

Testing in the medical world

Practical experiences with an FDA audit

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- 20 years experience
- 12 years in Software Testing & Quality Assurance
- Administrative, Technical, Governmental

- Test Consultant & Trainer of Improve Quality Services BV

- Certifications: ISEB/ISTQB, TMap, IREB, Prince II
- Accreditations: ISEB/ISTQB, TMMi

Regulating Bodies...

- Medical & Pharmacy for example
- No Free Choice

Their Function

- Safety: Hazard & Harm
- Product Quality: Qualification



Agenda

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

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



Consequences

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

U.S. Food and Drug Administration Home Page - Microsoft Internet Explorer

File Edit View Favorites Tools Help Address http://www.fda.gov/

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration Protecting and Promoting Your Health

Search

A - Z Subject Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Food
Drugs
Medical Devices
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Radiation-Emitting Products
Tobacco Products

FDA 101: Product Recalls
Read More
Watch Video

Science & Research

- Combination Products
- Critical Path Initiative
- Clinical Trials
- Pediatrics
- Rare Diseases
- Toxicological Research

More Science & Research

Regulatory Information

- How to Comment on Proposed Regulations
- Code of Federal Regulations
- Dockets Management
- FDA Federal Registers (FR)
- Laws FDA Enforces

Public Health Focus

- 2009 H1N1 Flu
- H1N1 Fraudulent Products Widget
- Letter Regarding Point of Purchase Food Labeling
- Stolen Tylenol® Arthritis and Tylenol® PM Caplets
- Safe Disposal of Medicines
- Speech: Measures to Eliminate *Vibrio vulnificus* from Consumption of Raw Shellfish

More Public Health Focus

News & Events

- October 19, 2009 - FDA Approves New Treatment for Advanced Form of Kidney Cancer
- October 19, 2009 - FDA Approves Seasonal Influenza Vaccine Fluarix for Pediatric Use
- October 19, 2009 - FDA, FTC Issue Joint Warning Letter to Web Site Offering Fraudulent H1N1 Flu Supplements

Get Updates

- E-mail Updates
- RSS Feeds
- RSS Help

Spotlight

- FDA Public Health Alert: Potential Medication Errors with Tamiflu for Oral Suspension
- Strategic Plan for Risk Communication
- Electronic Cigarettes
- Transparency Task Force
- Combination Products
- Drug Safety Information for Patients & Providers
- Licensed Vaccines

Report a Problem

- Drugs, Medical Devices... (MedWatch)
- To Report an Emergency
- To Report a Non-Emergency
- Report Suspected Criminal Activity
- For Industry: Reportable Food Registry

Recalls & Alerts

- Recalls & Safety Alerts
- Warning Letters

Quality Services

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...

"It works as I thought it would."

- 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



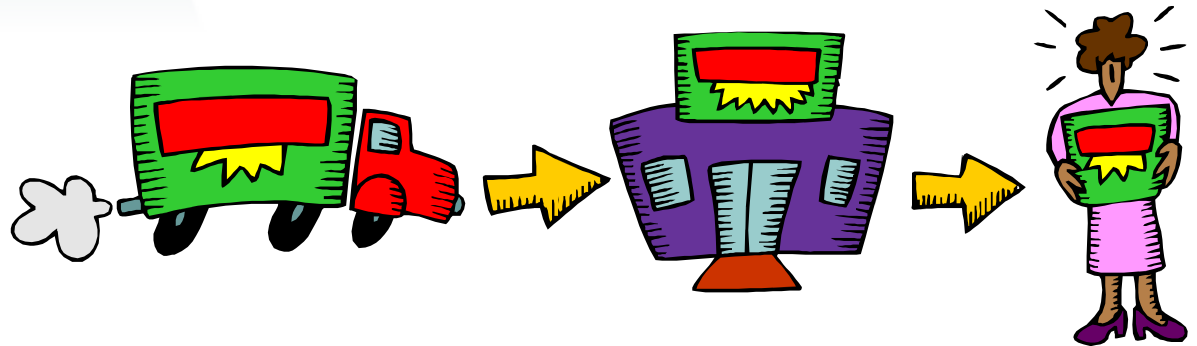
Lessons Learned

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



FDA as a model

- Medical
- Defense
- Automotive
- Public
- Finance





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