

Using Technology to Facilitate Validation & Auditing While Helping Sponsors Adjust to Novel Approaches

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AGENDA

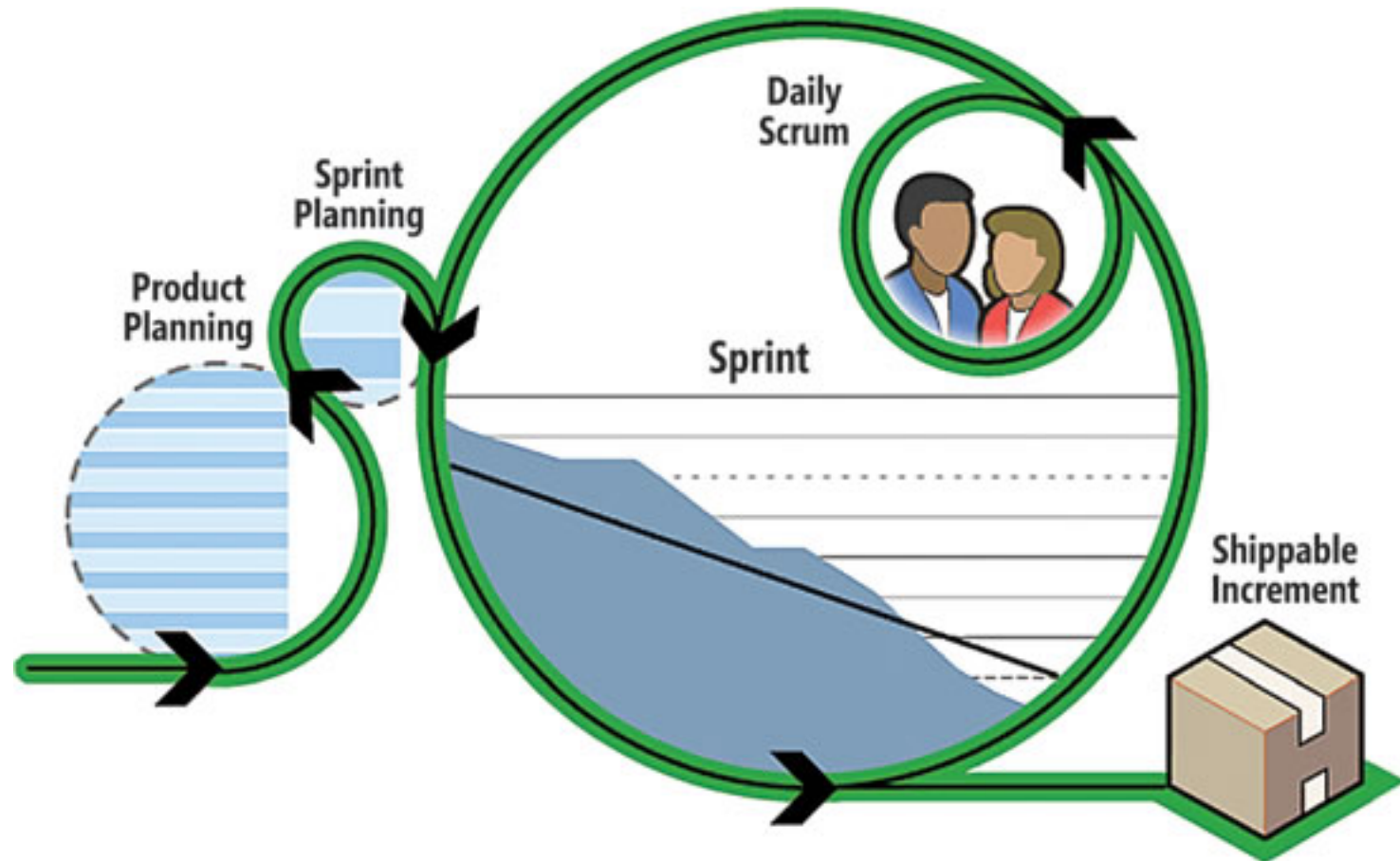
The Agile Development Environment

The SaaS Environment

The Challenges.....in Validation, Regulatory, & Customer

Addressing Those Challenges

The Agile Development Environment



The Agile Development Environment

Emphasizes working software, and productivity over documentation

But we expect a stack of documentation. The more, the better. What about Validation artifacts?

Expects changes in design, requirements, priorities

But the full set of requirements, down to each design detail, needs to be on paper before you can begin coding. Things shouldn't be changing much once you start.

Promotes collaborative team dynamics

OK but why? Developers have their job, testers have their's, tech writers have their's. Where does the collaboration come in?

Takes advantage of customer collaboration

We get that now. We tell vendors what we want and then we wait (and hope...) to see it when it's done.

The SaaS Environment

Software as a Service is the growing trend

".....one point is becoming very clear: SaaS is gaining trust as a solid alternative for global deployments across the enterprise. And this trend has been accelerating in the last six months."

SOURCE:

<http://www.forbes.com/sites/louiscolombus/2012/10/31/saas-adoption-accelerates-goes-global-in-the-enterprise/>

October 31, 2012

"This shift toward cloud-based Software as a Service (SaaS) model is only going to accelerate with newer technologies and broadening capabilities delivering equivalent or superior cloud performance compared to on-premise performance, the compelling time-to-market edge, and total cost of ownership considerations"

Source: <http://seekingalpha.com/article/1385831-investing-in-saas-stocks-the-trend-remains-strong>

April 30, 2013

Often means a single instance of software that all users are sharing

Does that mean we have to take upgrades whether we want them or not?

The Challenges

Validation – Keeping Up

- **In this fast-paced development environment, how can we prevent validation activities from crippling progress**



How can we streamline.....



How can we reduce validation burden...



.....and ensure Regulatory Compliance



How do we quell the anxiety.....



..... the worry & concern.....



....the

FEAR



Addressing the Challenges

Meeting Regulatory Requirements

- **Primary goal is to ensure, and prove, the software repeatedly and reliably does what it is purported to do**
- **There is no compromise on 21CFR Part 11 ER/ES**
 - **NOTE: With respect to validation, Part 11 ER;ES – Scope and Application recommends risk-based approach and discusses ‘enforcement discretion’**
- **As always, key documents, like FDA Guidance on Validation, need to be close at hand**
 - **However, also remember words like ‘recommend’, ‘suggest’ allow for flexibility**
 - **Ask yourself if your approach still achieves the goals and purpose of validation**
 - **Don’t ignore reasonable ‘expectations’. That is, while not regulations or requirements, some practices are just expected....and are reasonable and sound**

Helping Sponsors/Customers Get What They Need

- **The Need for Speed is not an excuse for cutting corners**
- **Focus Groups**
- **User Group Meetings**
- **Pre Release Period**
- **Customer Portal – release announcements, time to plan**

Helping Sponsors/Customers Get What They Need

- **Share test scripts**
- **Pre-audit videos**
- **'Validation Portal'** (hold that thought....)
- **Need to demonstrate that new approaches are not only acceptable, but offer real advantages**
- **Quality**

SDLC & Validation – Support from Technology

- **Test Automation**
- **CI**
- **Tracking Systems (Known Issues)**
- **Content Collaboration Systems**
- **Auto-generate technical dependency diagrams**
- **Automated Documentation Generator (from code)**
- **'Validation Portal' (hold that thought.....)**
- **Requirements / Test Tools**

Backlog / Requirements/ Tests

Firefox | https://columbo.ime...ents/features.html | Medidata Solu... | Recent - Google... | US SQA Candid... | Rave 2013.x.x Re... | [MCC-37359] [C... | New Tab

Medidata Coder 2013.1.0 Release Completion Form.xlsx [Read-Only] - Microsoft Excel

	A	B	C	D	E	F
	Test/Scenario Name	Description	Release Version	Executed By and Date	Browser Version	URL
188	CodingDecisionsReport - PB4.11.2-014	Verify user is able to select coded by option in the Coding Decisions Control Page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
189	CodingDecisionsReport - PB4.11.2-016	Verify user can check and uncheck the include autocoded checkbox in the Coding Decisions Control Page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
190	CodingDecisionsReport - PB4.11.2-017	Verify search results with autocoded items included are correct returned when clicking the Generate Report button in the Coding Decisions Report Page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
191	CodingDecisionsReport - PB4.11.2-018	Verify search results without autocoded items included are correct returned when clicking the Generate Report button in the Coding Decisions Report Page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
192	CodingDecisionsReport - PB4.11.2-020	Verify user can see the "Open", "Save", or "Cancel" popup when clicking export button on Coding Decisions Report Page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
193	CodingDecisionsReport - PB4.11.2-023	Verify same term that is autocoded and is manually coded shown correctly on the Report	2013.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
194	CodingDecisionsReport - PBMCC-37359-024	Verify the columns have the proper value	2013.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
195	CodingDecisionsReport - PBMCC-37359-025	Verify the mandatory columns in the Report.	2013.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
196	CodingDecisionsReport - PBMCC-37359-026	Verify the user is able to select values from the Export Columns	2013.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
197	CodingDecisionsReport - PBMCC-37359-027	Verify the combination of Current Status, Coded By and Export Column are shown on CSV	2013.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
198	CodingHistoryReport - PB4.11.5-001	Verify the study dropdown contains only the study the user has access too in the History Report page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
199	CodingHistoryReport - PB4.11.5-002	Verify the dictionary dropdown and dictionary version dropdown contains only the dictionary and version the user has access too in the History Report page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
200	CodingHistoryReport - PB4.11.5-003	Verify user is able to enter date in the From field in the History Report page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
201	CodingHistoryReport - PB4.11.5-004	Verify user is able to enter date in the To field in the History Report page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
202	CodingHistoryReport - PB4.11.5-007	Verify that user is able to enter text into text fields in the History Report page	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
203	CodingHistoryReport - PB4.11.5-018	Verify user can save report and verify report is saved in directory chosen	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata
204	CodingHistoryReport - PB4.11.5-020	Verify search results are displayed correctly on CSV	2011.1.0	IS - 20 Mar 2013	IE8	https://coder-validation.imedidata

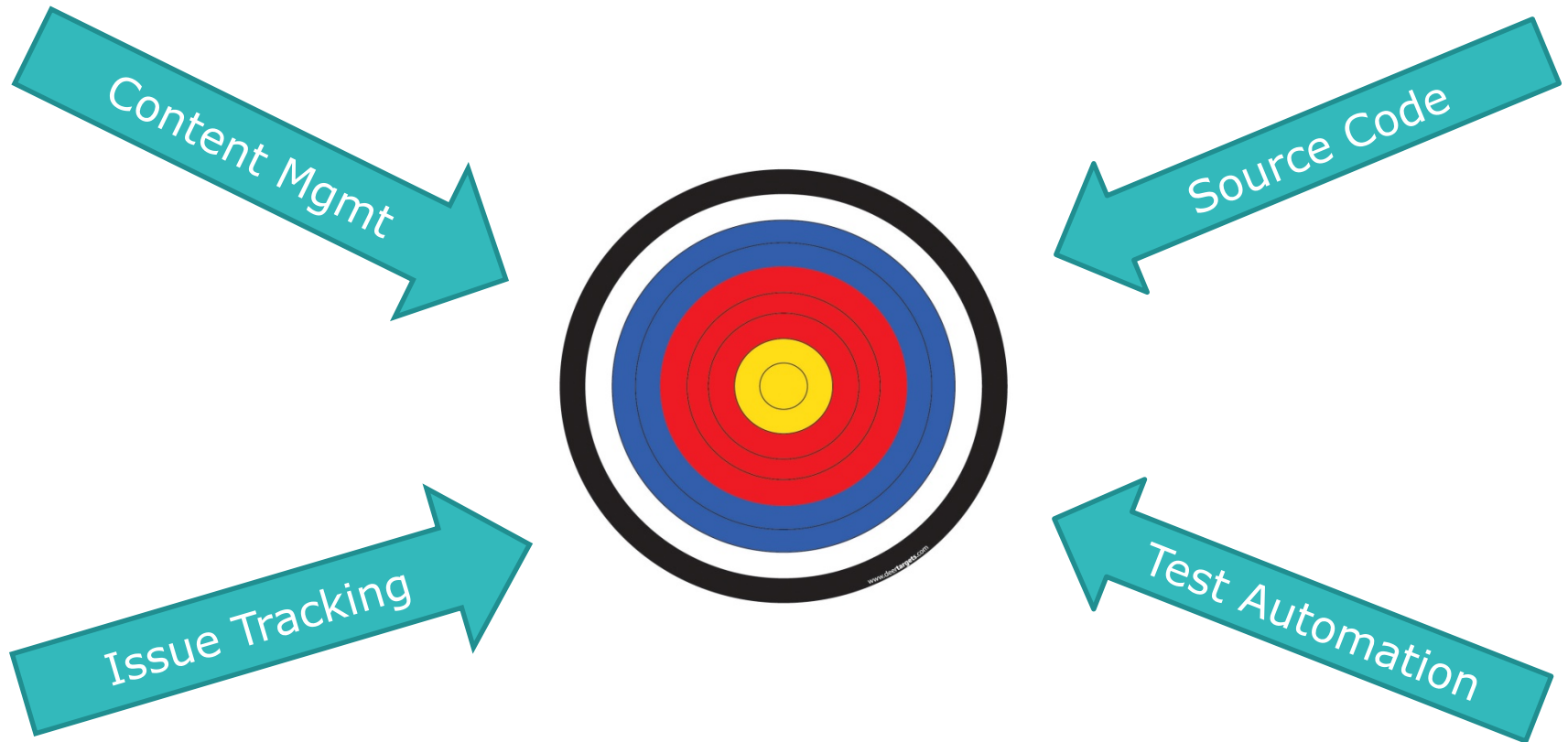
Ready | Count: 11 | 100%

SDLC & Validation – Support from Process Improvement

- **TDD**
- **Validation tasks in sprint backlog**
- **Acceptance of requirements/tests via inline tagging**
- **Recording of Reveals**
- **Minimization of signature requirements**

Now....back to the Validation Portal....

Automated Feeds



Validation artifacts originate in various places

To a 'Validation Portal'

The screenshot shows the Medidata Validation Portal interface. The top navigation bar includes 'Product/Modules/Services', 'Balance', and 'Version in Development (not production)'. The main content area is titled 'Medidata Validation Portal' and features a sidebar with a 'Design Overview' menu. The main content displays the 'Medidata Balance Design Specification' with sections for 'Introduction', 'How to Use this Design Specification Site', and 'Classes'. A 'Table of Contents' is visible on the right. Four teal callout arrows point to specific areas: 'Content Mgmt' points to the sidebar, 'Source Code' points to the 'Table of Contents', 'Issue Tracking' points to the 'Classes' section, and 'Test Automation' points to the 'How to Use this Design Specification Site' section.

Content Mgmt

Source Code

Issue Tracking

Test Automation

Ease of Review
Remote Access?

No Paper

Summary

- **Technology and Process evolution**
- **Regulatory backdrop**
- **Innovation with justification**
- **Understanding, education, evidence**

Thank You

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