

Testing in the medical world

Practical experiences with an FDA audit

Dutch Testing Day, 04-Nov-2009, by Patrick Duisters, Improve Quality Services BV

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- 20 years experience
- 12 years in Software Testing & Quality Assurance
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- Accreditations: ISEB/ISTQB, TMMi

Agenda

- Regulating bodies
- Consequences
- The Audit
- Lessons Learned
- FDA as a Model
- Questions



Regulating Bodies...

- Medical & Pharmacy for example
- No Free Choice

Their Function

- Safety: Hazard & Harm
- Product Quality: Qualification



FDA as a model

The **Food and Drug Administration** is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

- American market
- Independent
- Investigation for Verification: Audit
- Medical:
 - Code of Federal Regulations: 21CFR part 820
- Product & Process:
- Production & Development



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Consequences

- Proof
- Observations
- Warning letters
- Market closure
...or even Recall
- Follow-Up: Repo
- Often underestimated

The screenshot shows the FDA website interface. At the top, there is a search bar and navigation links. The main content area features a large banner for 'FDA 101: Product Recalls' with a 'Read More' and 'Watch Video' link. Below the banner, there are several sections: 'Science & Research', 'Public Health Focus', 'News & Events', 'Get Updates', 'Spotlight', 'Report a Problem', and 'Recalls & Safety Alerts'. The 'Recalls & Safety Alerts' link is circled in red.

Demands

- Mature & Deployed Processes
- Verification and Validation
- Formalization??



If it isn't written down, it hasn't been done

Documents are the only thing left now the product has gone



Building up the evidence...

- Policy
- Testing Quality System
- Test Approach
- Testing Strategy: Risk Based

based on PRISMA®

- Implementation of test strategy and test design techniques
- Proven quality and mitigated product risks
- TMMi addresses items: policy, training etc.



A checklist is not enough!



The Audit: context

- Manufacturer of medical systems
- Integration, Verification, Validation and Release team
- 50 Professional testers
- TMMi as a reference

- Test Process Manager

- Audit: late 2008: FDA
- Preparation, Execution, Follow up



Audit Preparation & Organization

Preparation

- Planning
- Desk Checks
- Briefing
- Mock Audit & Follow-Up

Organization

- Front Office
- Back Office
- Auditees



Audit Execution

- Introduction
- Questions
 - Starting Points
 - *Confirmation*
- Answers
 - Who, What, What Not, How,
 - *Confirmation*
- Closure
 - Reporting



Lessons Learned

- Mature process
- Understanding
- Preparation
- Review
- Briefing
- Mock Audit



FDA as a model

- Medical
- Defense
- Automotive
- Public
- Finance

