Benefits of Electronic Validation Lifecycle Management (eVLM) Systems: A Case Study

Charlie Maher
Managing Director, BioVoke
charlie.maher@cagents.com
808-255-7603

Framing the Problem
Last century

Last week
Budgeted $250,000,000

2 years late

FDA 483’s
4622 in 2015-16
$5-10B to remedy
$1-3B rejected product

Warning letters...
Recalls...
CAPAs...

Patient Safety
Patient Access
Brand Reputation
Speed to Market
Market Share
Employee Turnover

It all adds up...
...So how do we
unlock the power of our data to
improve product quality
reduce lifecycle cost and
manage product and project risk?

Risk-Based Validation using eVLM

eVLM System Overview
eVLM System Overview

Validate Changes
(Product/Process/Equipment/Facility, etc.)

- Characterize Product & Process
- Risk Assessment
- Control Strategy
- Design Review
- Plan C&Q Activities
- Create Verification Tests
- Electronic Test Execution
- Acceptance & Release
- Decommissioning
- Security & Access Controls
- Issue Management
- Project Management
- Equipment & Systems
- Change Control
- Scheduling
- Electronic Signatures
- System Audit Reporting

Periodic Re-validation

Case Study
Company Profile

- Emerging Biotech Firm
- Bringing manufacturing “in-house” from CMO
- Ambitious timeline and limited budget
- Product: Oral solution to aid in the digestion of sugars
- Process: Small scale (mostly manual) bulk biotech process

Project Timeline

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Funding Approval</td>
<td>March 2017</td>
</tr>
<tr>
<td>eVLM system live</td>
<td>May 2017</td>
</tr>
<tr>
<td>Component and system data upload</td>
<td>May 2017</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>June 2017</td>
</tr>
<tr>
<td>URS, SLIA</td>
<td>July 2017</td>
</tr>
<tr>
<td>Design Review</td>
<td>Aug 2017</td>
</tr>
<tr>
<td>Protocol Development</td>
<td>Nov 2017</td>
</tr>
<tr>
<td>Protocol Execution</td>
<td>Dec 17 – Feb 18</td>
</tr>
<tr>
<td>Final Reports – Project Complete</td>
<td>Mar 2018</td>
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</tbody>
</table>
Project Goals for eVLM

<table>
<thead>
<tr>
<th>Improve Quality</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimize Deviations</td>
<td></td>
</tr>
<tr>
<td>Minimize Protocol Gen. &amp; GDP Errors</td>
<td></td>
</tr>
<tr>
<td>Real-time End-to-end Traceability</td>
<td></td>
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<table>
<thead>
<tr>
<th>Reduce Cost</th>
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<tr>
<td>10% Cost Savings for C&amp;Q Project</td>
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<tr>
<td>Reduce Lifecycle Validation Cost</td>
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<th>Manage Risk</th>
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<tr>
<td>Risk-based validation process</td>
<td></td>
</tr>
<tr>
<td>Meet (or beat) ambitious project schedule</td>
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Project Execution

C&Q Project Team
- PM (1)
- Engineers (4 during Nov-Jan)
- eVLM syst. support (eVLM system validation & training)

eVLM System Validation
- eVLM syst validation templates:
  - Validation Plan
  - URS, FDS, FMEA
  - SOPs
  - PQ / Final Report
  - Software QC test docs
- eVLM system validation:
  - 60 hrs / 4 weeks
  - PQ in one day (leveraged)

Project C&Q Deliverables
- Master data (Inventory & specs)
- 20 systems / 500+ components
- eTOPS
- FMEA
- URS
- SLIA / CLIA
- Design Specs
- Protocols
- IV / OV / PQ (19 protocols)
- Deviations tracked/resolved
- Automatic Traceability Report
- Acceptance & Release Report

Total: 200+ Deliverables
## Outcomes

### Accuracy
- Tests linked to approved specs
- Automatic data verification during execution
- Automatic version control
- Automatic traceability report
- Single authoritative source – always available

### Data not Documents
- ~200 Binders not produced
- ~30,000 pages not printed
- Zero lost/destroyed documents
- Zero Doc Control personnel
- Zero Shelf space

### Speed
- Deliverable generation
- Issue resolution
- Electronic review & approval
- Reduce repetitive, error-prone work
- Standard process & workflow

### Project Management
- Dashboard
- KPI Reports
- Real-time status on any task
- Work is visible and measurable

### Access and Security
- Instant access by team members
- Secure cloud storage
- Robust backup and recovery

## User Feedback

"Like no paper approach"

"Protocol generation speed"

"No GDP Errors"

"Execution, reviews and approvals quick and easy"

"Enabled the team to really focus on the process rather than the paper"

"Helped organize product and process information, complete risk assessments, develop control strategy and finalize design specification - shaved weeks from our schedule"

"Some documents still needed"

"Training videos and OJT helpful"

"Reporting tools helped keep project on schedule"
Cost Savings

- On track to beat goal of 10% savings (blue line)
- No scope changes

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<tr>
<td>Minimize Deviations</td>
<td>35 Deviations (all minor)</td>
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<tr>
<td>Minimize Protocol Gen. &amp; GDP Errors</td>
<td>0 Protocol Gen errors / 0 GDP errors</td>
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<td>Data in the system, ready to quickly process changes and perform periodic re-validation</td>
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“Top 4” ways to get started with eVLM

1. **Pilot project**
   Try it on a project – then scale up to site or company

2. **Pioneer site**
   Try it at a site – then scale company-wide

3. **Take the plunge**
   Company-wide early adoption & transformation

4. **Leapfrog**
   Skip over paper and go right to eVLM

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eVLM in Action

*Protocol execution in progress*

*Signature stamp not needed!*

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ASTM E2500

Good Engineering Practice

- Requirements
- Specification and Design
- Verification
- Acceptance and Release
- Operation & Continuous Improvement

Risk Management

Design Review

Change Management

ASTM E2500 Key Concepts (sect 6.1)