

# Agile Development in a Regulated Environment

J.R. Jenks, CTO

AgileTek LLC

<http://www.agiletek.com>

The obstacles are not  
what you think they are.

# What Do You Mean, “Agile” ???

- Agile Development Methodologies
  - Extreme Programming (XP)
  - Scrum
  - Agile+
  - ...others

# What do you mean, “Regulated” ???

- Avionics (DO-178B)
- Industrial Control, Auto (IEC-61508)
- Medical Devices (CDRH 938, 585, 337)
- Gambling (GSA [Gaming Standards Association])



# Industry and Market Segments

	Avionics	Industrial Control, Auto	Medical Devices	Security
Standard/Accreditation	DO-178B	IEC-61508	CDRH 938, 585, 337	Common Criteria
Required by	Government (flight)	Government (industrial)	Government (Health)	Government, Financial
Certified by (US products)	FAA	TUV	FDA (CDRH)	NIAP/NSA
Defined by	RTCA/FAA	IEC	FDA (CDRH)	NIST/NSA/ISO/IEC
How certified/approved	System	Component	System	Component
Criticality/risk levels	Level A-E	SIL 1-4	Class I-III	EAL 1-7
Conformance vs. Risk-based	Conformance	Risk	Risk	Conformance
Function vs. Process	Process	Process	Process	Both
GHS Technology	INTEGRITY	INTEGRITY	INTEGRITY	INTEGRITY
INTEGRITY meets	Level A	SIL 3	Class III	EAL 6+

Source: Green Hills Software founder and chief executive officer Dan O'Dowd  
<http://www.embedded.com/showArticle.jhtml?articleID=174300025>

# Exercise (Part 1 of 2)

Who can fill in this blank?

The biggest problem with agile in a regulated environment is \_\_\_\_\_.

Agile is all about making  
your mistakes early.

# Manifesto for Agile Software Development

We are uncovering better ways of developing software by doing it and helping others do it. Through this work we have come to value:

- Individuals and interactions over processes and tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

That is, while there is value in the items on the right, we value the items on the left more.

Kent Beck	James Grenning	Robert C. Martin
Mike Beedle	Jim Highsmith	Steve Mellor
Arie van Bennekum	Andrew Hunt	Ken Schwaber
Alistair Cockburn	Ron Jeffries	Jeff Sutherland
Ward Cunningham	Jon Kern	Dave Thomas

Regulated is all about  
the evidence.

# FDA Audit Items (1 of 2)

<i>FDA Audit Item</i>	<i>FDA Requirement</i>	<i>How Agile+ Complies</i>
Standard Operating Procedures (SOPs)	Recommendation: Follow a set of standards	Agile+ embodies standard practices from CMM, IEEE, and others
Evidence that procedures are followed	Existence of key documents	<ul style="list-style-type: none"><li>▪ Requirements Spec</li><li>▪ Architecture Diagram</li><li>▪ Design Spec</li><li>▪ Development Plan</li><li>▪ Validation, Verification &amp; Test Plan</li><li>▪ Traceability Matrices <i>(available on request)</i></li></ul>

# FDA Audit Items (2 of 2)

<i>FDA Audit Item</i>	<i>FDA Requirement</i>	<i>How Agile+ Complies</i>
Device Hazard Analysis (DHA) <i>(For Medical Devices Only)</i>	Conduct DHA to determine <i>Level of Concern</i> of software	Not included in Agile+. However, straightforward for an Agile+ organization to add a special DHA procedure if one does not already exist

# DO-178B Required Data

- 11.1 Plan for Software Aspects of Certification (PSAC)
- 11.2 Software Development Plan (SDP)
- 11.3 Software Verification Plan (SVP)
- 11.4 Software Configuration Management Plan
- 11.5 Software Quality Assurance Plan
- 11.6 Software Requirements Standards
- 11.7 Software Design Standards
- 11.8 Software Code Standards
- 11.9 Software Requirements Data
- 11.10 Design Description
- 11.11 Source Code
- 11.12 Executable Object Code
- 11.13 Software Verification Cases and Procedures
- 11.14 Software Verification Results
- 11.15 Software Life Cycle Environment Configuration Index
- 11.16 Software Configuration Index
- 11.17 Problem Reports
- 11.18 Software Configuration Management Records
- 11.19 Software Quality Assurance Records
- 11.20 Software Accomplishment Summary

# Remember That Exercise?

The biggest problem with agile in a regulated environment is \_\_\_\_\_.

The answers to this exercise aren't about agile.

The answers to this exercise are about problems that exist in organizations whether they use agile or not.

## Exercise (Part 2 of 2)

The blank you thought you were filling:

The biggest problem with agile in a regulated environment is \_\_\_\_\_.

The blank you were really filling:

My company has a problem with \_\_\_\_\_ . If I used agile, I'd be able to see my problems with \_\_\_\_\_ earlier and I could solve them earlier.

For Further Information  
Please Contact:

**J.R. Jenks**

[jrjenks@agiletek.com](mailto:jrjenks@agiletek.com)

1400 E. Touhy, Des Plaines, Illinois 60018

Phone: 847-691-8890 Fax: 847-813-4903

<http://www.agiletek.com>