Olivia Kasik and Omar Silver
Agile in the Federal Space: Best Practices for Keeping Documentation Lean
Agenda

Federal IT Approach to Documentation

Case Study: Challenges and Solutions

Discussion/Q&A
Federal IT Overview

Policies

Laws

Agency SDLCs

Federal IT Governance
Federal IT Governance
Federal IT:
Comprehensive documentation is a critical component of software development

Agile:
Working software over comprehensive documentation
Case Study: FDA EON IMS Agile Team
# EON IMS: What is it?

## System Overview
- EON IMS stands for Emergency Operations Network Incident Management System
- Adverse events management system for food and drug related recalls and product problems
- Supports decision making for stakeholders across 6 distinct organizations

## Program Highlights
- FDA Program established in 2006 as Waterfall
- Transitioned to Agile in 2010
# EON IMS: Team Structure

<table>
<thead>
<tr>
<th>EON IMS Agile Team Roles</th>
<th>Scrum Team Equivalent</th>
<th>Description of Responsibilities</th>
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<tbody>
<tr>
<td>Program Managers</td>
<td>Scrum Master</td>
<td>The Program Managers are responsible for monitoring and controlling projects and removing obstacles for the Development Team.</td>
</tr>
<tr>
<td>FDA Contracting Officer’s Representative (COR)</td>
<td>Product Owner</td>
<td>As a liaison to the various FDA stakeholder groups, the FDA COR is critical to providing direction to the team; however, the FDA COR is not the final decision maker as there are many Critical Partners identified by the FDA EPLC.</td>
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<tr>
<td>Development Team (with Technical Writer)</td>
<td>Development Team</td>
<td>The Development Team is structured similarly to a traditional Scrum development team with the addition of a Technical Writer.</td>
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EPLC Framework

Initiation Stage Gate
Concept Stage Gate
Planning Stage Gate
Requirements Stage Gate
Design Stage Gate
Development Stage Gate
Test Stage Gate
Implementation Stage Gate
Operations & Maintenance Stage Gate
Disposal Stage Gate

Initiation Readiness Review
Concept Readiness Review
Planning Readiness Review
Requirements Readiness Review
Design Readiness Review
Development Readiness Review
Test Readiness Review
Implementation Readiness Review

Waterfall Approach
The Challenges

1. Accounting for Stage Gate Reviews
2. Managing Multiple Stakeholders
3. Planning for Non-Sprint Documents
4. Creating Lean Documentation
Challenge 1: Accounting for Stage Gate Reviews

**SGR Risks**

- **Schedule**
- **Document CM**
- **Resource Utilization**
Challenge 1: Accounting for Stage Gate Reviews

Waterfall Approach

Sprint Activities

Requirements Review and Accept
Design
Prototype
Test
Challenge 1: Solution

The team used the Project Process Agreement (PPA) to combine the Requirements, Design, Development, Testing, and Implementation SGRs into a single stage gate.
The Challenges

1. Accounting for Stage Gate Reviews
2. **Managing Multiple Stakeholders**
3. Planning for Non-Sprint Documents
4. Creating Lean Documentation
Challenge 2: Managing Multiple Stakeholders

The team had two checkpoints for documentation during the development lifecycle:
  1. Sprint Planning
  2. Sprint Evaluation

To stay on schedule, the team needed to ensure stakeholders were committed to the major milestones, so documentation reviews did not cause delays.
Challenge 2: Solution

Targeted Communication Approach

- Commitment to project schedule
- FDA COR buy-in
- Short, focused meetings
- Agile Meetings
- Government Standard Meetings
The Challenges

1. Accounting for Stage Gate Reviews
2. Managing Multiple Stakeholders
3. Planning for Non-Sprint Documents
4. Creating Lean Documentation
Challenge 3: Planning for Non-Sprint Documents

In addition to SGR and sprint documentation, the team had non-sprint related documentation requests.

**Examples**

- Security-related documents
- Management plans
- Data calls
- SOPs/Runbooks
Challenge 3: Solution

1. Added each document to the project schedule and product backlog.
2. Groomed the document as a feature or multiple features.
3. Assigned the feature(s) to the appropriate sprint.
The Challenges

1. Accounting for Stage Gate Reviews
2. Managing Multiple Stakeholders
3. Planning for Non-Sprint Documents
4. Creating Lean Documentation
Challenge 4: Creating Lean Documentation

The team needed to create lean documentation that didn’t detract from other sprint work but also met the customer’s requirements.

The Critical Partners could reject documentation or ask for revisions for the following reasons:

- Noncompliance with the EPLC (e.g., template)
- Incomplete sections
- Missing information
- Poor formatting, grammar, mechanics, etc.
The team used our sprint retrospectives to develop these **7 best practices** for keeping documentation *lean*!

1. Reference the source of information rather than duplicating/re-writing

2. Document the as-is state rather than the to-be state

3. Document in real time during conversations

4. Assign document owners

5. Utilize good technical writing skills

6. Use pair-writing for lengthy or new documents

7. Make informed decisions about adding to documents vs. creating new documents
## Summary of Challenges and Solutions

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Solutions</th>
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<tbody>
<tr>
<td>1. Accounting for the Stage Gate Reviews</td>
<td>1. Tailor the EPLC framework to align with the team’s agile method</td>
</tr>
<tr>
<td>2. Managing multiple stakeholders</td>
<td>2. Obtain stakeholder buy-in through a targeted communications approach</td>
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<tr>
<td>3. Planning for non-sprint documents</td>
<td>3. Add non-sprint documents as features to sprints</td>
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<tr>
<td>4. Creating lean documentation</td>
<td>4. Implement the team’s 7 best practices for creating lean documentation</td>
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Case Study: Outcomes

As a result of these solutions, our team:

• Reduced the time between sequential deliveries of requirements, design, development, and testing documentation for our customer
• Increased customer acceptance of our documentation (100% acceptance rate) and decreased the time spent on stage gates
• Expanded our program to additional stakeholder groups and increased our overall program funding
• Contributed to the EPLC 2.0, a more Agile-friendly version of the FDA’s standard software development framework
Let’s Hear about Your Experience!

1. What are some challenges you’ve experienced with documentation in heavily-regulated environments?

2. What are some solutions that your team came up with to overcome documentation challenges?
Questions?

If you have additional questions or comments, please feel free to contact us:

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