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New Medical Devices: FDA Regulations and Best Practices
An Overview

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Outline

- Overview of the Food and Drug Administration (FDA) approval process for medical device
- Device Classification and Regulatory Controls
- Types of Regulatory submissions
- Regulatory Compliance – Requirements on: Product and Company
- Pre-Market Notification – 510 (k) process: Predicate Device and Substantial Equivalence
- New Product Development Strategy: Key Aspects
- GxP, Systems Engineering and Design for Six Sigma (DFSS) in Medical Device Development

FDA CFR Title 21 controls U.S market

- FDA CFR Title 21 regulates food and drugs manufactured or consumed in the United States.

- The Code of Federal Regulations (CFR) contains the rules and regulations for the various departments (like CDRH for medical devices) and agencies of the US federal government.

- Each of the 50 titles of the CFR addresses a different regulated area.

- The regulations outlined in CFR Title 21 Part 11 set the ground rules for organizations subject to FDA oversight to being new devices to the market.

- CFR Title 21 Part 11 requires that the electronic records and signatures are trustworthy, reliable, and equivalent substitutes for paper records.
- Offers guidelines for security of computer systems in FDA-regulated industries.

Subject companies must prove compliance.

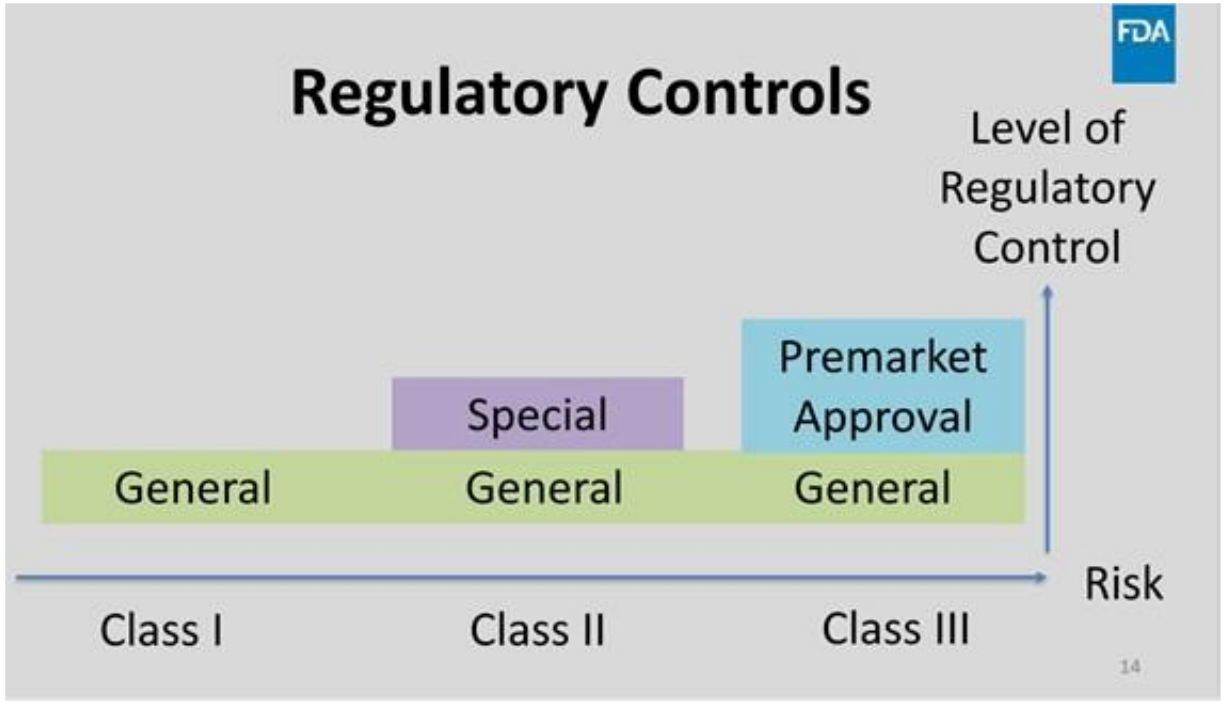
Globally several REG ORGs.

-China FDA, Health Canada, Europe EN-13485/MDR (MDD), Australia: Therapeutic Goods Administration….

Regulatory Controls

The Center for Devices and Radiological Health (**CDRH**) is the FDA's branch responsible for Regulating medical Devices

FDA uses a risk based product approval process



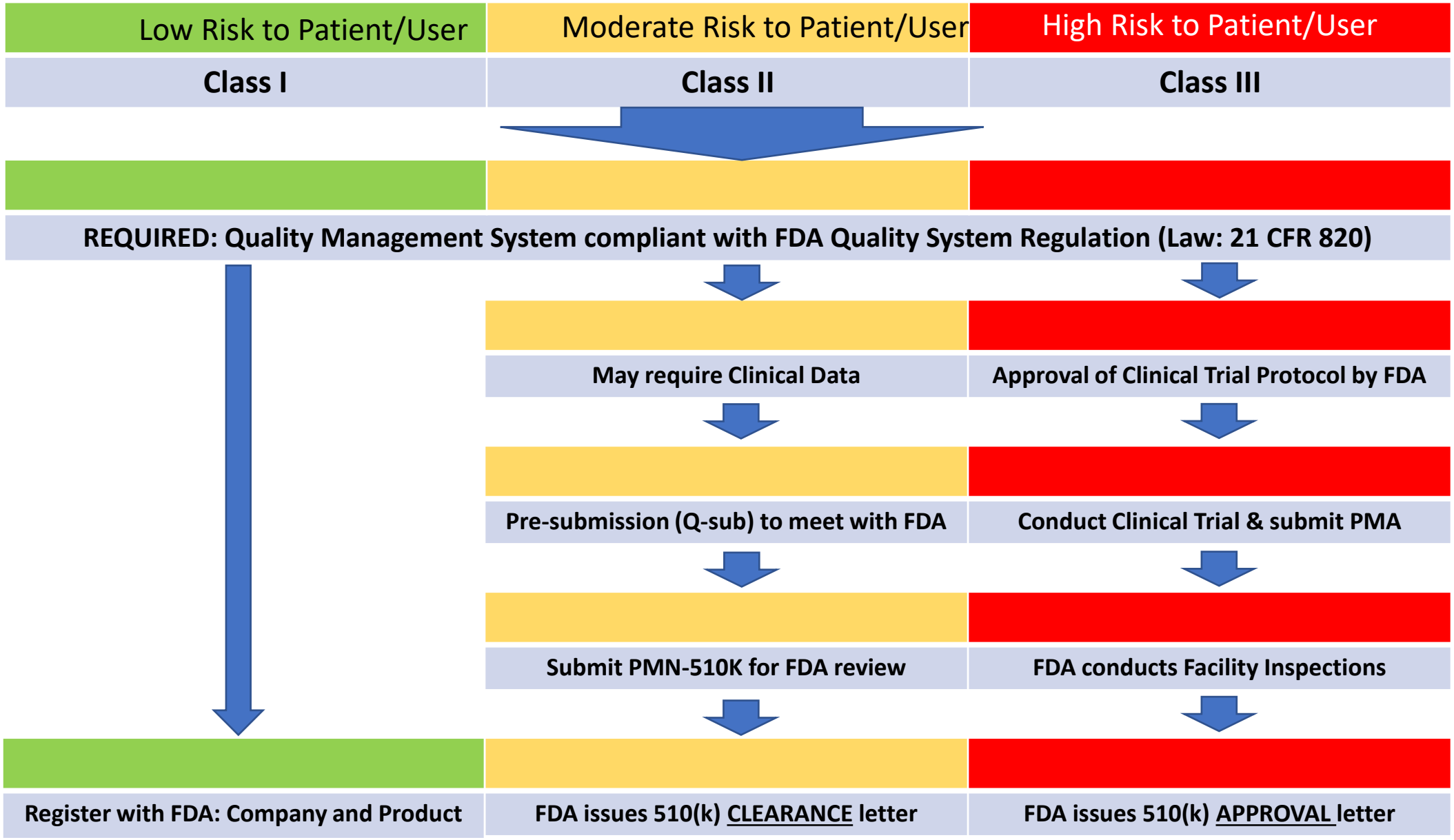
- **Low risk** - General controls required - Class I
- **Moderate risk** – General + Special controls - Class II
- **High risk** - General controls & PMA Class III

<u>Note FDA controls U.S market</u>

Globally several REG ORGs.

-China FDA
-Health Canada
-EN-13485/MDR (MDD)
-Australia: Therapeutic Goods Administration
….

The 30K feet view of the simplified FDA approval process



Device Classification dictates the rigor of regulatory controls

Steps to bring a new medical device to market

1. Classify the medical device & understand applicable regulatory controls
   -the rigor of the required regulatory control depends on this!
2. Determine and prepare the **correct** Premarket Submission
3. Send Premarket Submission for FDA review
4. Comply with applicable Regulatory controls

TIMING!

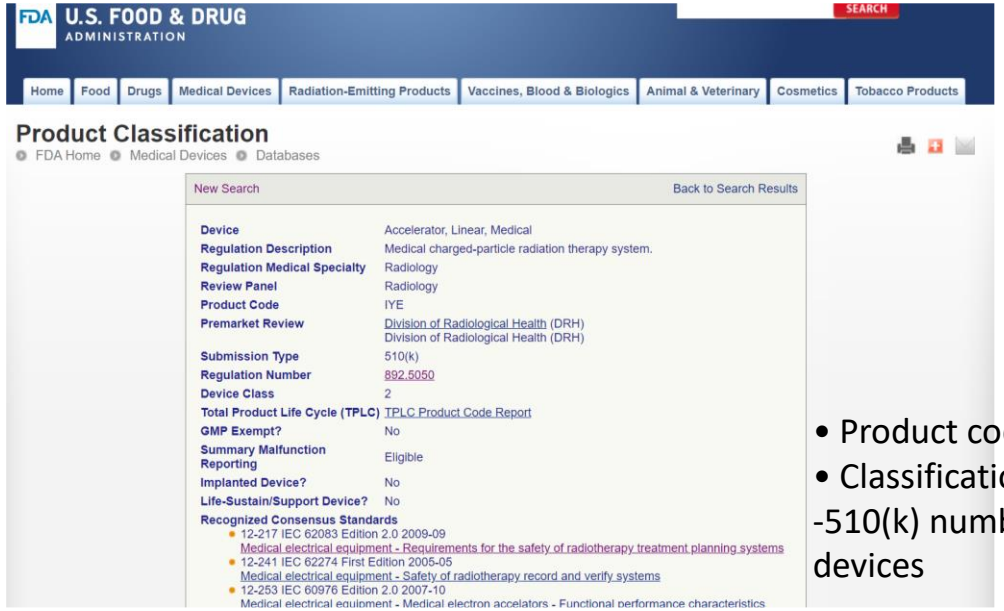
Let’s look at each step a bit more in detail

1

Classify the medical device & understand applicable regulatory controls

-the rigor of the required regulatory control depends on this!

1) Compliance: The **PRODUCT** component :



- Product codes
- Classification regulation -510(k) numbers for similar devices

CLASSIFICATION	CLASS I	CLASS II	CLASS III
Families (FDA database)	780	800	120
Risk Level	Lowest	Moderate	Highest
Regulatory control	General control	General control+ Special control	General control+ Special control+PMA
Regulatory pathway	Registration only or 510(k)	Mostly 510(k); Some need Clinical Trials	Pre-Market Approval (PMA)

FDA database www.fda.gov

- Has over 1600 devices divided into 16 specialties called Panels (Eg: Radiology)
- Most Devices, ~50% are cleared through Pre Market Notification (PMN) – i.e 510 (k)
- Class-III devices go through the most rigorous Testing and FDA Review – Time, >3x & money (>5M $) 😟

So, what are these General & Special controls

2) Compliance: The **COMPANY** component

FDA : 21CFR 820* to comply with by Medical Device Manufacturers

FDA requires ALL Medical Device Manufacturers to have a QMS that complies with GMPs (GMPs; 21 CFR Part 820)

GMPs: Good Manufacturing Practices

Class I

Class III: PMA +

Class II

General Controls	General Controls & Special Controls
Document Control	Document Control
Labeling / Packaging Control	Labeling / Packaging Control
Record Control	Record Control
Recall Management	Recall Management
Adverse Event / MDR Reporting	Adverse Event / MDR Reporting
Identification / Traceability / Distribution	Identification / Traceability / Distribution
Advisory Notices	Advisory Notices
Returned Products	Returned Products
Installation	Installation
	Design Controls
	Risk Management
	Software Validation
	Post-market Surveilance

*By the way, it is Law!!

2 Determine and prepare the **correct** Premarket Submission

Submission types: IDE, 510(k), PMA, HDE, De Novo

Classify the Device

Low Risk	Moderate Risk	High Risk	High Risk
Class I?	Class II?	Class III based on clinical risk?	Class III by default?

YES

May be exempt from Clinical trials & Special Controls

Class I and Class II Exempt Devices

PART 610	GENERAL BIOLOGICAL PRODUCTS STANDARDS
PART 660	ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS
PART 862	CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
PART 864	HEMATOLOGY AND PATHOLOGY DEVICES
PART 866	IMMUNOLOGY AND MICROBIOLOGY DEVICES
PART 868	ANESTHESIOLOGY DEVICES
PART 870	CARDIOVASCULAR DEVICES
PART 872	DENTAL DEVICES
PART 874	EAR, NOSE, AND THROAT DEVICES
PART 876	GASTROENTEROLOGY-UROLOGY DEVICES
PART 878	GENERAL AND PLASTIC SURGERY DEVICES
PART 880	GENERAL HOSPITAL AND PERSONAL USE DEVICES
PART 882	NEUROLOGICAL DEVICES
PART 884	OBSTETRICAL AND GYNECOLOGICAL DEVICES
PART 886	OPHTHALMIC DEVICES
PART 888	ORTHOPEDIC DEVICES
PART 890	PHYSICAL MEDICINE DEVICES
PART 892	RADIOLOGY DEVICES

www.fda.Gov

YES

Most need 510 K

YES

Approved as De Novo?

NO

Submit PMA and Investigational Device Exemption (IDE) in anticipation conduct Clinical Trials. Meet with FDA for test plan approval

YES

Submit 513 (g) application to Reclassify the device as De Novo

YES

Is the device actually only low or moderate risk?

NO

NO

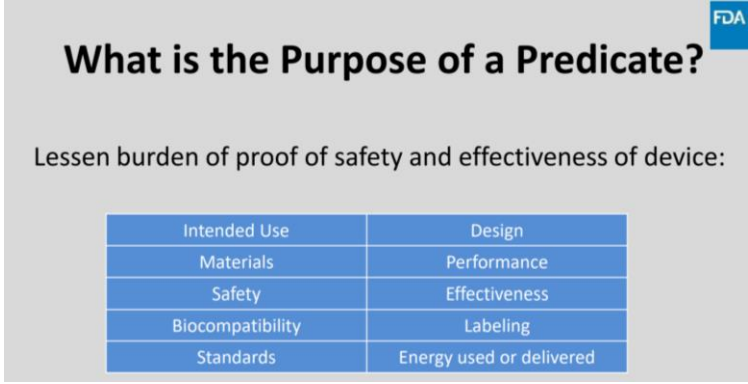
Does the Device have a Predicate?

YES

Submit PMN

- Small Business Qualification
- HDE: Humanitarian Device Exemption
- New, Novel Device? – Direct De Novo option

510 (k) Pathway Decision



- Demonstrate safety and effectiveness
- Substantial equivalence (SE) to a legally-marketed device (Predicate)

Product Classification

http://medicaldeviceacademy.com/fda-device-classification/

Identify a device similar to yours
Use the registration and listing database
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
Identify the 3-letter product code
Click on the code to go to the product classification page

Key word search the FDA dataset.
Indications of use is very important.

Predicate Device

The legally market device(s) to which equivalence is drawn is the PREDICATE DEVICE.

- Does NOT mean the devices must be identical.
- SE of the new device and the selected Predicate device has to be established for FDA to accept the 510K Application.

https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

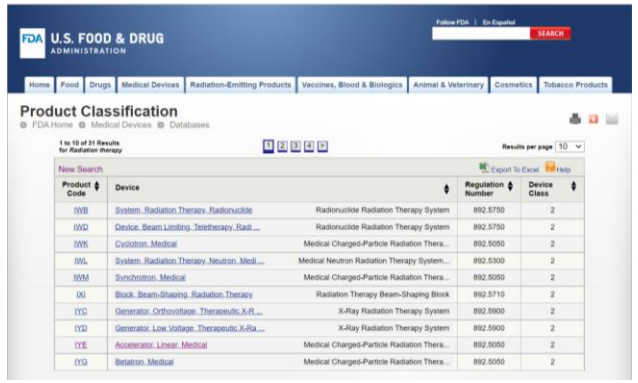
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] | FDA

How to select Valid Predicate Device

1. Identify Clinical Use

Intended Use	Indications for Use
The general purpose of the or its function	The disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended

2. Search FDA database for similar products



- Trade names of similar devices
- Manufacturer(s) of similar devices
- 510(k) numbers for similar devices
- Product codes

3. Compare Technology

- Materials
- Design
- Energy Source
- Other Features

4. Compare Performance

- Well-established scientific methods
- Medical Device Reporting (MDRs)
- Manufacturer and User Facility Device Experience (MAUDE) database
- Recalls, Market Withdrawals, & Safety Alerts

Burden of Proof on the Manufacturer

1. Same Intended Use AND same Technological characteristics
2. Same Intended Use BUT different characteristics, with NO NEW Risk

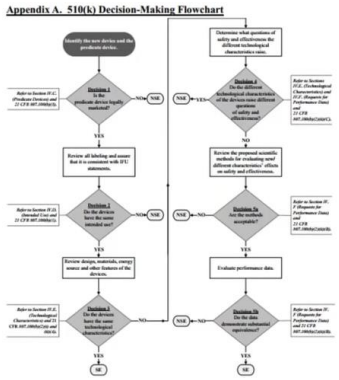
YES

Substantially Equivalent (SE)
- 510 (k) Pathway

NO

NSE
Class-III or
De Novo

Substantial Equivalence



www.fda.gov

For SE decisions, 6 steps:

- Is the predicate legally marketed? If it was removed/recalled from the mkt, not a good choice.
  Sometimes business get 510 cleared but don't put the device in the market for financial or other reason, that is ok. Ideally it should be the one 510k cleared and now in mkt.

- Do they have same indications of use?
  Either they are same or slightly modify the intended use and demonstrate how they are same.
  More changes made, more risk of NSE.

- Are they of same technological characteristics? If yes, good, but not necessary. If different, then go to Next step.

- Do the different technological characteristics raise different questions about safety and effectiveness?
  This is a tough qn for companies…..

- Are the methods still safe and effective/acceptable? Hpw to validate? Electro-magnetic compatibility, Safety Standards testing, biocompatibility, etc – use one of the standard testing FDA recognizes.

- Does the data demonstrate SE? Testing shows that and shows no new risk.

Submit 510(k) package
Contents for FDA Review

Group 1 – Cover Sheet Forms
Section 1.0 – Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2.0 – CDRH Premarket Review Submission Cover Sheet

Group 2 – What Others Can See
Section 3.0 – 510(k) Cover Letter
Section 4.0 – Indications for Use Statement
Section 5.0 – 510(k) Summary

Group 3 – Templated Sections
Section 6.0 – Truthful and Accuracy Statement
Section 7.0 – Class III Summary and Certification
Section 8.0 – Financial Certification or Disclosure Statement
Section 9.0 – Declarations of Conformity and Summary Reports

Group 4 – Comparing Your Product vs. Predicate(s)
Section 10.0 – Executive Summary
Section 11.0 – Device Description
Section 12.0 – Substantial Equivalence Discussion

Group 5 – Ensuring Patient Safety
Section 13.0 – Proposed Labeling
Section 14.0 – Sterilization and Shelf Life
Section 15.0 – Biocompatibility

Group 6 – Software and Electronics
Section 16.0 – Software
Section 17.0 – Electromagnetic Compatibility and Electrical Safety

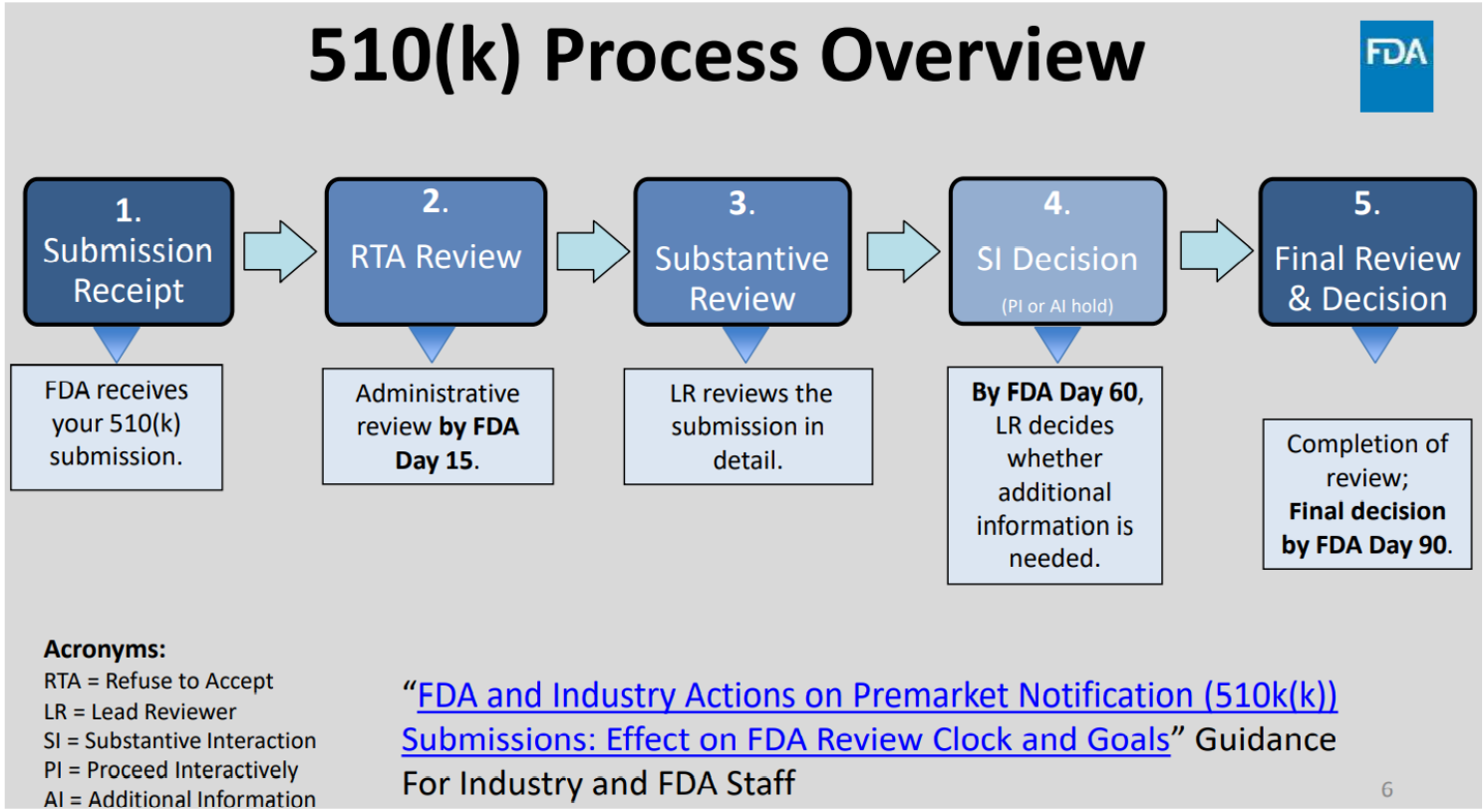
Group 7 – Performance Testing
Section 18.0 Performance Testing – Bench
Section 19.0 Performance Testing – Animal
Section 20.0 Performance Testing – Clinical

510K submission package contains a few 1000 pages to several 3” binders
Includes Design History File (DHF), Device Master Record (DMR),
Performance testing (test methods, acceptance criteria, results, review)- Bench, Animal or clinical
Two copies of 510 (k), one should be electronic

3 Send Premarket Submission for FDA review

Eg.: Class II device

Submit Premarket Submission
- Prepare eCopy
- Pay MDUFA User Fee (if required)
- Mail submission to FDA



510K(k)submission package contains a few 1000 pages to several 3" binders

Key facts: 510 (k) and RTA Review

- 510(k) submit a e copy. E confirm same day. Or up to a week

- RTA is refusal to accept screening. FDA introduced RTA in 2012, because a lot of submissions were inadequate.
- RTA review is through a checklist of >20 pages to make sure everything is there in order, then you get an acceptance
  from an RTA screener.
- More than 50% cases are rejected during RTA. Usually, they ask for correction, missing items, then you restart the clock at 0.
- Once through with the RTA process, now in the formal 510 (k) review cycle. Next 45 days probably no communication from FDA.
- If we hear within 45 days, its likely for 2 reasons.
  1. more info needed- for Additional Info (called AI request) .
  2. Interactive Review- this is a good sign. Means in the next 30days there is going to be a likely decision, probably positive.
- AI and the process to provide the requested info for each qn, provide rationale etc followed by FDA review can stretch the 510k timeline.

De Novo: An alternate 510 (k) process

- If there is NO SE predicate device

- If the Risk when used as intended can be demonstrated not to raise above the moderate level (i.e Class I or Class II), then FDA may grant permission to submit De Novo application

- If FDA finds the Risk is High, then the application may default into PMA

- Therefore, De Novo process requires pre-submission meeting with FDA

- De Novo may represent a less expensive route to market than a PMA, De Novo may add 6 to 18 months to the normal 510 (k) process.

- But has clear competitive advantage.

- Tough trade-off decisions for Businesses.

The Q-Submission Program: What is it & Best Practices

Q-sub is a mechanism to request interactions with the FDA related to medical device submissions

- Help guide product development, develop protocols, and prepare premarket applications

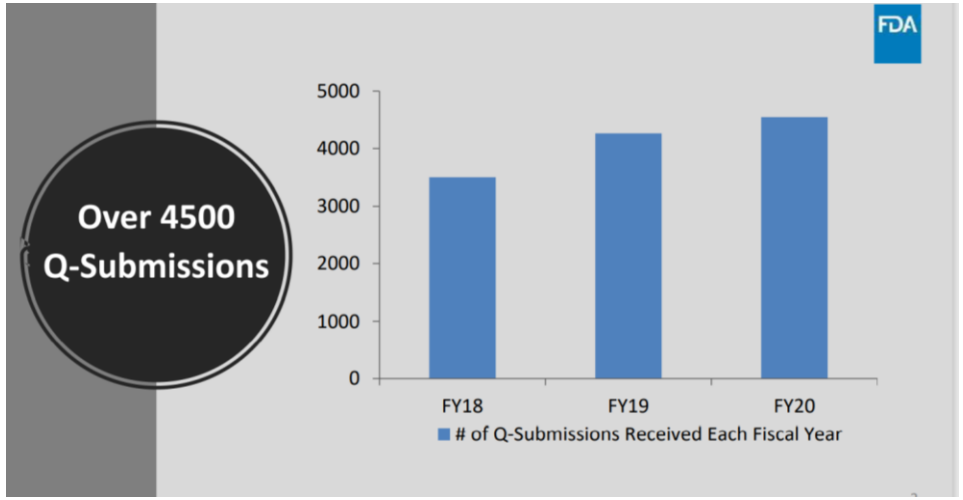
Pre-Subs

A formal request for written feedback on a future IDE or marketing submission

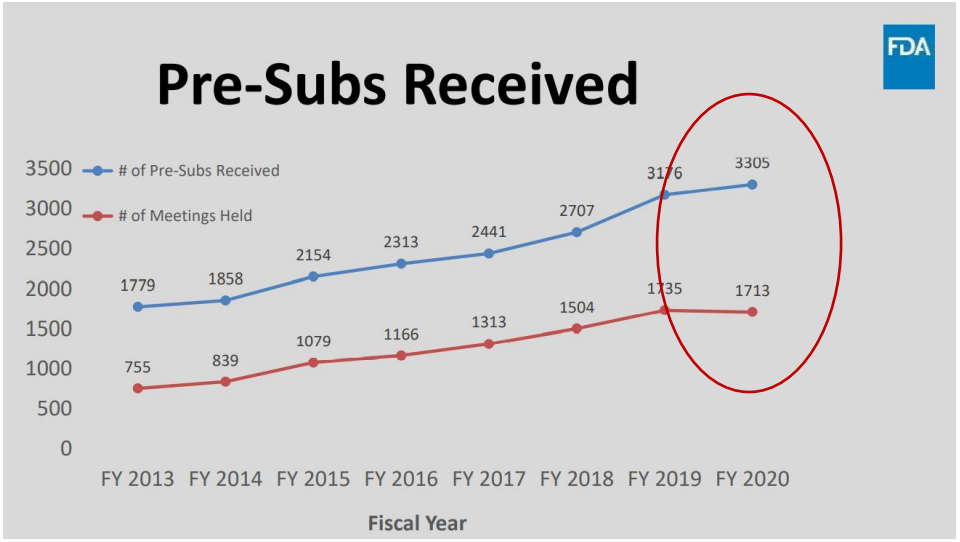
- Pre-Submission Meeting
- Pre-Submission Written Feedback

- Feedback is provided in writing and a meeting is held, if one is requested
- Can support future premarket submission, IDE, Accessory Classification Request or CLIA Waiver
- One type of Q-Submission

Coming to mainstream slowly!



Ave: 70 days



Q-Submission Types

- Pre-Subs
- Submission Issue Request
- Informational Meeting
- Study Risk Determination
- Breakthrough Request & Interaction
- STeP Request & Interaction
- PMA Day-100 Meeting
- Accessory Request
- Early Collaboration

Premarket Approval Application (PMA)

Eg.: Class III device

Under federal law, class III devices are subject to approval of a (PMA)

Class III devices: support or sustain human life,
or preventing impairment of human health,
or that may present a potential unreasonable risk of illness or injury

- General controls and special controls are deemed insufficient to provide reasonable assurance of the safety and effectiveness
- Administrative elements + good science and scientific writing is a key for PMA approval

PMA is the most stringent type of device regulatory category required by FDA.
PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure safety and effectiveness for its intended use(s)

PMA devices often involve new concepts and many are not of a type marketed prior to the 1976 Medical Device Amendments. Therefore, they **do not have a classification** regulation in the CFR. The FDA product classification database will only cite the device type name and product code.

New type of device + High Risk + NSE to a predicate device → PMA
New type of device + Moderate Risk + NSE to a predicate device → De Novo

Clinical Trials Needed!

https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

Investigational Device Exemption (IDE) for Clinical Trials

- Clinical studies are most often conducted to support a PMA. An IDE exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

- Only a small percentage of 510(k)s require clinical data to support the application.

- Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

- All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study.

- With approved IDE, device can be shipped lawfully for the purpose of conducting investigations of the device without complying with other commercial distribution requirements of the FD&C Act

- Companies need not submit a PMA or PMN 510(k), register their establishment, or list the device while the device is under investigation.

- Companies of IDE's are also exempt from the Quality System (QS) Regulation except for design controls (21 CFR 820.30).

Good Clinical Practices (GCP)

GCP: Regulations and requirements that must be complied with while conducting a clinical study.
Applies to the manufacturers, sponsors, clinical investigators, institutional review boards, and medical device.

4

Comply with applicable Regulatory controls

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

Are you compliant?

This is a key question which any Medical Device , Pharmaceutical, company find challenging to answer.

It is mandatory for these organizations to comply with stringent quality, safety, and Regulatory requirements in each geography where the products are distributed.

The current trend is moving towards a worldwide harmonization of quality and safety.

Whether you are a manufacturer or a supplier, continuous improvements and customer satisfaction rests principally on the quality standards of your business.

What is the Cost?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Ms. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K091209
Trade/Device Name: PortalVision Advanced Imaging
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 23, 2009
Received: April 24, 2009

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

VARIAN medical systems

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304-1038
USA
Tel +1 650 493 4000
www.varian.com

Indications for Use Statement

510(k) Number (if known): K091209

Device Name: PortalVision Advanced Imaging

The PortalVision Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter _____
(Per 21 CFR § 801.109)

The Regulatory Cost

510(k) Pre-sub – No FDA user fee
510(k) Submission:
- $10,953 is standard user fee (FY 2019)
- $2,738 is small business fee (FY 2019), but prior qualification is required

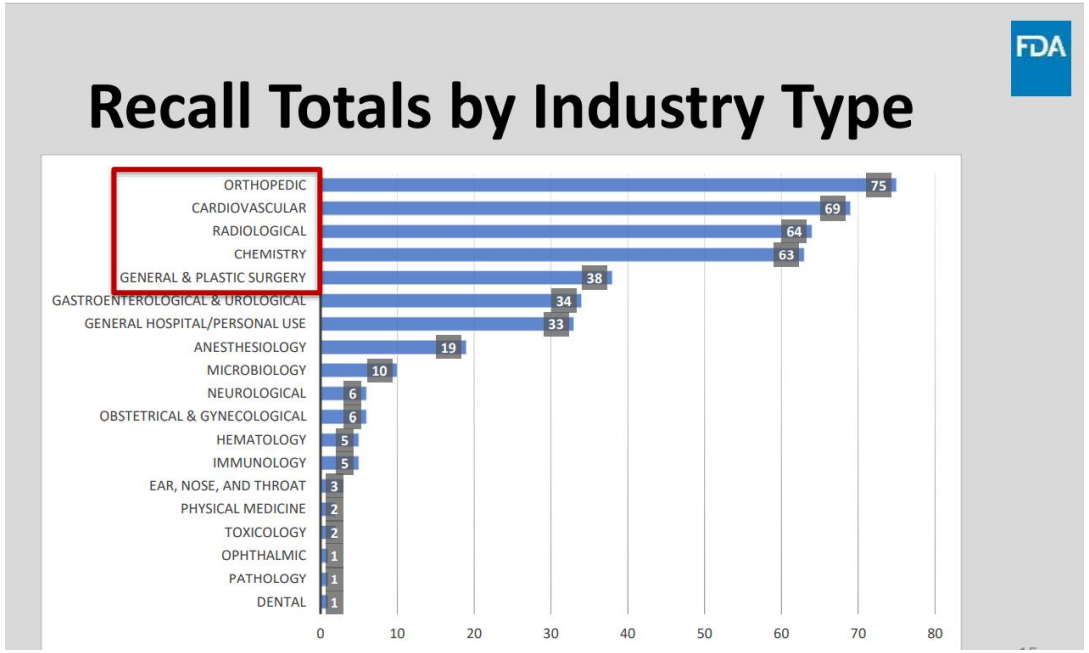
Regulatory Consulting Fees:
- $2,181 is pre-sub consulting fee
- $10,911 is 510(k) consulting fee ($12,000 for both)

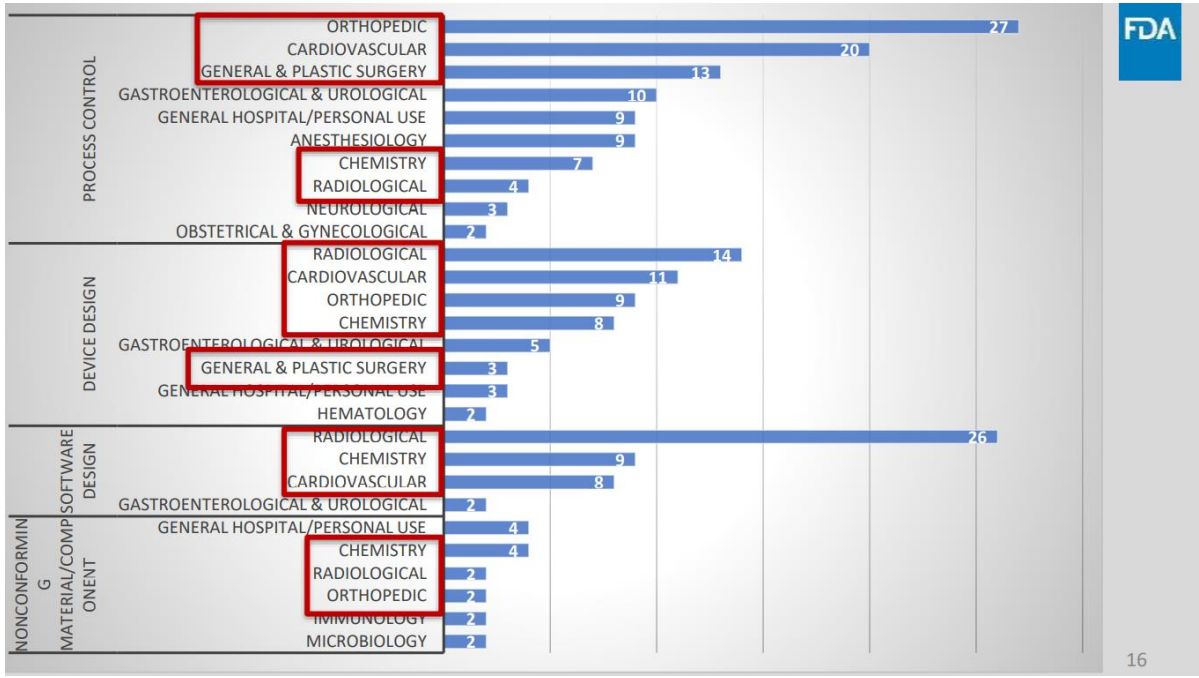
Biocompatibility Testing = $13,000 min.
Electrical Safety & EMC Testing = $50,000 min.
Benchtop Testing ? – Product Specific
Animal Testing - $100K+
Clinical Study - $1 million+

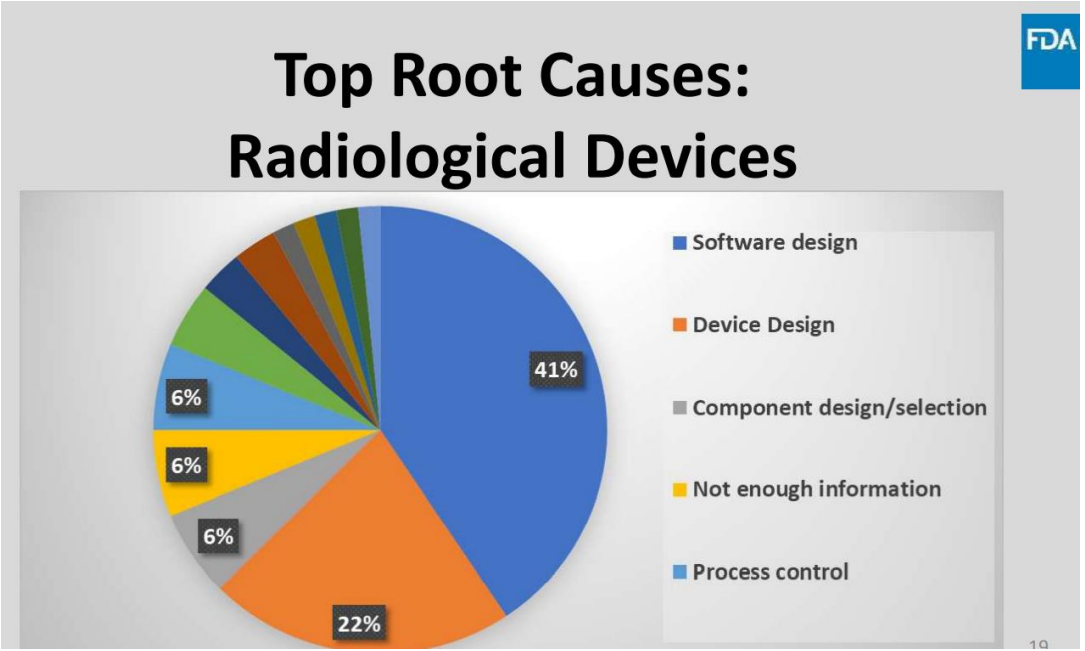
Fee keeps going up every yr a few %, **small business qualification is every yr. Aug 1.**
Clinical, 600 patient may be 1 million
Testing cost is the **BIG money item**
So very important to come up with the test plan early and review with fda in presub meeting

Don’t forget the Quality Cost – could be enormous

Quality matters: 2021 FDA Data - Class II device Recall analysis



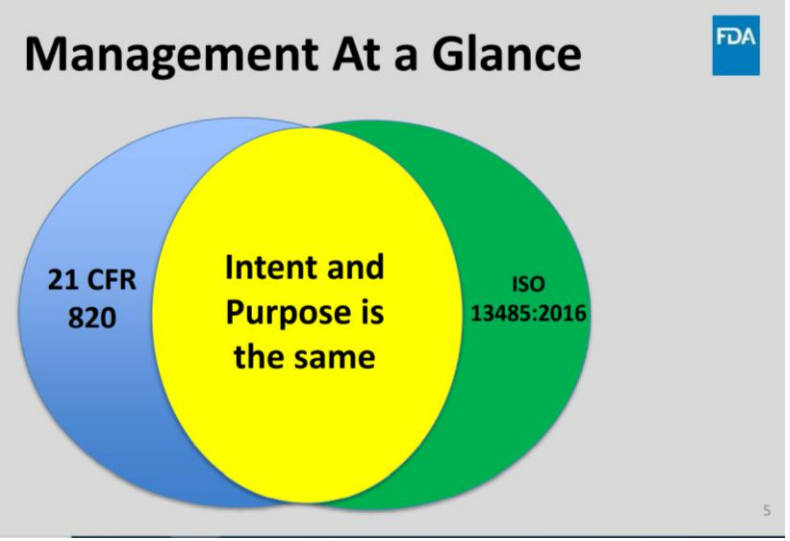




Key Takeaways

1. In our analysis of Class 1 and Class 2 recalls, top root causes were attributed to process control or device design issues
2. Root cause investigation should be conducted in a systemic manner to ensure the root cause(s) are accurately identified for the recall
3. Firms with multiple recalls - systemic issues

Device manufacturer is obligated to implement Quality management system (QMS)



U.S FDA

21 CFR 820

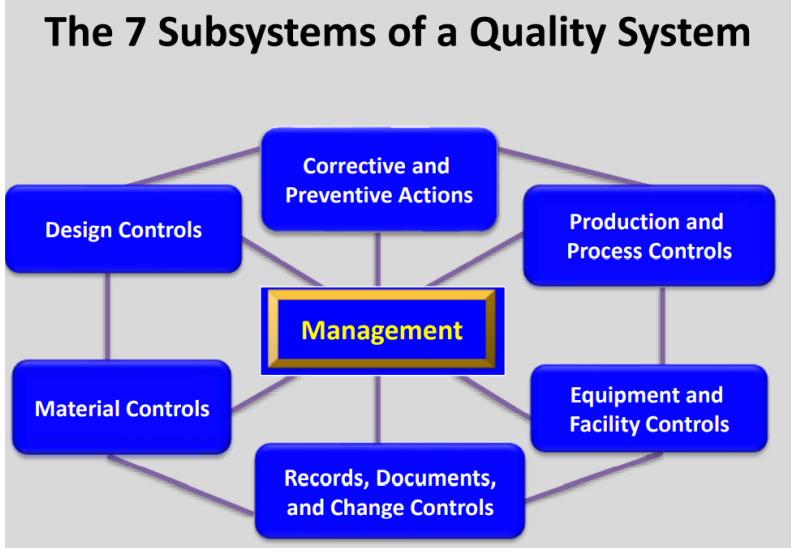
- 1978 Good Manufacturing Practice (GMP)
- current GMP
- 1990 Safe Medical Device Amendments
- 1996 Quality System Regulation
- 2012 Amendments
- Today

ISO 13485:2016

- GHTF 1992 (Harmonization)
- ISO 9001:1994
- ISO 13485:1996
- ISO 13485:2003
- IMDRF 2011 (Convergence)
- MDSAP 2012
- Today

EU

The 7 Subsystems of a Quality System



21 CFR 820.20
Management responsibility

Management with executive responsibility is responsible for:

- Quality policy
- Appointing management representative
- Management review

ISO 13485
Clause 5.1 Management commitment

Top management is responsible for:

- Quality policy and objectives
- Management reviews
- Communicating importance of meeting requirements
- Availability of resources

Establish an adequate organizational structure.

Document interrelation of all personnel that perform work that impact quality and ensure independence and authority necessary to perform that work.

GxP standards were established by FDA

G: good
x: Variable – “Manufacturing”, “Clinical”, “Laboratory”
P: practices

GxP is a set of regulations and quality guidelines formulated to ensure the safety of life sciences products throughout product lifecycle.

The purpose is to ensure that the regulated organizations comply with the standard processes of various functions.

GxPs are mostly similar across all countries. The guidelines mainly focus on the following areas:

- **Traceability** – ensuring that the development history of the product can be reverse engineered.
- **Accountability** – Identifying the contribution of every individual involved in the development process.
- **Data Integrity** – Ensuring the reliability of data.

Why is GxP important?

Since the regulations of GxP are global, every company is affected by it. Therefore, meeting the GxP requirements is highly important. Though there are several GxPs, a few of them are highly important:

1.Good Manufacturing Practices (GMP) – GMP are the guidelines recommended by REG agencies for the control of manufacturing of products such as medical devices.

2.Good Clinical Practices (GCP) – GCP are international quality standards defined by ICH, the International Conference on Harmonization (ICH) that state the clinical trial regulations for testing on human subjects.

3.Good Laboratory Practices (GLP) – are the standards set by the FDA for non-clinical laboratory tests for assessing the safety and efficacy of the product.

To place a product in any market, it is necessary for a company comply with the GxP regulations.

21 CFR 812, *Investigational Device Exemptions* covers the procedures for clinical studies
21 CFR 50, *Protection of Human Subjects* : Elements of informed consent
21 CFR 56, *Institutional Review Boards* : approve clinical investigations protocols
21 CFR 54, *Financial Disclosure by Clinical Investigators*, covers the disclosure of financial
21 CFR 820 Subpart C, *Design Controls of the Quality System Regulation*, provides the requirement for design control

FDA can audit any registered medical device manufacture even without Notice!!
And the consequences od defects could be financial to 'STOP SHIP' order.

Product Requirements – Safety and Regulatory

1. Product shall comply with FDA regulation CFR 820.21: pRAD shall be developed, manufactured, marketed and serviced through established SOPs, WIs etc under design, document and change control

Subpart A - General Provisions
- § 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.

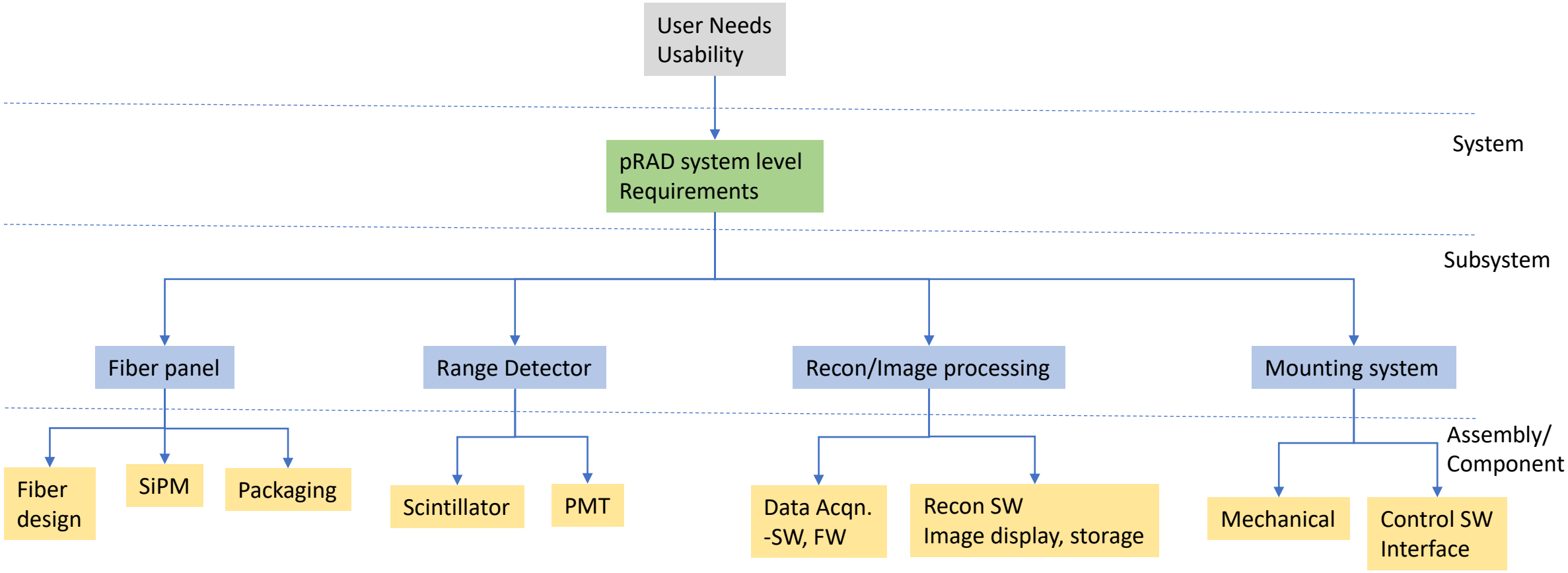
Subpart N - Servicing
- § 820.200 - Servicing.

Subpart O - Statistical Techniques
- § 820.250 - Statistical techniques.

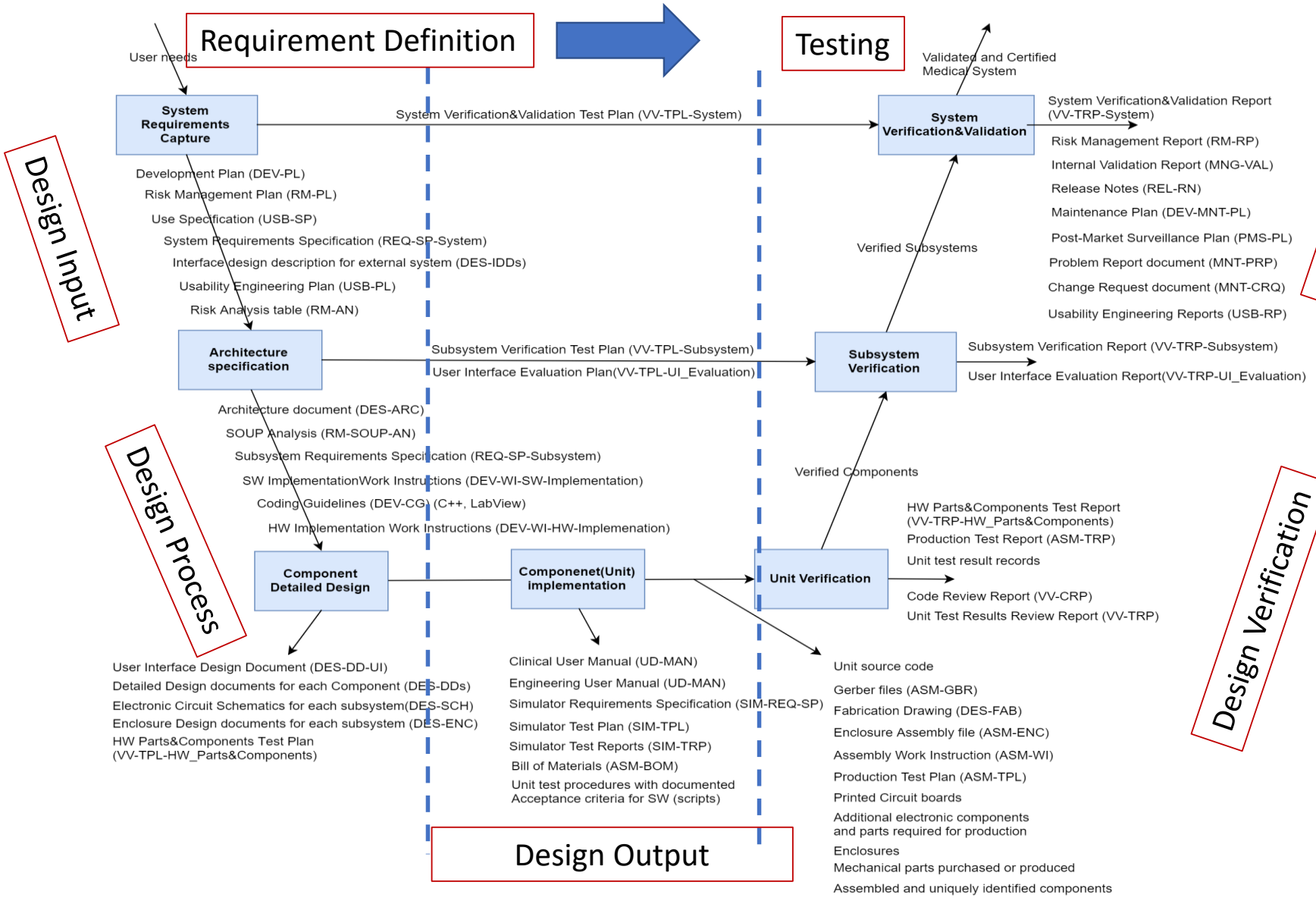
Performance Requirements

Example Use of Design for Six Sigma (DFSS) effective through Product Design Lifecycle

Eg: Quality function Deployment (QFD) for proton radiography system Requirements



Systems Engineering Implementation in Medical Device Design Control



Delivers

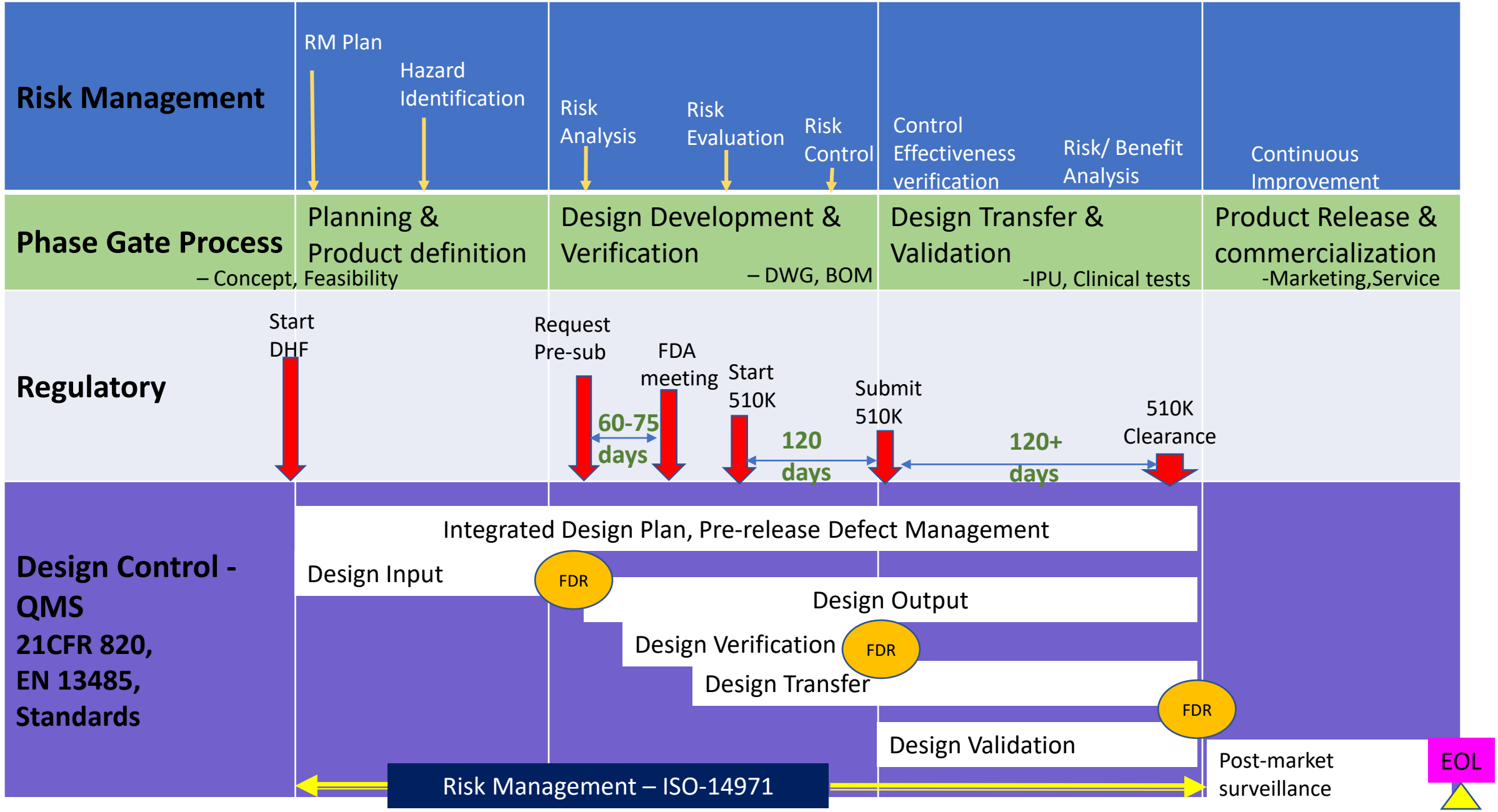
- ✓ **Requirements**
- ✓ Design Specifications
  - **-Flowdown & Allocation**
- ✓ Rigorous Verification
- ✓ Traceability
- ✓ Design History File (DHF)
- ✓ DHF Master Index
- ✓ Manufacturing
  - Plan
  - SOPs, WIs
  - -DMR
  - -Supply Chain Qual.
- ✓ Servicing
- ✓ Post-Launch surveillance

Phase Reviews & key Deliverables

Design Input	Design output	Verification	Validation and Design Transfer	Product release/ Post- market surveillance
Business Plan Development Plan User Needs Usability System Requirements Subsys Requirements SW/FW Requirements (Reliability) Risk Management Defect Management	Drawings Specifications Interface control Design History File BOM Field Replaceable units	Verification Plan Sample size Test methods Training Traceability Verification Report	Validation Plan Validation Report DHF DMR Supply chain Supplier control SOPs WIs Quality control	Complaint handling sys CAPA Risk management

DHF-Design history file
DMR- Design master record
CAPA- Corrective Action Preventive Action
SOP- standard operating procedure
WI- Work instruction
Sw- Software
FW- firmware
BOM- Bill of materials

New product development : Strategy and Best Practices



FDR- Formal Design Review; EOL- End of product Life; QMS- Quality Management System

TAKEAWAYS

- ✓ Multiple Regulatory agencies in different regions of the Globe:
  common Purpose – Safety and Efficacy of medical Devices
- ✓ www.FDA.Gov is an excellent resource for device –related, Field failures, Guidance documents and more
- ✓ Reviewed the seemingly complex FDA regulatory process for bringing medical devices to Market
- ✓ Incorporate Risk identification, Analysis and Mitigation throughout the product lifecycle
- ✓ Reviewed key Regulatory Controls impacting the Device development process AND the Manufacturers
- ✓ Reviewed real-world examples of implementing GxP, System Engineering and Six Sigma Tools and methods
- ✓ for high quality Design and Processes