Delivering the Goods

Harmonizing Regulated and Agile Practices

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This Presentation Covers …

- **My 25+ year prior history with this topic**
- **Five "Hows" to Be Agile and Compliant**
- **Case Study of a Med. Device company's Agile and Regulated Practices**
- **Your Questions**

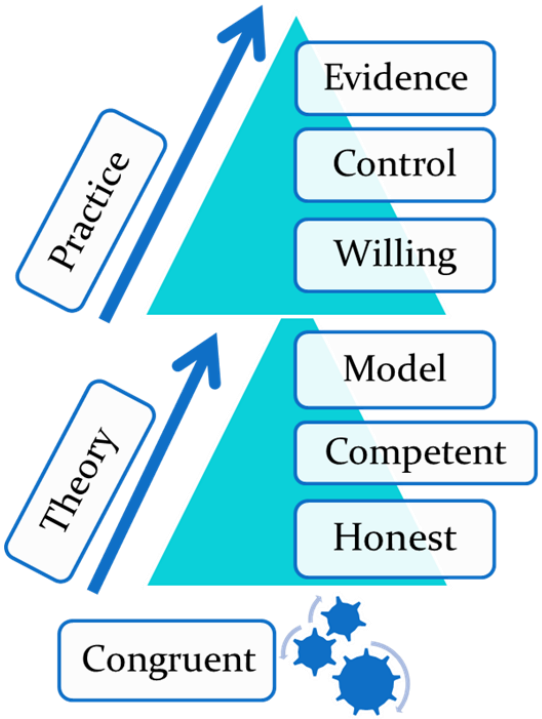
The Problem

Conforming to Regulations while Preserving Agile Practices

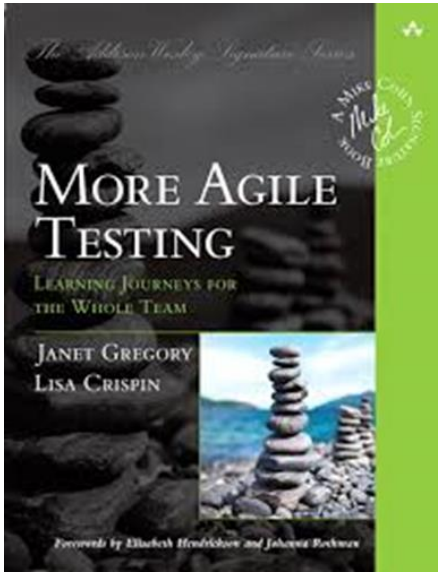
Solution Path

- **Establish Specific Goals**
- **Define Deliberate Development**
- **Implement Risk Mitigation**
- **Generate Evidence and**
- **Close Gaps**

Some of My History



What is Good Evidence?



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A Framework

Theory

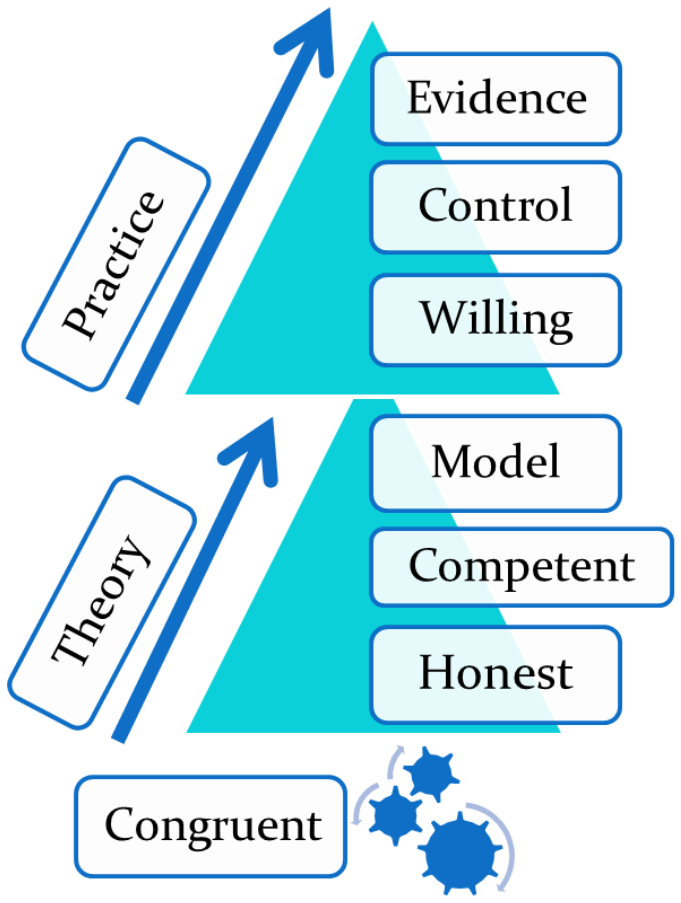
- **Principles and Mindset**

Practice

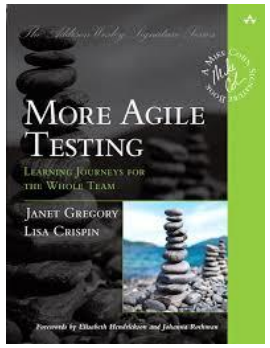
- **Behaviors and Actions**

…While Congruent

- **Centered and Healthy**



META-EXECUTION …

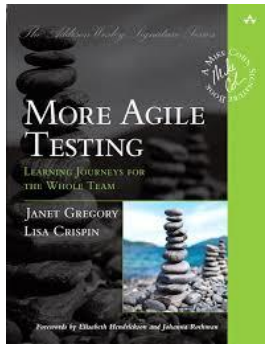


Regulatory Compliant Agile Testing

- **Would stakeholders be happy if they saw/heard what I am doing right now?**

- **Is it important to share this information in the future?**

… META-EXECUTION



Regulatory Compliant Agile Testing

- **What is the most effective and efficient way to Memorialize this information – without breaking flow?**

- **Specific project "Hows" just become context specific details.**

Good Evidence

Regulatory Compliant Agile Testing

- **Types and Qualities of Good Evidence**

What is Good Evidence?

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THE FIVE HOWS …

Establish Specific Goals

- **How are you Regulated?**
- **What are the Expectations?**
- **Find your specific auditor's playbook**

… THE FIVE HOWS …

Define Deliberate Development

- **Establish**
  - **Write, Draw, Explain - Development**
  - **Does it accomplish the Goal?**
  - **Are you capable of doing it?**
- **Maintain**
  - **Train and Sustain**

… THE FIVE HOWS …

Implement Risk Mitigation

- What can you foresee could go wrong?
  - Make a list, track, and manage it
- Be Reasonable and Prudent
- Nothing is Riskless
  - Some Risks gets accepted

… THE FIVE HOWS …

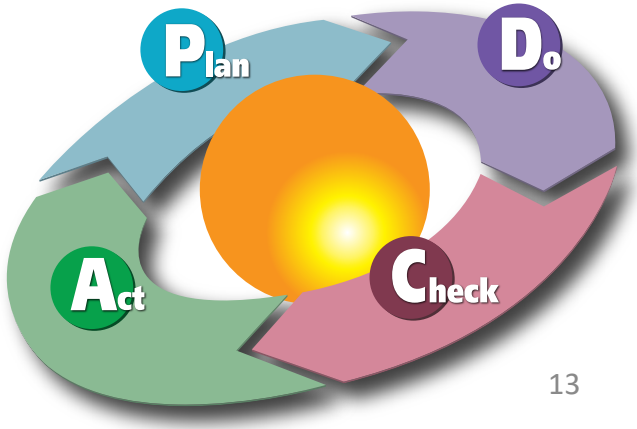
Generate Evidence

- **If it is part of the official story**
  - **Memorialize it**
  - **Always add, never destroy**
  - **Include who, what, when, and why**

… THE FIVE HOWS

Close Gaps

- Review and Revise
  - Retrospectives
  - Show Corrections and Improvements
- Show you are Under Control
- Don’t require Perfect

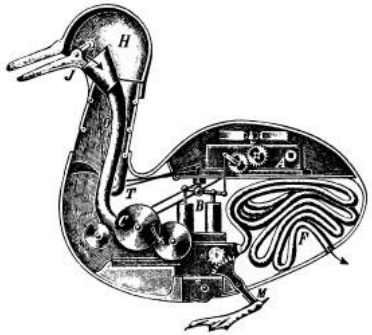


"MedDev" Case Study

BEFORE WE START

System Thinking is needed

- **Holistic approach focusing on the way that a system's constituent parts interrelate**
- **Complex behaviors over ever-smaller defined parts**



MEDDEV

Company and Products

- **Develops and manufactures medical devices used by doctors in hospitals**
- **Devices manage and change vast amounts of diagnostic data**
- **Several national and international regulations**
- **Internal project governance which mandates practices related to regulatory compliance via the Quality System**

MedDev Teams

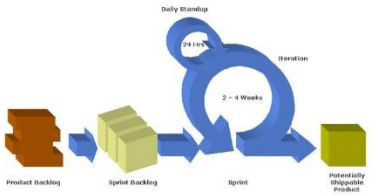
Teams

- Domain experts and software development
- About 130 team members are organized into 8 scrum teams
- 50% employees, 50% are contractors
- Each scrum team is responsible for an independent component of MedDev's product

MEDDEV SCRUM

Scrum

- **Using a scrum framework for 18 months that inherited some practices from the former Waterfall approach**
- **Scrum team is comprised of programmers, testers, subject matter experts and analysts**
- **Each scrum team has a scrum master and a product owner**



MedDev Reg. Compliance

Regulatory Compliance

- **MedDev has a team of regulatory compliance experts composed of a dozen domain experts**
- **Each expert has deep knowledge of relevant regulations for MedDev. Regulations may relate to product development, client onsite trials and system operations.**
- **RegComp experts act as advisors to Product Owners**

MedDev Reg. Comp. Group

Regulatory Compliance Group

- **Representative to Agencies, Customers, and Suppliers**
- **RegComp establishes and maintains the MedDev Quality System and SOPs to the associated regulatory requirements and compliant practices**
- **RegComp trains everyone relating to regulatory compliance as expressed in the Quality System**

MedDev Quality System

Quality System

- **The overarching controlling Policies and Procedures of MedDev**
- **Required by Law**
- **Examined by Governmental Agencies and Customers**

MedDev Sprints

Sprints

- MedDev scrum sprints are two weeks long
- After each sprint compliance evidence is delivered to the RegComp
- This information is assembled into a package (Design History File) which is made available to internal and external auditors as needed
- No special tasks are required to create the regulated artifacts

MedDev Done

Done Checklist

- **Indicates what it means for a requirement to be completely implemented**
- **Constructed by the team, but informed by the Quality System and requirements from the RegComp group**
- **The product owner and the team agree on what it means for a story to be done**

MedDev Product Backlog

Product Backlog

- **The team product owner manages requirements with a product backlog**
- **Includes requirements which may be in the form of a user story**
- **May include a story that encapsulates a traditional specification**
- **Product Owner manages the product backlog**

MedDev Release Planning

Release Planning Event

- **When a new project starts the scrum teams holds a release planning event**
- **During release planning, regulatory risks and regulatory practices are reviewed**
- **RegComp team is available to the scrum teams for consultation**

MedDev Backlog Refinement

Backlog Refinement

- **Scrum teams have standard refinement sessions which may include RegComp to detail product backlog entries**
- **Refined backlog entries have may be tagged as needing special regulatory compliance attention, e.g., Link to Program Risks**
- **Story size is in Story Points**

MedDev Sprint Planning

Sprint Planning

- **Standard negotiation re: what is in the Sprint**
- **Stories are decomposed into Tasks and Associated Hours**
- **Regulatory compliance is built into the normal work - capturing artifacts as required**

MedDev Daily Standup

Daily Standup

- **Scrum teams have standard daily standup meetings**
- **Per their training, team members also raise any concerns they may have related to regulatory compliance**
  - **RegComp is then consulted**

MEDDEV TRACEABILITY

Tracability

- Scrum teams trace their software testing, programming activities to requirements and design artifacts
- This information is delivered to the RegComp team at the end of the sprint

MedDev Sprint Demo

Sprint Demo

- **Standard demo to stakeholders including members of the RegComp team**

MedDev Retrospectives

Retrospective

- **Standard scrum team retrospective**
- **Suggestions that would modify or reinterpret the Quality System are a conversation with RegComp**

MedDev Release

Release

- Stories completed in the sprint require no further software engineering work and are potentially shippable product
- …but there is a set of additional 1 to 4 weeks of Program Level activities performed by back office, non-scrum teams to transform potentially shippable product into official shippable product

MedDev Version Control

Version Control and Archiving

- **Per the Quality System, artifacts the scrum teams create and reference are in version control systems which can be audited (with zero notice) by members of the RegComp team and external stakeholders.**
- **The achieve is preserved for 17 years after the last sale of the product**

SUMMARY

Execute the Five "Hows" in your Context

- **Establish Specific Goals**
- **Define Deliberate Development**
- **Implement Risk Mitigation**
- **Generate Evidence and**
- **Close Gaps**

Questions and Stories

Thank you for attending this session.

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