Medical Product Software Development and FDA Regulations

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The Intent Of Regulating Software

Medical Device Safety and Efficacy

Patients

Operators

Bystanders

Environment

Service Personnel
Many Stakeholders – Keeping A Total Solution In Mind

- Safety
  - Patients
  - Operators
  - Bystanders
  - Service People
  - Environment

- Medical Practitioners

- Quality Systems and Q&RA

- Customers and Business Needs
  - Reviewers
  - Internal Auditors
  - External Reviewers

- People Doing The Work

All Needs Met
Many Stakeholders – Keeping A Balanced Solution In Mind

Safety
- Patients
- Operators
- Bystanders
- Service People
- Environment

Medical Practitioners

Quality Systems and Q&RA

Customer and Business Needs

Reviewers
- Internal Auditors
- External Reviewers

People Doing The Work

All Needs Met

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Software Development Practices and FDA Compliance
Medical Product Software Development and FDA Regulations

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Types of Regulated Software

**Medical Device Software**

- Software that is actually a part of the medical device itself
- Software that is an accessory to a medical device
- Software that itself is a medical device
Types of Regulated Software

Medical Device Software
- Software that is actually a part of the medical device itself
- Software that is an accessory to a medical device
- Software that itself is a medical device

Non-Device Software that is part of:
- The production system
- The quality system
- Systems that are used to create and maintain records required by FDA regulations
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FDA is a public health agency, charged with:

- protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws.

It is FDA's job to see that:

- the food we eat is safe and wholesome,
- the cosmetics we use won't hurt us,
- the medicines and **medical devices** we use are safe and effective,
- and that radiation-emitting products, such as microwave ovens, won't do us harm

- One of our nation's oldest consumer protection agencies.
- Located in district and local offices in 157 cities across the country
FDA Inspection Responsibilities

Total Establishments*  113,170

Medical Devices  32,358

*FDA defines establishments as a business or other facility under one ownership and at one geographic location or address that processes, manufacturers, labels, repacks, stores, distributes, tests, or otherwise manipulates products under the jurisdiction of FDA. In addition, certain individuals or groups of individuals whose activities fall under the jurisdiction of FDA are also establishments. The sum of all categories is greater than the total because some establishments do business in more than one category.
FDA Overview

- **Administrative Enforcement Powers**
  - Unannounced and Announced Inspections
  - Inspectional Observations - 483
  - Warning Letters
  - Adverse Publicity
  - FDA-Initiated Recalls and Monitoring Company-Initiated Recalls
  - Delay, Suspension, or Withdrawal of Product Approvals
  - Preclusion of Government contracts
  - Detention and Refusal of Entry into U.S. Commerce of Imported Products

- **Judicial Enforcement Powers**
  - Civil Enforcement Powers (Seizure)
  - Criminal Enforcement Powers (Prosecution)
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Medical Device Definition

- Medical devices range from
  - Simple Devices
    - Tongue depressors and bedpans
  - Complex Devices
    - Programmable pacemakers
    - Laser surgical devices

- Medical Device Classification – Class I, II, and III
  - Class I devices include those with the lowest risk
  - Class III devices includes those with the greatest risk.
Medical Device Definition

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals,
  - and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
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820.30 Design Control

820.30(a) General

- (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall:
  - establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

- (2) The following class I devices are subject to design controls:
  - (i) Devices automated with computer software; and
  - (ii) The devices listed ..... Below:
    - Catheter, Tracheobronchial Suction
    - Glove, Surgeon’s
    - Restraint, Protective
    - System, Applicator, Radionuclide, Manual
    - Source, Radionuclide Teletherapy
Software – Special Attention

General Principles of Software Validation

3.3 Software Is Different From Hardware

- “Because of its complexity, the development process for software should be even more tightly controlled than for hardware, in order to prevent problems that cannot be easily detected later in the development process”.

- “…… software engineering needs an even greater level of managerial scrutiny and control than does hardware engineering”.

[1]
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Basic Regulatory Requirements

21 CFR 807 Establishment Registration

21 CFR 807 Medical Device Listing

21 CFR 807 Premarket Notification 510(k)

21 CFR 814 Premarket Approval PMA

21 CFR 820 Quality System Regulation

21 CFR 801 Labeling

21 CFR 803 Medical Device Reporting

Quality System Regulation

A - General Provisions

B - Quality System Requirements

C – Design Controls

D – Document Controls

E – Purchasing Controls

F – Identification and Traceability

G – Production & Process Controls

H – Acceptance Activities

I – Nonconforming Product

J – Corrective & Preventive Action (CAPA)

K – Labeling & Packaging Control

L – Handling, Storage, Distribution & Installation

M - Records

N - Servicing

O – Statistical Techniques

Production & Process Controls

820.70(a) General

820.70(b) Production & Process Changes

820.70(c) Environmental Control

820.70(d) Personnel

820.70(e) Contamination Control

820.70(f) Buildings

820.70(g) Equipment

820.70(h) Manufacturing Material

820.70(i) Automated Processes
Regulation of Software

**Basic Regulatory Requirements**

- **21 CFR 807**
  - Establishment Registration
- **21 CFR 807**
  - Medical Device Listing
- **21 CFR 807**
  - Premarket Notification 510(k)
- **21 CFR 814**
  - Premarket Approval PMA
- **21 CFR 820**
  - Quality System Regulation
- **21 CFR 801**
  - Labeling
- **21 CFR 803**
  - Medical Device Reporting

**Quality System Regulation**

- B - Quality System Requirements
- C - Design Controls
- D - Document Controls
- E - Purchasing Controls
- F - Identification and Traceability
- G - Production & Process Controls
- H - Acceptance Activities
- I - Nonconforming Product
- J - Corrective & Preventive Action (CAPA)
- K - Labeling & Packaging Control
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- O - Statistical Techniques

**Quality System Requirements**

- 820.100 Corrective & Preventive Action
Regulation of Software

**Basic Regulatory Requirements**

- **21 CFR 807**
  - Establishment Registration
- **21 CFR 807**
  - Medical Device Listing
- **21 CFR 807**
  - Premarket Notification 510(k)
- **21 CFR 814**
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- **21 CFR 820**
  - Quality System Regulation
- **21 CFR 801**
  - Labeling
- **21 CFR 803**
  - Medical Device Reporting

**Quality System Regulation**

- **A - General Provisions**
- **B - Quality System Requirements**
- **C – Design Controls**
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- **N - Servicing**
- **O – Statistical Techniques**

**Quality System Requirements**

- 820.25(a) General
- 820.25(b) Training
- 820.22 Quality Audit
# Software Basic Requirements

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## Software Validation

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Procedures and Plans

You must be able to demonstrate that you are “Operating In A State Of Control”

- Establish, in advance of activities, what you are going to do.
- Do what you say you are going to do.
- Be able to provide objective (documented) evidence.
Software Development

- SW Life-Cycle Model
- SW Requirements Analysis
- SW Requirements Verification
- SW Architectural Design
- SW Architecture Verification
- SW Detailed Design
- SW Detailed Design Verification
- SW Coding
- SW Code Verification
Testing

- Unit Test
- Integration Test
- SW System Test
- Beta Testing
Verification & Validation

**SW Verification**

“Engineering Correctness Checks”

**SW Validation**

“Intended Use Confirmation”
Supporting Processes

- COTS Software Components
- SW Risk/Hazard Analysis
- SW Human Factors (Use Errors)
- SW Change Control
- SW Configuration Management
- SW Problem Tracking & Resolution
- SW Traceability
- Non-Product Software Validation
- Corrective and Preventive Action (CAPA)
# Release

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- Training
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Software Quality and Software Safety

The Reason

WHY

we need to have a comprehensive and effective Software Development Life Cycle
The Intent Of Regulating Software

Medical Device Safety and Efficacy

- Patients
- Operators
- Bystanders
- Environment
- Service Personnel
Understanding Defects

Defects

Start → Development Process → Ship

[2]
Understanding Defects

Defects

Start → Development Process → Ship

Defects Injected

[2]
Understanding Defects

Defects Injected

Defects Detected and Corrected

Defects Shipped

Start → Development Process → Ship

[2]
A Journey To Fewer Defects
Overall Software Quality

Inject Fewer Defects
Defect injection rates can be reduced by performing these activities highly effectively and introducing Causal Analysis.
Defect injection rates will increase if you do not perform these activities well or you decide not to do the activity at all.
Defect Injection Rates are directly related to the completeness and the effectiveness of each of these activities.
Software Quality Model
Understanding Defect Injection Rates

Defects per 1000 lines of code
A Journey To Fewer Defects
Overall Software Quality

Defects

Inject Fewer
Detect More Effectively
Detect Earlier

Start → Development Process → Ship

[2]
Software Quality Model
Increasing Effectiveness
A Journey To Fewer Defects
Overall Software Quality

Defects

Inject Fewer

Detect More Effectively

Detect Earlier

Zero?

Fewer Defects

Start -> Development Process -> Ship

[2]
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Software Safety Model
Risk/Hazard Analysis & Use Error Analysis

Risk/Hazard Analysis
Use Error Analysis

Harm To:
- Patients
- Operators
- Bystanders
- Service Personnel
- Environment

- Software Requirement
  - Verification
- Software Detailed Design
  - Verification
- Software Coding
  - Verification
- System Validation
- Beta Site Testing
- Customer

Unit Test
Integration Test
Software System Test
System Test Validation
Software Safety Model
Risk/Hazard Analysis & Use Error Analysis

Risk/Hazard Analysis
Use Error Analysis

Induced By:
- Basic Functionality
- Software Defects
- Use Errors
- Environment
- Interfaces

Software Development
- Requirements
- Design
- Coding
- Testing
- Validation
- Customer
Software Safety Model
Risk/Hazard Analysis & Use Error Analysis
Software Safety Model
Risk/Hazard Analysis & Use Error Analysis

Risk/Hazard Analysis
Use Error Analysis

- Software Requirements
  - Verification
- Software High-Level Design
  - Verification
- Software Detailed Design
  - Verification
- Software Coding
  - Verification

- Software Requirements → Software High-Level Design
- Software High-Level Design → Software Detailed Design
- Software Detailed Design → Software Coding

- Unit Test
- Integration Test
- Software System Test
- System Validation
- Beta Site Testing
- Customer
Software Safety Model
A Continuous Process Throughout the Life Cycle

Risk/Hazard Analysis
Use Error Analysis

Software Requirements
Software High-Level Design
Software Detailed Design
Software Coding

Verification
Verification
Verification
Verification

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Use Error Analysis

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- Verification

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- Verification

Software High-Level Design
- Verification

Software Detailed Design
- Verification

Software Coding
- Verification

Unit Test
Integration Test
Software System Test
System Validation
Beta Site Testing
Customer
Use Error

User Error – Blames The User For Doing Something Wrong

Use Error – Developer takes accountability for developing software that allowed the user to make an error

And.....the developer incorporates Use Error Analysis into the risk management process resulting in the implementation of built-in safeguards to protect against Use Error
Use Error (Human Factors) Considerations

- Skill Level Variation
- Environmental Variation
- Compromising Factors
- Physical and Sensory Characteristics
- Perception
- Cognition
- Expectancies
- Mental Models
- Home Use
## Software Safety Model
Risk/Hazard Analysis & Use Error Analysis

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<th>Potential Harm To Operators</th>
<th>Potential Harm To Bystanders</th>
<th>Potential Harm To Service Personnel</th>
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<td><strong>YES</strong></td>
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<td><strong>Environment</strong></td>
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<td><strong>Interfaces</strong></td>
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You are developing a function where the user will be asked to manually enter a patient’s age.

You realize that if the age is entered incorrectly that an incorrect diagnosis might be made.
### Software Safety Model

#### Risk/Hazard Analysis & Use Error Analysis

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<th>Potential Event</th>
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<td>Incorrect Diagnosis</td>
<td>Major</td>
<td>Enter Date of Birth (cross check)</td>
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Recall Statistics


Software-related recalls – 242
Software recalls due to changes – 192 (79%)

“Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial production and distribution”

FDA Guidance (2002) General Principles of Software Validation
Maintenance Challenges

Oversimplification of the task
Customer and Patient expectations
Increased requirements on system
Changes
Design additions and/or modifications
State of the documentation
Knowledge level
Personnel changes
Software components (COTS)
Hardware components
Interfaces
Cybersecurity issues

Maintenance Challenges
Creating A Balance

Challenges
- Oversimplification of the task
- Customer and Patient expectations
- Increased requirements on system
- Changes
- Design additions and/or modifications
- State of the documentation
- Knowledge level
- Personnel changes
- Software components (COTS)
- Hardware components
- Interfaces
- Cybersecurity issues

Processes
- Requirements management
- Anomaly management
- Technology transition management
- Risk management
- Training
- Change control
- Software development life cycle
- Technical reviews
- Validation planning
- Testing
- Configuration management
- Documentation updates
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## The Regulation
- The Quality System Regulation 21 CFR 820

## FDA General References
- Medical Device Quality System Manual
- Design Control Guidance
- Do It By Design
- Medical Device Use Safety (Human Factors/Use Errors)
- Guide To Inspections Of Quality Systems (QSIT)

## FDA Software Specific References
- General Principles of Software Validation
- Software Pre-market Submission Guidance
- Off-The-Shelf Software Guidance

## Industry References
- ANSI/AAMI SW68
- ISO 62304
- ISO 13485
- ISO 14971
FDA Software Specific References
- General Principles of Software Validation
- Software Pre-market Submission Guidance
- Off-The-Shelf Software Guidance

Industry References
- ANSI/AAMI SW68
- ISO 62304
General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Document issued on: January 11, 2002

This document supersedes the draft document, "General Principles of Software Validation, Version 1.1, dated June 3, 1997.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
FDA Software-Specific Guidance Documents

Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Document issued on: May 11, 2005


For questions regarding this document concerning devices regulated by CDRH contact David S. Buckles at (301) 443-8527. For questions regarding this document concerning devices regulated by CBER contact Linda Wise at (301) 427-6196.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics
Center for Biologics Evaluation and Research
Office of Blood Research and Review

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices

Document issued on: September 9, 1999

This document supersedes document, Guidance on Off-the-Shelf Software Use in Medical Devices, June 4, 1997.

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
ANSI/AAMI SW68:2001
Medical Device Software - Software life cycle processes
Medical Product Software Development and FDA Regulations
Software Development Practices and FDA Compliance

FDA Website           www.fda.gov

Click On “Medical Devices”
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Or, enter a word or phrase to search for in documents:

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Some additional items of interest can be found on the Consumer Information page.

Quality Control Material
- Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft
- Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90-4236)

Quality Systems
- FDA Launches Initiative to Improve the Development and Availability of Innovative Medical Products
- GMP Information / Quality Systems Information
- Guide to Inspections of Quality Systems (QSTT)
- Guideline on General Principles of Process Validation
- Improving Innovation in Medical Technology: Beyond 2002
- Improving Innovation in Medical Technology: Beyond 2002 - Executive Summary
- Medical Device Manufacturer's Survey Evaluation of FDA Quality System / Good Manufacturing Practice Inspections
- Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff
- Reengineering: Good Manufacturing Practices (GMP) Inspection Process
- Schedule for GMP/QS Workshops with CDRH Participation
- Y2K Issue for Production Processes and Quality System Software
Medical Product Software Development and FDA Regulations
Software Development Practices and FDA Compliance

FDA Website
http://www.fda.gov/cdrh/humanfactors/

FDA's Human Factors Program
Promoting Safety in Medical Device Use

• What is Human Factors?
• Why is Human Factors Engineering Important for Medical Devices?
• What is FDA's Human Factors Program?

Information for Manufacturers and Distributors
• Quality System Regulation
• Human Factors Guidance
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• Other Human Factors Documents
• Labeling Guidance
• Other Labeling Documents

Contact Us
• Report Problems With Medical Devices
• Contact the Human Factors Team

Additional Resources
• Special FDA Initiatives
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• Other Patient Safety Sites
• Other Resources

Updated June 17, 2003
Medical Product Software Development and FDA Regulations
Software Development Practices and FDA Compliance

Quality System Regulation

Medical Device Quality System Manual

Do It By Design

Design Control Guidance

Medical Device Use Safety Human Factors Risk Mgmt

Guide To Inspections Of Quality Systems (QSIT)

Off-The-Shelf Software Guidance

Software Pre-Market Submission Guidance

General Principles of Software Validation

ANSI/AAMI SW68:2001 Software Processes

SW Life-Cycle Model
SW Requirements Analysis
SW Requirements Verification
SW Architectural Design
SW Architecture Verification
SW Detailed Design
SW Detailed Design Verification
SW Coding
SW Code Verification
Unit Test
Integration Test
SW System Test
Beta Testing
SW Verification
SW Validation
COTS Software Components
SW Risk/Hazard Analysis
SW Human Factors (Use Errors)
SW Change Control
SW Configuration Management
SW Problem Tracking & Resolution
SW Traceability
SW Non-Product Software Validation
Corrective & Preventive Action (CAPA)
Design Transfer
Design History File
Training
Software Quality Audits
Medical Product Software Development and FDA Regulations

Introduction
Regulated Software
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Software Quality Model
Software Safety Model
Software Maintenance
Corrective Action and Preventive Action (CAPA)
Reference Material
Conclusion
Low Defect Injection Rates

- Software Requirements
- Software High-Level Design
- Software Detailed Design
- Software Coding

Verification

Risk/Hazard Analysis
Use Error Analysis

CAPA

Early and Highly Effective Defect Detection Steps

- Unit Test
- Integration Test
- Software System Test
- System Validation
- Beta Site Testing
- Customer
It’s All About Making It Safe
Your Families! - Your Loved Ones! - Your Friends!
Each and Every One Of YOU!

Patients
Operators
Bystanders
Environment
Service Personnel
Thank You!

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MedicalDeviceSoftware.com

UC Irvine Extension Program
Medical Product Development
Medical Device Engineering
BME X401
Software-Controlled Medical Devices
Software Engineering & Compliance

References
