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

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Framing the Problem

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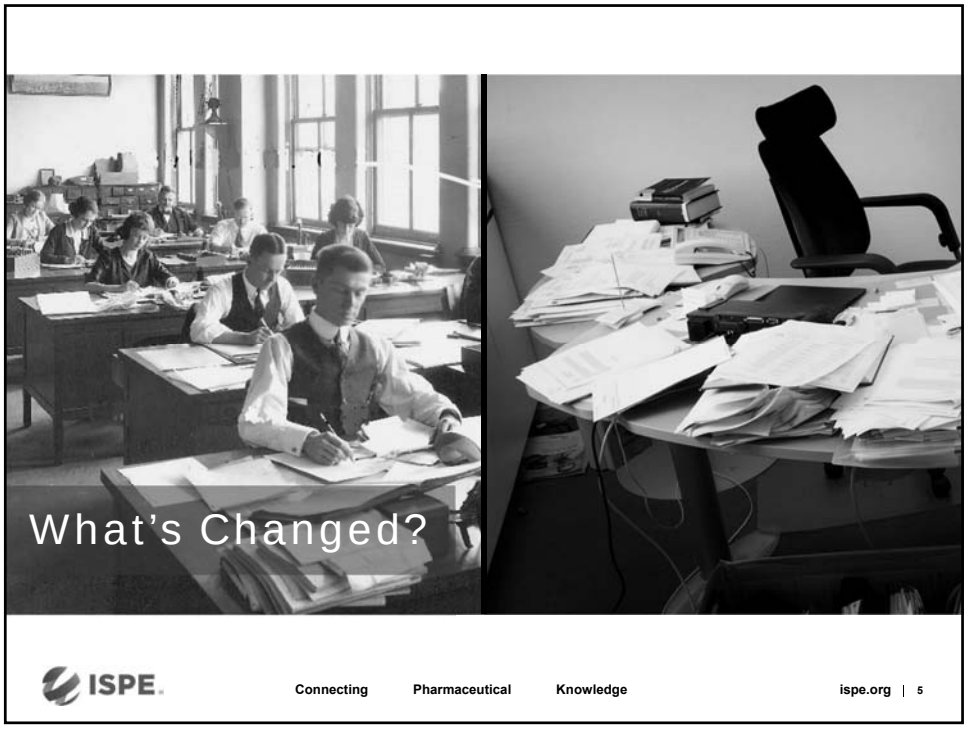

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Budgeted: $250,000,000

Actual: $750,000,000

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

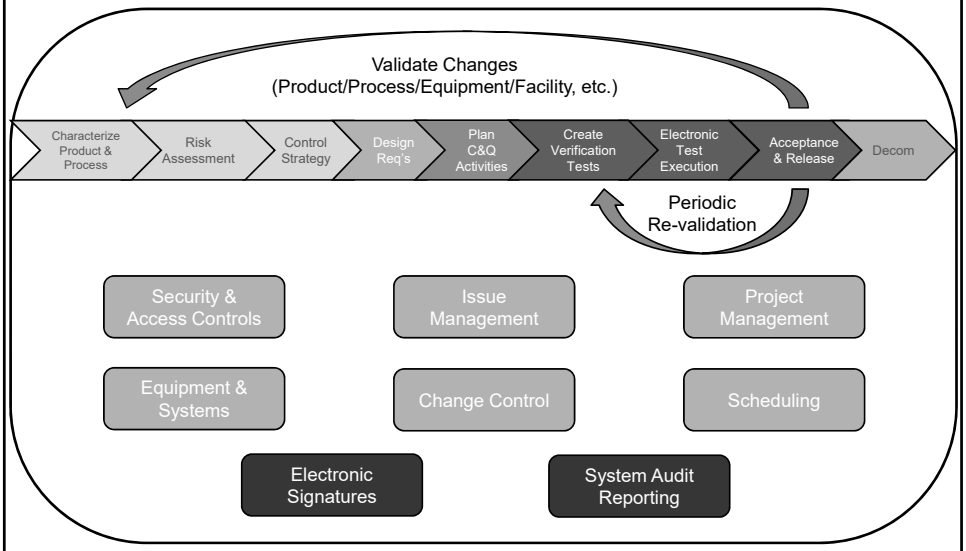
reduce lifecycle cost and

manage product and project risk?

Risk-Based Validation using eVLM

eVLM System Overview

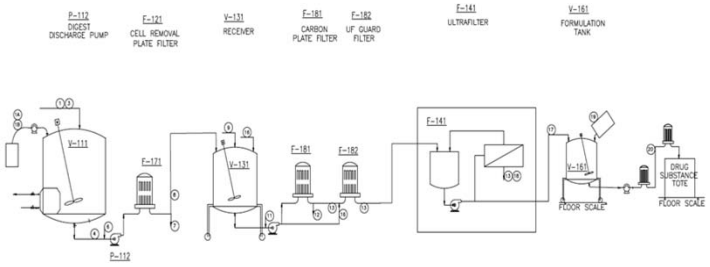
eVLM System Overview



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

Milestone	Date
Project Funding Approval	March 2017
eVLM system live	May 2017
Component and system data upload	May 2017
Risk Assessment	June 2017
URS, SLIA	July 2017
Design Review	Aug 2017
Protocol Development	Nov 2017
Protocol Execution	Dec 17 – Feb 18
Final Reports – Project Complete	Mar 2018

Project Goals for eVLM

Improve Quality	Result
Minimize Deviations	
Minimize Protocol Gen. & GDP Errors	
Real-time End-to-end Traceability	

Reduce Cost	Result
10% Cost Savings for C&Q Project	
Reduce Lifecycle Validation Cost	

Manage Risk	Result
Risk-based validation process	
Meet (or beat) ambitious project schedule	

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

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

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

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

Access and Security
- Instant access by team mbrs
- 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"

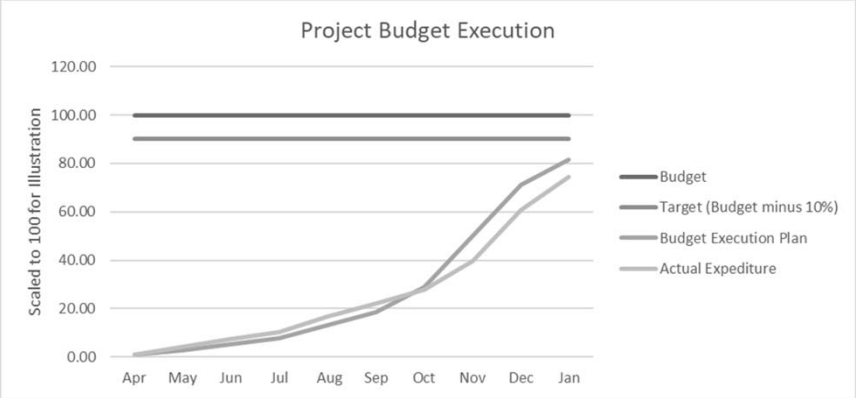
"Helped organize product and process information, complete risk assessments, develop control strategy and finalize design specification - shaved weeks from our schedule"

"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

Project Goals for eVLM

Improve Quality	Result
Minimize Deviations	35 Deviations (all minor)
Minimize Protocol Gen. & GDP Errors	0 Protocol Gen errors / 0 GDP errors
Real-time End-to-end Traceability	Yes

Reduce Cost	Result
10% Cost Savings for C&Q Project	On track to beat 10% savings
Reduce Lifecycle Validation Cost	Data in the system, ready to quickly process changes and perform periodic re-validation

Manage Risk	Result
Risk-based validation process	Yes
Meet (or beat) ambitious project schedule	Yes

"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

eVLM in Action

Protocol execution in progress

Signature stamp not needed!

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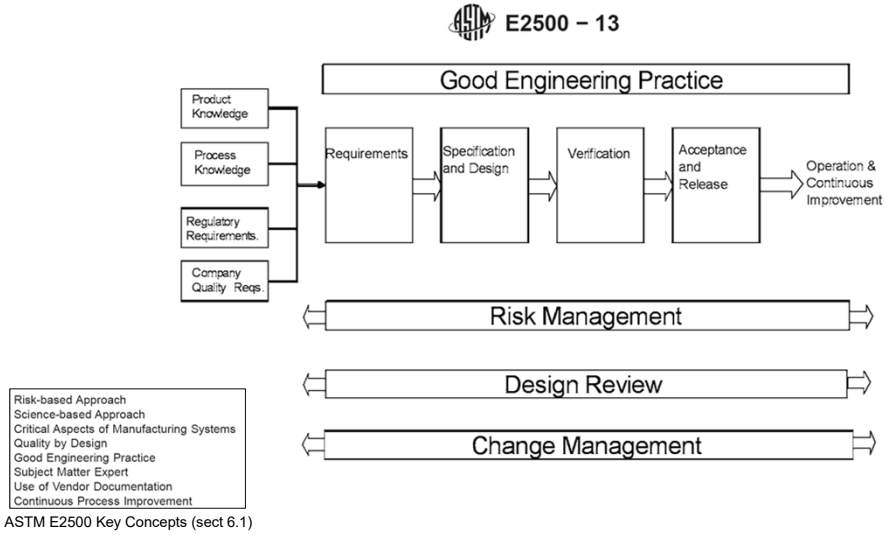
ASTM E2500



Risk-based Approach
Science-based Approach
Critical Aspects of Manufacturing Systems
Quality by Design
Good Engineering Practice
Subject Matter Expert
Use of Vendor Documentation
Continuous Process Improvement

ASTM E2500 Key Concepts (sect 6.1)