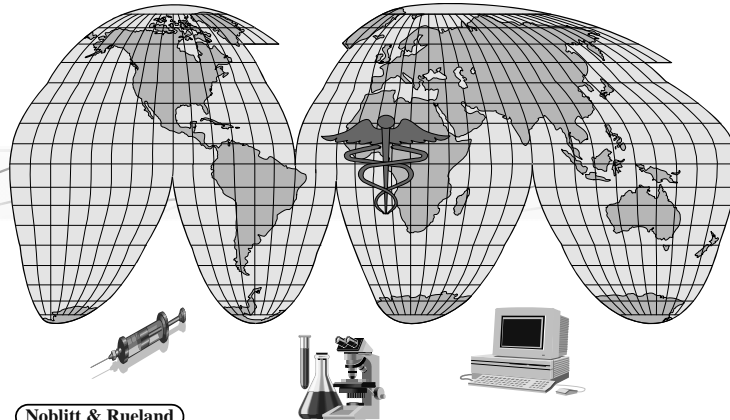


UCI Medical Device Regulatory Awareness Workshop



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Noblitt & Rueland

- Training & Consulting Company
- 23rd Year
- Specializing in FDA & ISO related issues
- Primarily focused on medical devices
- Trained over 4000 medical device manufacturing employees on numerous FDA & ISO topics
- Consulting on Medical Device submissions, 510(k), CE Mark, PMA submissions, compliant quality systems, QSR/GMP, ISO 13485, auditing, software, Risk Analysis, Design Control, IEC 60601-1, Electronic Recordkeeping, clinical studies, and FDA problems, etc.

Dennis Rubenacker Biography

Dennis L. Rubenacker is co-founder and Senior Partner of the consulting firm of Noblitt & Rueland specializing in FDA electronic recordkeeping, design control, risk assessment, software development and software quality management for the medical device industry. He has extensive experience dealing with product development, software development and software quality assurance for medical device instrumentation. Mr. Rubenacker has held software engineering, software quality assurance, electronics engineering, project management, and management consulting positions in the research and development of medical devices, aerospace systems, and consumer electronics. His medical product line experience includes monitoring, diagnostic, and therapeutic critical-care devices. His experience includes clinical chemistry analyzers, immunoassay analyzers, microbiology analyzers, implantable & external defibrillators, glucose monitors, pacemakers, cardiac output computers, ejection fraction computers, oxygen saturation computers, retroperfusion pumps, cardiac imagers, EKG monitors, infusion pumps, catheter-sensor interfaces, home healthcare monitoring devices, as well as, manufacturing process instrumentation. He has been involved with the FDA, Los Angeles district, grass roots partnering subcommittee on electronic recordkeeping and has lectured on FDA electronic recordkeeping with several organizations including the Food and Drug Law Institute (FDLI). Mr. Rubenacker has assisted both domestic and international companies including companies ranging in size from less than \$1,000,000 in sales to Fortune 100 companies. Mr. Rubenacker received his B.S. in Electrical Engineering with highest honors from the University of Illinois and is a member of the Institute for Electrical and Electronic Engineers (IEEE), RAPS, OCRA and ASQ.

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Brent Noblitt Biography

Brent Noblitt is co-founder and Senior Partner of the consulting firm Noblitt & Rueland. Mr. Noblitt specializes in international and U.S. medical device strategic planning, development, and marketing. His consultation has been used to market medical devices throughout the world. Mr. Noblitt's associations range from start-up ventures to Fortune 100 corporations. His marketing background and technical training allows him to comprehend and advise on the marketing planning process and opportunities of various technologies. Prior to founding Noblitt & Rueland, Mr. Noblitt held management & executive positions in the medical device industry. Mr. Noblitt's product experience includes various critical care devices, cardiac output computers & pulmonary catheters, extravascular lung water computers, ultrasound devices, phono-angiography, computerized patient databases, patient monitoring systems, disposable & reusable pressure monitoring devices & accessories, ejection fraction computers, continuous mixed venous oxygen saturation systems & catheters, surgical laser systems, implantable defibrillators, pacemakers, continuous blood pressure control systems, as well as, home healthcare delivery systems. His academic training includes a B.S. and M.S. in Electrical Engineering-Biomedical from Purdue University complemented by an M.B.A. degree earned from Pepperdine University and he is a member of ASQC-Biomedical & Healthcare Divisions, Association for the Advancement of Medical Instrumentation (AAMI), and the Orange County Regulatory Affairs Association (OCRA).

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Medical Device Regulatory Awareness Training

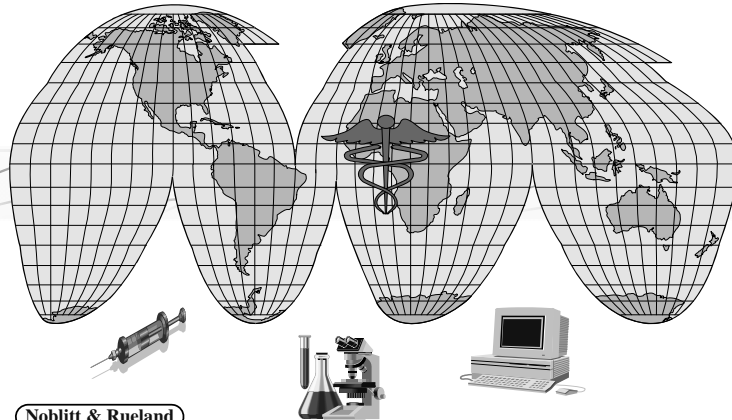
● SEMINAR OBJECTIVES

- Gain insight into the regulatory aspects of medical devices.
- Understand the major regulatory issues that a company will need to deal with now and in the future.

Medical Device Regulatory Awareness Training

- A. Overview U.S. & European/International Requirements
- B. FDA Purpose & History
- C. Device Definition & Classifications
- D. Submissions
- E. Quality Systems
- F. FDA Establishment Registration & Device Listings
- G. Start-up Strategy & Misc. Issues
- H. Question & Answer

Regulatory Overview



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How does FDA protect the public health?



THROUGH ENFORCEMENT

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Major Examples

- Abbott Laboratories
 - Consent Decree, >\$100 Million, initial fine and payments
- Schering Plough
 - Consent Decree, \$500 Million
- C.R. Bard
 - Criminal, \$63 Million
- Wyeth
 - Consent Decree, \$30 Million
- GlaxoSmithKline
 - Consent Decree, \$650 Million penal bond

This does not begin to address share price reduction, negative publicity, and operational costs to correct.

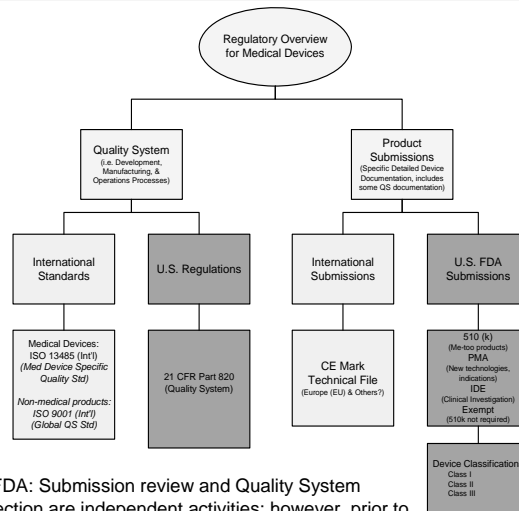
FDA Enforcement Tools

- | | |
|--|---|
| ● NAI (No), VAI (Voluntary), OAI (Official Action Indicated) | ● Prosecution |
| ● 483 Observations | ● Civil Penalties |
| ● Warning Letter | ● Debarment from industry |
| ● Recall | ● Import Detention |
| ● Seizure | ● Criminal Proceedings, etc. |
| ● Consent Decree | ● Withdrawal of Product Approval |
| ● Injunction | ● Disqualification (clinical investigators) |

Other Ways FDA Protects

- Not Approving or Clearing Medical Device Submissions
- Product Recalls
- Etc.

Regulatory Overview



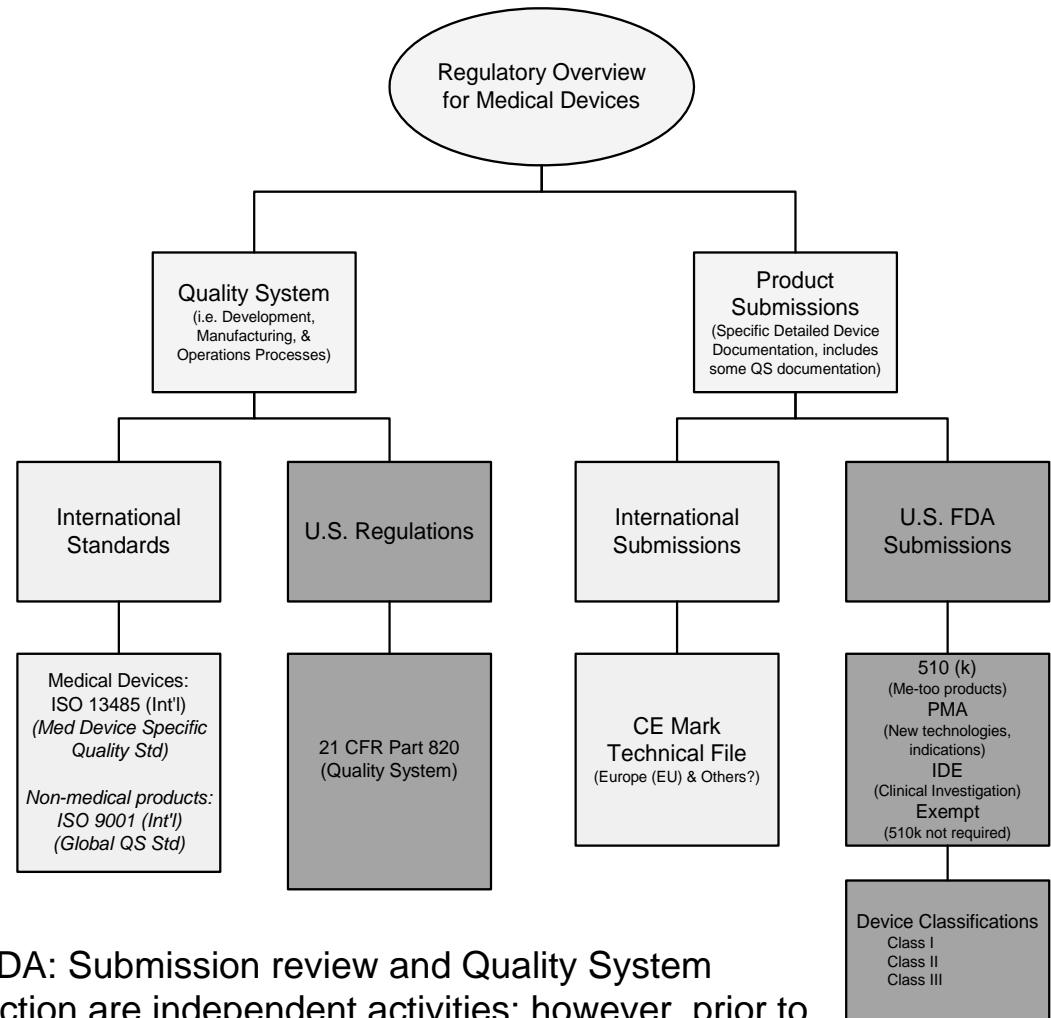
- Japan
- Canada
- Others?
- Many countries are moving toward CE Mark concept.



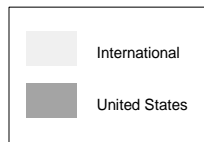
US FDA: Submission review and Quality System inspection are independent activities; however, prior to manufacturing your QS must be FDA compliant. (fyi...an FDA inspection is not mandatory).

Europe: CE Mark Technical File and QS review and inspection occur at the same time. (Device classification dependent)

Regulatory Overview



- Japan
- Canada
- Others?
- Many countries are moving toward CE Mark concept.



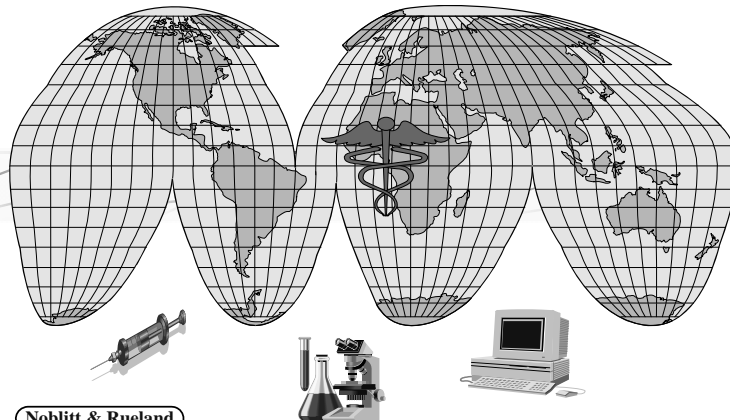
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FDA Purpose & History



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Regulatory Hierarchy

- **Mission: FDA**
 - Protect Public Health
- **Laws: FDA**
 - Food, Drug & Cosmetic Act (1938)
 - Safe Medical Devices Act (1990)
 - Medical Device User Fee and Modernization Act (2002)
 - Etc.
- **Regulations: FDA**
 - 21 CFR Parts 800-1299 CDRH Responsibility
 - 21 CFR Part 820 (CGMP/QS Regulation)
 - 21 CFR Part 11 (Electronic Records & Signatures)
 - Etc.

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Regulatory Hierarchy

(continued)

- **Directives: EU (European Union)**
 - Active Implantable Device Directive
 - Medical Device Directive
 - In-Vitro Diagnostic Device Directive
- **Standards**
 - ISO 13485, ISO 9001, ISO/IEC 12207
 - ISO 14971 (Risk Management), IEC 60601-1, UL 1998
 - IEC 62304, IEEE 1012, Software V&V Plan, etc.
- **Guidance Documents / Policies**
 - FDA, Design Controls Guidance
 - FDA, General Principles of Software Validation
 - FDA, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
 - Many others...including some device specific guidance

FDA Purpose

- **Protect Public Health**
 - Establish controls
 - Review & inspect safety & efficacy of medical devices
 - Regulate design & manufacturing
 - Inside US &
 - Outside US for use in US

FDA History

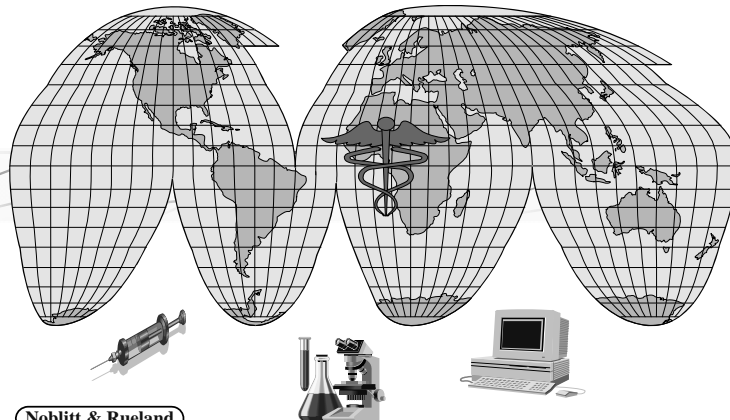
- “The Act” ~1938
 - Food, Drug, and Cosmetic Act
- GMP, 21 CFR Part 820 ~1976
 - Good Manufacturing Practice
- Device Amendments (1976)
 - Classification, pre & post amendments devices

FDA History

(continued)

- Safe Medical Devices Act of 1990
 - Preproduction Design Validation
 - Global Harmonization
- New CGMP/QS Regulation (1996)
 - Design Control
- Full QSIT Implementation (2000)
- Medical Device User Fee and Modernization Act (2002)
- Etc., etc., expect new & changing regulations!

Device Definition



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U.S. Medical Device Definition

(Food, Drug & Cosmetic Act: Sec 201(h))

... an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) 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
- (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal 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 principal intended purposes.

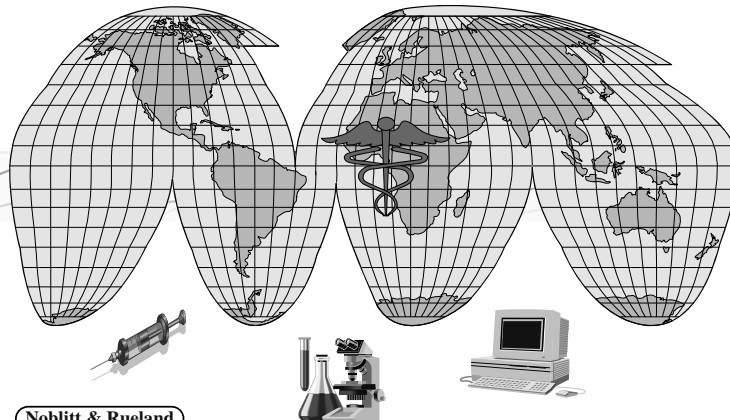
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Medical Device Examples

- Tongue Depressor
- Sunglasses
- Breast Implants
- Blood Analyzer
- Blood Pressure Monitor
- MRI
- Blood Bank Software
- Condoms
- Infusion Pump
- Implantable Defibrillator
- Cardiac Monitor
- Iphone Radiology Application

Device Classifications



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Device Classifications (Food, Drug, Cosmetic Act)

- **Class I**
 - General controls (e.g. quality system & labeling) are sufficient to provide reasonable assurance safety and effectiveness.
 - The device does not present an unreasonable risk of illness or injury.
 - The device is not life-supporting or life-sustaining.
 - Generally exempt from Premarket Notification; however, some Class I devices require 510(k) submission.
 - Examples:
 - Tongue depressor
 - Sunglasses
 - Suture Removal Kit

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Device Classifications

(Food, Drug, Cosmetic Act)

(continued)

● Class II

- Devices that are subject to special controls because the Agency believes that general controls are insufficient to safety and effectiveness.
- Performance standards.
- 510(k) Premarket Notification (submission) unless exempt
- Examples:
 - Esophageal Dilator
 - Suture, Nonabsorbable Synthetic Polyester
 - Bone Fixation Screw
 - In Vitro blood pressure monitor
 - Cardiac Monitor

Device Classifications

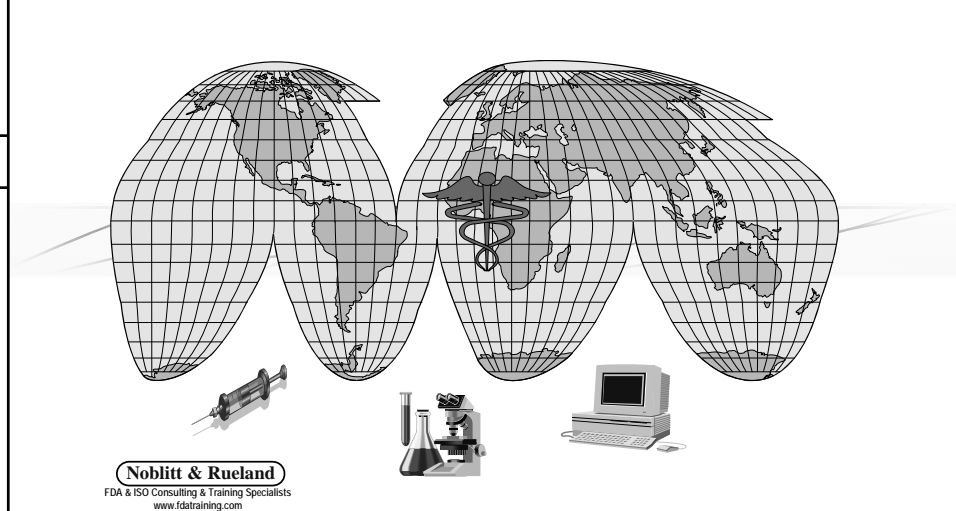
(Food, Drug, Cosmetic Act)

(continued)

● Class III:

- General and special controls are not sufficient to provide reasonable assurance of the safety and effectiveness of the device.
- The device is life-supporting or life-sustaining or is of substantial importance in preventing impairment of human health.
- The device presents a potential unreasonable risk of illness or injury.
- Usually subject to Premarket Approval (PMA).
- Examples:
 - Cervical Expandable Dilator
 - Spinal Pedicle Screw
 - implantable defibrillator

Submissions



Premarket Submissions

- Types of Premarket Submissions
 - Investigational Device Exemption (IDE)
 - Investigational use only.
 - Device is safe.
 - 30 day Review goal by FDA
 - 510(k) Premarket Notification
 - Device is substantially equivalent to legally marketed device with respect to safety and efficacy (as safe and as effective as predicate device).
 - Device does not raise any new safety issues.
 - Class II Devices
 - Typically clinical studies are not required (~90%)
 - 90 day Review goal by FDA (FY'09 Ave 98 days including industry time)
 - FDA User Fee \$4,049 or \$2,024 (Companies <\$100mil)
 - Premarket Approval (PMA)
 - Device is safe and effective.
 - Device has no predicate.
 - Typically Class III devices
 - Clinical studies required (usually adds substantial cost)
 - Average elapsed time from submission to decision by FDA: 284 days ('08), 506 days ('02)
 - FDA User Fee \$220,050 or \$55,013 (Companies <\$100mil)
 - FDA waives PMA user fee for companies (<\$30mil) and first PMA

Premarket Submissions 510(k)

- A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).
- FDA reviews 510(k) submissions with a 90-day timeline (goal). If there are unaddressed scientific issues, the review scientists can ask for additional information (RAI) and put the submission temporarily on hold.

Premarket Submissions 510(k) (continued)

- If FDA finds the information provided by the sponsor meets the standard of equivalency or is substantially equivalent (SE), the product is cleared for marketing in the United States. If FDA finds that there is no predicate for the device, or that the new device does not have equivalent performance to the identified predicate, then the device is found not substantially equivalent (NSE).
- There is no 510(k) form but instead a requested format for the submission.

Types of 510(k) Submissions

- 510(k) Submission Types
 - Traditional
 - Special (for changes to a device)
 - Abbreviated (must show conformance to standards)
- Non-Conventional Submissions
 - De Novo (no predicate, low risk)
 - Combination (device, drug, or biologic combinations)

Traditional 510(k)

- ~3500 to ~4000 per year submitted to FDA
- No Form, but flexible format
- Since 1976, Device Amendments
- Used for any original 510(k) and can be used for a modification to a previously cleared device
- Traditional 510(k) format may be used under any 510(k) circumstances

Special 510(k): Device Modification

- When appropriate
 - Significant modification to manufacturer's legally marketed device
 - Modification does not affect intended use or alter fundamental scientific technology.
 - Refer to flow chart in *Deciding When to Submit a 510(k) for a Change to an Existing Device* to determine if significant.
 - Manufacturer can *demonstrate adherence to Design Controls*
 - Data generated as result of design control adherence must be available for FDA inspection.
- FDA review goal– 30 days

Abbreviated 510(k)

- When appropriate
 - new device or modification to existing device for which Special 510(k) is not appropriate and
 - manufacturer conforms or will conform to
 - Device Specific Guidance issued by FDA, or
 - Special Controls to address specific risks or issues concerning the device, or
 - Consensus Standards
- Expedited review
 - Slower than Special
 - Faster than Traditional (goal)

Premarket Submissions IDE

- An IDE allows investigational device to be used in a clinical study in order to collect safety and effectiveness data to support PMA or 510(k) submission.
- An IDE permits device to be shipped lawfully for the purpose of conducting investigations without complying with requirements of the FD&C Act that apply to devices in commercial distribution.
- Non-significant risk devices do not need formal FDA IDE submission; other exemptions may also apply. However, this does not necessarily mean that some of the same documentation is not created or kept...just not submitted.

Premarket Submissions PMA

- A PMA is an application submitted to FDA to request approval to market a class III medical device.
- PMA approval is based on scientific evidence providing a reasonable assurance that the device is safe and effective for its intended use or uses. For IVDs, there is a unique link between safety and effectiveness since the safety of the device is not generally related to contact between the device and patient. For IVD products, the safety of the device relates to the impact of the device's performance, and in particular on the impact of false negative and false positive results, on patient health.
- FDA reviews PMA submissions in a 180-day timeline. If there are unaddressed scientific issues, the review scientists can ask for additional information and put the submission temporarily on hold. If a product is a first of a kind, or if it presents unusual issues of safety and effectiveness, it is generally reviewed before it is approved by an advisory panel of outside experts. Approval of a PMA requires review of the manufacturing processes, an inspection of the manufacturing facility, a bioresearch monitoring audit of clinical data sites, as well as comprehensive review of the premarket data.

Premarket Submissions

PMA

(continued)

- If FDA finds that a product is safe and effective, it receives an official approval order for marketing in the United States. If FDA finds that a product is not safe and effective, it may be non-approved.
- A manufacturer considering a PMA should consult 21 CFR 814.
- PMAs require quite a bit of resources (esp. \$\$\$, time)

Premarket Submissions

Guidance & Direction

- General Guidance Examples
 - Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (on CD ROM)
 - Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (on CD ROM)
 - Deciding When to Submit a 510(k) for a Change to an Existing Device
 - The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry
 - The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- Device specific guidance

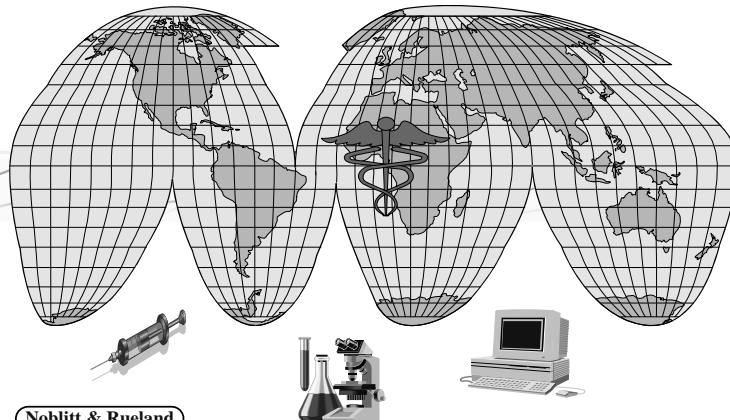
De Novo Submission Route

- De Novo (Section 513(f)(2))
 - No Predicate
 - Low Risk
 - Guidance available

Combination Products

- Combination Products
 - Drug/Device, Drug/Biologic, Device/Biologic, etc.
 - Drug-Eluting Cardiovascular Stents
 - Dental Prophylaxis Pastes incorporating a Drug
 - Inhalers
 - -others
 - New Office of Combination Products
 - Assign FDA Center with primary jurisdiction for review
 - CDRH-Device
 - CBER-Biologics
 - CDER-Drugs
 - Ensure consistency & timeliness, dispute resolution by overseeing reviews

Quality Systems



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Quality System Definition

FDA Definition: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

- The process and the implementation of a quality system needs to be documented.
- Continuous process
- FDA Regulations & International Standards defined expectations

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U.S. Sales

- All medical device manufacturers must comply with the FDA quality system regulation 21 CFR Part 820 in order to sell products in the U.S., including foreign companies.
- FDA legally can and will inspect manufacturers for compliance to 21 CFR Part 820. When is the question!
- FDA inspects quality records for evidence of (non)compliance to the quality system regulation.

FDA = United States Food and Drug Administration

Acronyms

- cGMP= GMP = QSR = 21 CFR Part 820
- cGMP= Current Good Manufacturing Practice
- GMP= Good Manufacturing Practice
- QSR= Quality System Regulation (also Records)
- 21 CFR Part 820= the actual GMP/QSR in the Code of Federal Regulations (Medical Device specific)

- QS= Quality System

International Sales

- In general, all manufacturers need to comply with the quality system requirements of ISO 13485 to sell internationally.
- ISO 13485 inspections are performed by notified bodies (\$), not FDA.
- ISO 13485 is similar to FDA regulation, but not the same.
- Most manufacturers selling globally have one quality system that complies with both FDA 21 CFR Part 820 and ISO 13485.

ISO = International Standards Organization

FDA GMP/QSR Regulation

- 21 CFR Part 820, Medical Devices, Current Good Manufacturing Practices (cGMP); Quality System Regulation (QSR)
- Revised Oct. 1996
- Major new sections:
 - Management Responsibility
 - Design Controls

FDA GMP/QSR

21 CFR Part 820

Management Responsibility

- **Subpart B—Quality System Requirements**
- **§ 820.20 Management responsibility.**
 - (a) *Quality policy.* Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.
 - The rest of the sections provide additional details.
- During a QS inspection the FDA will inspect the Management Subsystem either directly or indirectly (i.e. any failure or non-compliance of the QS is a result of a management issue).

FDA Medical Device Quality System Regulation (QSR)

21 CFR Part 820

PART 820—QUALITY SYSTEM REGULATION

Subpart A—General Provisions

Sec.
 820.1 Scope.
 820.3 Definitions.
 820.5 Quality system.

Subpart B—Quality System Requirements

820.20 Management responsibility.
 820.22 Quality audit.
 820.25 Personnel.

Subpart C—Design Controls

820.30 Design controls.

Subpart D—Document Controls

820.40 Document controls.

Subpart E—Purchasing Controls

820.50 Purchasing controls.

Subpart F—Identification and Traceability

820.60 Identification.
 820.65 Traceability.

**Subpart G—Production and Process
 Controls**

820.70 Production and process controls.
 820.72 Inspection, measuring, and test
 equipment.
 820.75 Process validation.

Subpart H—Acceptance Activities

820.80 Receiving, in-process, and finished
 device acceptance.
 820.86 Acceptance status.

Subpart I—Nonconforming Product

820.90 Nonconforming product.

**Subpart J—Corrective and Preventive
 Action**

820.100 Corrective and preventive action.

**Subpart K—Labeling and Packaging
 Control**

820.120 Device labeling.
 820.130 Device packaging.

**Subpart L—Handling, Storage, Distribution,
 and Installation**

820.140 Handling.
 820.150 Storage.

820.160 Distribution.

820.170 Installation.

Subpart M—Records

820.180 General requirements.
 820.181 Device master record.
 820.184 Device history record.
 820.186 Quality system record.
 820.198 Complaint files.

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

FDA Medical Device Quality System Regulation (QSR)

21 CFR Part 820

PART 820—QUALITY SYSTEM REGULATION

Subpart A—General Provisions

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820.184 Device history record.

820.186 Quality system record.

820.198 Complaint files.

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

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Quality System Regulation: Key Points

- § 820.3 Definitions
- § 820.20 Management responsibility
- § 820.30 Design controls
- § 820.40 Document controls
- § 820.70 Production and process controls
- § 820.100 Corrective and preventive actions
- § 820.120 Device labeling
- § 820.180 Records

Seven Subsystems of the QSR

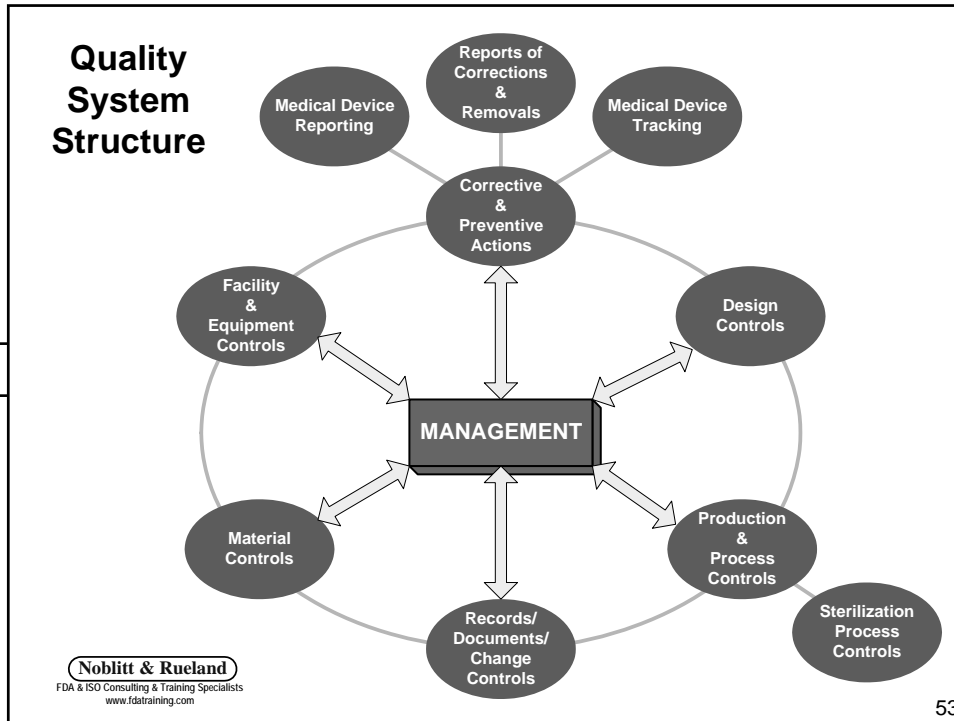
- Four Major Subsystems
 - Management Controls-Subpart B
 - Design Controls-Subpart C
 - Corrective and Preventive Action-Subpart J
 - Production & Process Controls-Subpart G
- Three Subsystems by Linkage (e.g.)
 - Records/Documents/Change Controls-Subparts D & M
 - Facility & Equipment Controls-Subpart N
 - Material Controls-Subparts E, F, H, I, K, L

Quality System Structure



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International Quality System Standard

ISO 13485

Quality management systems—Medical devices—System requirements for regulatory purposes

American National Standard

ANSI/ISO 13485:2003
(Revision of ANSI/AMISO 13485:1998)

Medical devices—Quality management systems—Requirements for regulatory purposes

Approved 6 June 2003 by Association for the Advancement of Medical Instrumentation

Approved 18 June 2003 by American National Standards Institute

Abstract: Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

Keywords: medical device, quality management system

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FDA & ISO 13485

- FDA has no plans to change the QSR
- Fundamentally the Same
- No Conflicting Requirements
- QSR is more Prescriptive; especially for:
 - Records
 - Documents

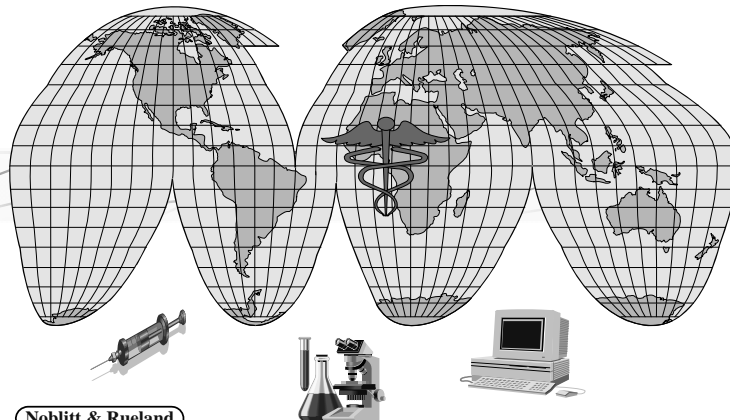
FDA & ISO 13485

- Heightened emphasis on:
 - Utilization of RISK MANAGEMENT
 - Corrective & Preventive Actions (CAPA System) for Continuous Improvement
 - Management's Leadership & Responsibility

Quality Systems -Bottomline-

- In general, one of two quality systems accepted/required around the world
 - US: 21 CFR Part 820 (QSR/GMP)
 - Internationally: ISO 13485
- Most companies selling in the US and internationally are implementing one quality system that meets both.

FDA Establishment Registration & Device Listing



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Establishment Registration

- Establishments involved in the production and distribution of medical devices intended for marketing or leasing (commercial distribution) in the United States are required to register with the FDA
- FDA Registration fee for each establishment is \$2,029 (2012)
- Provides FDA with locations and type of facilities for activities such as inspection planning, communications, recalls, etc.

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Who must register?

- Manufacturers
 - Finished goods manufacturers, contract manufacturers, contract sterilizers, specification developers, repackagers or relabelers, reproducers of single-use devices, remanufacturers, and manufacturers of components or accessories that are sold or leased directly to the end user
- Initial Importers
- Foreign Establishments (manufacturers & exporters)

Who does not have to register?

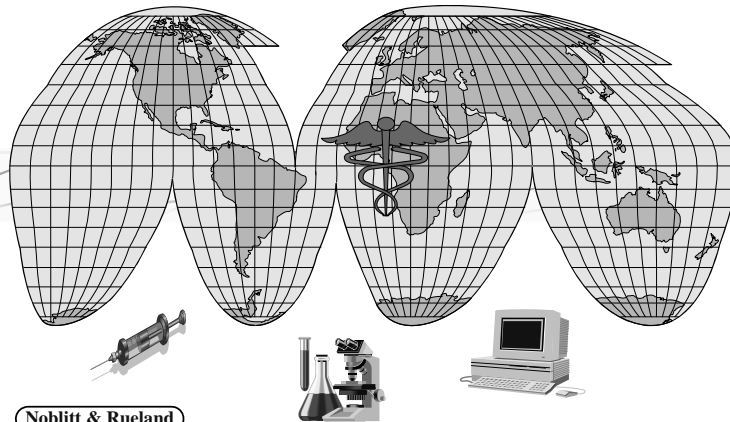
- Non-medical device manufacturers
- Contract & Component manufacturers so long as they do not manufacture “a device or accessory that is capable of functioning regardless of whether it is packaged, sterilized, or labeled”

(Definition of Finished Medical Device, 21 CFR Part 820)

Device Listing

- All medical device manufacturers must list their devices with FDA
- Simple process, no cost
- Provides FDA with information in case of product type issues, rating risk to public safety for inspection prioritization & scheduling, etc.

Start-up Strategy & Misc. Issues



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Regulatory Start-up Considerations

- Classification of Product
- Probable regulatory avenue
- Funding
- Knowledge
- Exit Strategy

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Classification & Probable Regulatory Avenue

- Need to determine the Device classification early
- Class I or II exempt (no regulatory submission required)
- Class I or Class II non-exempt
 - 510(k) submission required (\$ to \$\$)
 - Clear predicate(s) identifiable?
- Class III
 - 510(k) required for only a few Class III devices
 - PMA Submission required for most Class III (\$\$\$ to \$\$\$\$\$)
 - Probability of approval and achieving clinical endpoints during clinical studies
 - U.S. (PMA) vs European (CE Mark)

Funding & Knowledge

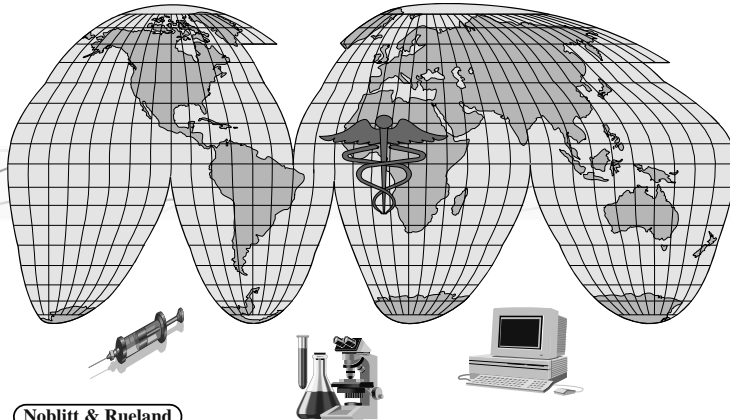
- 510(k)
 - Generally speaking, \$2K - \$50K+ to achieve FDA 510(k) clearance
 - ~90-180+ days from submission to FDA clearance
- PMA products in general \$100K - \$1M+ to achieve FDA approval
 - Substantial clinical data/trials needed
 - ~250 days to 3+years from submission to approval
- Internal hire vs External consultant
 - Periodic ongoing regulatory/quality support will be needed
- Brick & Mortar vs Virtual Company

Exit Strategy

- U.S.
 - Quality System not required to obtain 510(k) clearance
 - If exit strategy is to obtain 510(k) clearance and divest the company or sell the submission, a quality system may not be needed (i.e. no manufacturing planned)
 - Quality System is needed for PMA approval
 - FDA will inspect prior to granting PMA approval
- Virtual Company Infrastructure is acceptable by FDA
 - Utilization of consultant(s) for regulatory expertise
 - Submissions & installation of Quality System if necessary
 - Design & manufacturing can be done by vendors (i.e. contract manufacturers)

Welcome to the World of Medical Devices!

Thank You!



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