployed at Lilly

Key Elements of Lilly Deployment

• Leveraged incumbent experience (vTeam)
• Invested in a “User validated” business cases
• Created an Enterprise roadmap for PLM
• Utilized the PLM eco-system (vendors/partners)
• On-going management of the process with all constituents
#1 vTeam experience at Lilly

CMC management & CMO synchronization

- Approved operations
- Scorecards
- RFQ management
- Business Agreements
- vTeam SOPs
- vTeam SOP Tools
- Site Visit Reports
- Quality Agreements

Sourcing and Vendor Management

vTeam Quality System Management

Technical and Quality Oversight and Collaboration

Portfolio, Material and Document Management

- Quality Events
- Reviews and approvals
- Discussions
- CMO Training
- Project Plans
- Lot genealogy
- COAs, Technical Reports
- Version control

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#1 vTeam experience at Lilly

CMC management & CMO synchronization

**Value Realized**

- Deployed system in 5 months (FDA part 11 validated & hosted environment)
- 1 year increase 300% project pipeline
- 4x external users (CMO’s) vs internal users
- Now expanding into combination products & medical devices
#2 Lilly Business Case

Supported internally by 6–Sigma Analysis

CMC management & CMO synchronization

Corporate Goal

• Grow device enabled revenues from 17% to 40%

Requires

• A collaborative development platform
• More efficient reuse of platform content
• Synchronization with corporate governance
• Assured compliance integrity (DHF/DMR/Reg)
• Improved CMO collaboration and tech transfer
• Reduced number of disparate systems

What is driving this initiative?

2020 Financial Estimates

<table>
<thead>
<tr>
<th></th>
<th>Current Device Revenue</th>
<th>Future (2020) Device Revenue</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>$3,842.5</td>
<td>$12,925.0</td>
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(40% of total sales including a 2.46% industry growth rate)

3.3X INCREASED $$

2012 Financial Highlights

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
<th>Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$22,403.4</td>
<td>$20,186.8</td>
<td>11%</td>
</tr>
<tr>
<td>Research and development</td>
<td>$5,299.1</td>
<td>$5,000.0</td>
<td>6%</td>
</tr>
<tr>
<td>Research and development as a percent of revenue</td>
<td>23.4%</td>
<td>25.7%</td>
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</table>
#2 Lilly Business Case
Supported internally with 6–Sigma Analysis

CAD Management Use Case Only (Developed by Lilly 6-Sigma Team)

<table>
<thead>
<tr>
<th>Milestone 1</th>
<th>Milestone 2</th>
<th>Milestone 3</th>
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<tbody>
<tr>
<td>16-24</td>
<td>25-39</td>
<td>40-60</td>
</tr>
<tr>
<td>42-66</td>
<td>67-104</td>
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<td>90-118</td>
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</tr>
<tr>
<td>42-66</td>
<td>119-224</td>
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#3  PLM Roadmap at Lilly

3 Milestones to Achieve Transformational NGD for Devices….

Specific Agile-PLM Functionality to be deployed:

• **Milestone 1** - Implement PC + EC for Design Control (integrated CAD/BOM Mgmt) and collaboration
  - Leveraging this foundation to enable CAE synchronization!

• **Milestone 2** – Implement PPM + IM + OPLA + PQM for Product Requirements/Design (Innovation Mgmt) and electronic Design History File (DHF) / Device Master Record (DMR) and collaboration with quality oversight

• **Milestone 3** – Implement PG&C + PCM for product regulatory compliance and product sourcing of the Bill of Materials
#3 PLM Roadmap at Lilly

Expansion plans beyond Devices R&D

PLM paradigms that address our existing CM&C pain points

### Key Pain Points

- Lack of portfolio view for CM&C Activities
- Inadequate linkage among all the product-related data
- Lack of a standard way of managing documents
- Lack of a tool to facilitate workflow execution
- Labor intensive internal and external collaboration

### PLM Paradigms

1. Project and Portfolio Management
2. Product Data Management
3. Document Management
4. Structured Workflows and Approvals
5. Internal and External Collaboration
#4 & #5 Leveraging the Eco-System & Monitoring

Utilizing all resources & monitoring/supporting user experience

- Consistently engaging with PwC and Oracle
- Routine “Lunch & Learn” initiatives
- Weekly team reports
- Internal newsletters and awareness sessions etc.
- Network with industry peers
Background and Problem Statement

- CAE generates large volumes of data and results.
- Traceability and compliance of CAE files are not robust.
- CAD and CAE are not systematically linked.
- CAE model management is informal, and lacks formal processes.
- Collaboration across Engineering, TPOs, and CMOs is difficult.
- Use of CAE to support regulatory compliance is increasing.

Lacking both process and data management, the use of CAE is not currently streamlined.
Current Process for CAE Data and Results Management

• We lack a common view of CAD/CAE data, its versions and revisions.

• Connectivity of CAE files with complex BOMs is not systematically maintained.

• CAE management is currently lightweight, and lacks automation support.

• Manual approach to CAE file management is not repeatable, and is complex for large workloads.

• With clear FDA mandates, the need for robust processes and automation is clear.

CAE Data and Results managed informally, without change control, and lacking links to CAD.

Pre-Processing | Solving | Post-processing | Reporting
Vision for CAE Management in PLM

- Similar rigor for CAE data management in PLM as we expect today for CAD.
- Data structures for CAE will behave similarly, with related files managed and linked to both their CAD.
- Version/revision control managed automatically by PLM.
- Robust CAE methodologies, consistent across product platforms (CAE Templates).
- CAE tools managed using PLM will allow efficiency gains and reduce the design cycle.
**Challenge:** Synchronizing the design model & analysis
Need to capture model/analysis (virtual verification) at each revision & phase

**Design Model/Analysis Continuum**

**Design Feasibility**
- Change Mgmt

**Design Verification/Validation**
- Change Mgmt

**Design Commercialization**

**Model Revision**
- CAD: PLM
- CAE model "local"
- CAE Report-DHF
- Manual Tractability (CAE to CAD Ver/Rev) – QC process

**Model Analysis**
- Archived CAE Models
  - FEA – structural analysis
  - CFD – fluid analysis
  - FEA – heat transfer
  - Moldflow – injection molding
  - Mathcad/Matlab – numerical calculations for system modeling

- Multiphase analysis

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Challenge: Standardizing the process & archiving for CAE models

Standard methodology across phases improves performance & compliance

Design Model/Analysis Continuum

- Design Feasibility
- Design Validation
- Design Commercialization

• SOP ???
• What about CAE models ??
Solution: Standardizing the process & archive in Agile
Std. methodology across phases improves performance & compliance
Solution: Reduction of development cycle across phases
Scenario 1: Initial design verification/validation

Design Model/Analysis Continuum

#1 Initial Design Analysis Value
- Control of CAD model iterations
- Synchronization of CAE/CAD
- Better/faster analysis of design feasibility
- Provides structure for re-use of CAD/CAE in future phases
Solution: Reduction to practice across phases
Scenarios 2: Manufacturing support/scale-up

Design Model/Analysis Continuum

#2 Design Commercialization Value
- Enable scale-up by leveraging “validated” CAD/CAE models for Design and tools
- Support tech transfer & CMO collaboration “tool scale up”
- Leverage commercial knowledge with development

Initial CAD Model approved in Agile

CAE “check-out” of CAD Model

CAE Analysis “checked-in” to Agile

CAD/CAE Approved in Agile

Change Mgmt
Solution: Reduction to practice across phases
Scenario 3: Sustaining engineering

**Design Model/Analysis Continuum**

#3 Continuous improvement “Sustaining engineering”
- Re-use of CAD/CAE models
- Document iterative history of design (audits)
- Enable competitive design analysis scenarios
- Improve creation of validation evidence
- Create a Knowledge repository for improved R&D ROI

**Initial CAD Model approved in Agile**

**CAD/CAE Approved in Agile**

**CAE Analysis “checked-in” to Agile**

**CAE “check-out” of CAD Model**

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Benefits

• Standardized processes – leading to common rules of data management for all engineering users and standard traceability.
• Reduced number of physical prototypes.
• Greater efficiency and reduced development cycle time.
• High quality data – for Numerical models/material.
• Full visibility to users (with appropriate rights) of WIP – enabling collaboration across locations and time zones.
• Data and model reuse.
• Complete audit trail – all relationships of CAE and CAD data are linked to users’ actions and appropriately timestamped, in compliance with 21 CFR P 11.
• Compliance with FDA mandates – submissions include CAE results, and help reduce time, risk, and cost to gain approval.
Next Steps

• Develop a prioritized set of requirements for managing CAE data and processes in PLM.
• Bring together internal and external stakeholders to understand their positions and foster a collaborative solution to the problem.
• Provide a forum for discussing how proprietary data and expertise will be managed and kept private for all parties.
• Understand the need for managing (and migrating into PLM) legacy CAE data.
• Develop a timeline for creating the required capabilities for CAE data and process management in PLM.
• Create an industry-led forum (working group?) for CAE management in PLM.
Thank You

Q&A