Medical Device Compliance
A Practical Perspective

SPRINGBOARD SOLUTIONS

Agenda

- Framework
- Cost
- Challenges
- Approach
- What's New

Executive Summary

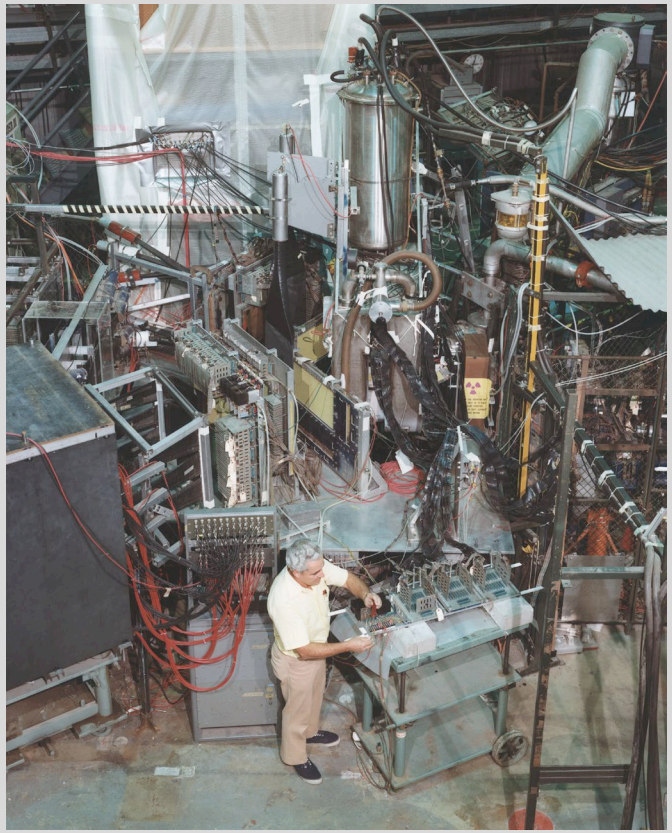
- The cost of compliance is significant although can be minimized with thorough analysis and planning
- Quality Management System Regulation (QMSR) ISO 13485:2016, establishes the business framework for a Medical Device company
- The QMSR affects every function of a Medical Device company and must be realized by all employees
- Adopting a culture of compliance early on from the top down, is critical
- Bridging People, Process, Tools and Technology early on with the regulations is key

About Springboard Solutions LLC

Dan Raymond,
Founder & Principal Consultant

- Springboard Solutions LLC Formed in 2024
- Founder previously held dual, simultaneous responsibilities (VP Engineering & Director Quality/Regulatory) for Medical Device company producing Class II proton radiation therapy systems to treat cancer
- Springboard Solutions provides medical device consulting across FDA QMSR, ISO 13485, 510(k), systems integration, and AI-enabled compliance
- Partnership with Valere (named Top AI Company 2024 by Clutch)
- Help medical device companies solve the challenges that sit at the intersection of engineering complexity and regulatory reality with solutions that Bridge People, Process, Tools & Technology to the Regulations
- www.springboardsolutionsllc.com

The Reference Medical Device and Technology



(analogous complexity illustration)

- Proton radiation therapy system, the most complicated medical device without question
- Class II Device (FDA product code LHN)
- Low volume, high complexity with very long project cycles
- Approximately 20 complex assemblies (e.g., proton particle accelerator, 100ton precision gantry, patient positioning robot, x-ray imaging, etc…)
- Complex hardware, software, and firmware
- Sophisticated overarching safety system
- Interfaces with numerous clinical software systems to control patient treatment workflow
- Includes networks within the product and interfaces to client networks
- Requires a purpose designed facility to contain radiation, as well as provide 100's of interfaces to very specific facility utilities
- Proton radiation therapy systems provided the deepest possible regulatory education touching every part of the QMSR

The Reference Medical Device and Regulations

- 6yrs working directly with Washington, DC Regulatory Attorney
- Assigned simultaneous ”Acting Director Quality/Regulatory” responsibilities in addition to VP of Engineering
- Medical Device with Complex User Requirements
- Medical Device with large set of international standards (requirements) to comply with
- Design Inputs (requirements) for 20 complex assemblies
- Hazards and failure modes risk analysis for all assemblies
- Very complicated requirements management matrix to establish traceability
- Multiple verification ”layers” before system validation (assembly, installation, integration, design)
- Independent (external) safety, risk, EMI and EMC evaluation requirements
- 510(k) premarket submittal, consisting of approximately 6000 pages

Regulatory Framework

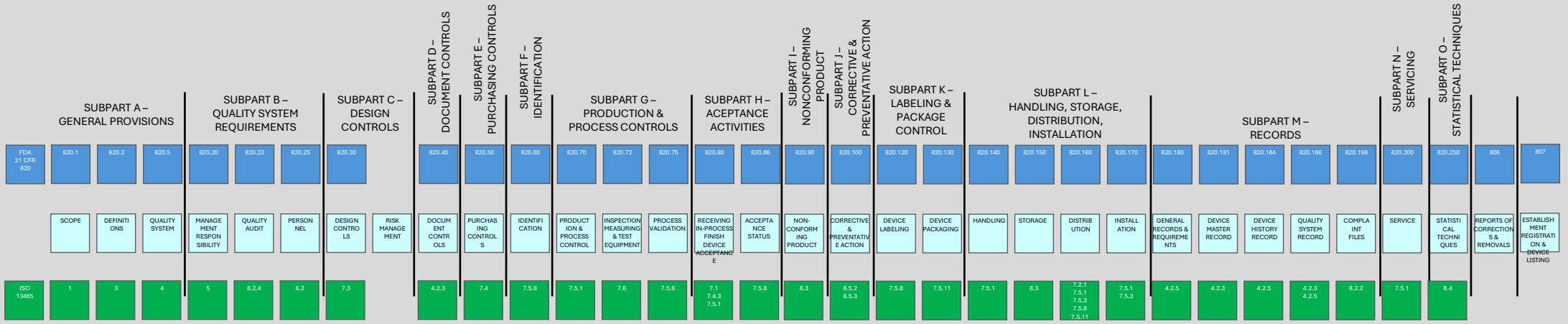
MEDICAL DEVICE LIFE CYCLE

CONCEPT → DESIGN → MANUFACTURE → PACKAGING & LABELING → COMMERCIALIZATION → POST MARKET VIGILANCE & SURVEILANCE

Premarket Approval phase

Post Surveillance phase

MEDICAL DEVICE REGULATIONS (QMSR)



Harmonized
Active as of
February 2, 2026

21 CFR 820

ISO 13485

Regulatory Framework = Business Framework

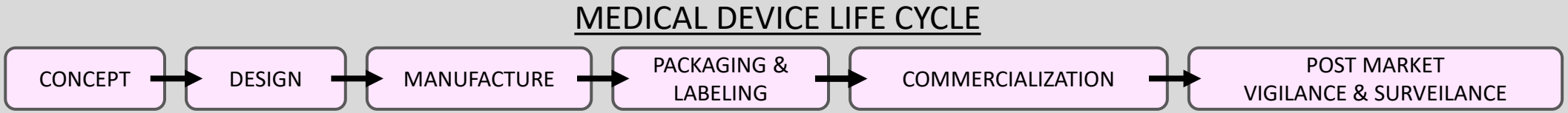
REGULATIONS AFFECT ENTIRE BUSINESS

MANAGEMENT | FINANCE | HR | ENGINEERING | CLINICAL | QUALITY | SERVICE | MANUFACTURING | SALES/MARKETING

BUSINESS SYSTEMS

- QUALITY MANAGEMENT
- REQUIREMENTS MANAGEMENT
- ELECTRICAL COMPUTER AIDED DESIGN
- MECHANICAL COMPUTER AIDED DESIGN
- PRODUCT LIFE CYCLE MANAGEMENT
- ENTERPRISE RESOURCE MANAGEMENT
- MANUFAC EXECUTION SYSTEM

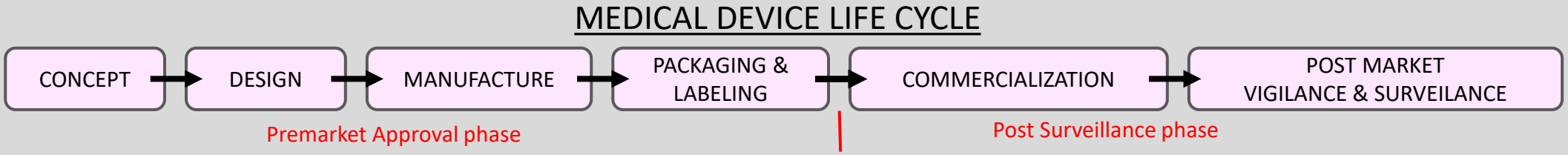
Cost of Compliance



Cost Contributors (and not limited to):

- Systems Engineering to manage client, external, safety and design requirements
- Sizeable quality/regulatory staff to guide and process pre and post market activities
- Extensive risk analysis that must be traceable and verified
- Layers of design and manufacturing documents that must be verified
- Rigorous supplier management with extensive checks and balances
- Managing nonconformances
- Extensive internal and external verification and validation processes
- Robust quality management system
- Scalable business systems capable of processing regulatory activities and are integrated with one another
- Business systems analysts to sustain and update business systems with regulatory updates
- Clinical trial expenses
- Certification fees (audit and recertification)
- External regulatory counsel
- Clearance filing documents and fees
- Registration fees
- Regular quality management system inspections (significant business interruption)
- Addressing inspection warnings likely requiring technical, clinical and regulatory resources
- Post market complaint process which reach back into design and risks likely requiring technical, clinical and regulatory resources
- Robust IT capability to address cyber security, continuous software validations and data storage

Cost of Compliance



Classification of Device (I, II, III) will drive cost (low, med, high risk)

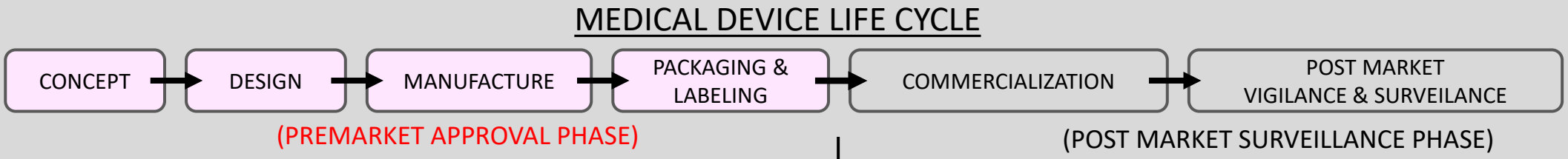
Estimated Premarket Costs[1]

- Concept & Design, 8 – 15% of total budget
- Development & Testing, 20 – 30% of total budget
- Clinical Trials, 40 – 60% of total budget
- Regulatory Submission, 2 – 8% of total budget
- Manufacturing & Scale-up, 15 – 20% of total budget

Estimated Post Market Surveillance Costs[2]

- 5 – 10% (or higher) of annual revenue

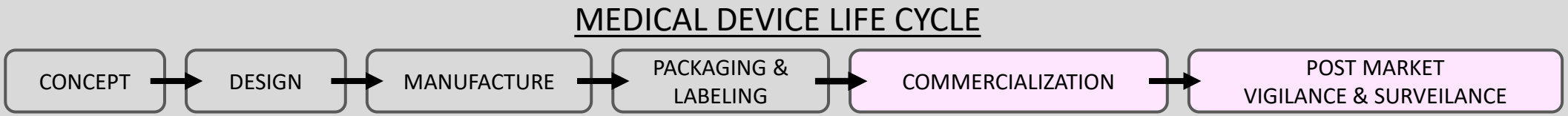
The Challenges of Compliance



- Organizational tension between technical and regulatory priorities
- Very complex traceability amongst Design Inputs, Risks, and Verifications (requirements management)
- Supplier management & Non-Conformances
- Device Master Records and Device History Records
- A tremendous amount of process and documentation that must be balanced with
  - Cost and Schedule pressures
- All in support of 510K clearance

FDA Center for Devices & Radiological Health

The Challenges of Compliance



(PREMARKET APPROVAL PHASE)

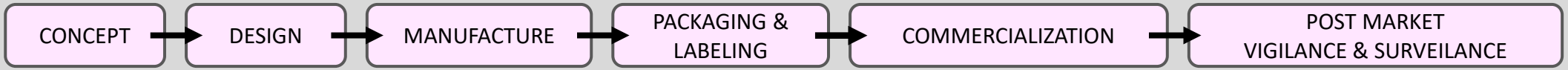
(POST MARKET SURVEILLANCE PHASE)

- Preventative Maintenance over entire declared life cycle
- Complaint Process, down stream rigor and resources (technical, legal, etc…) to address:
  - Complaints
    - Root-Cause Analysis
    - CAPA
    - Medical Device Report
    - Corrections and Removal
- Assembly, sub-assembly obsolescence
- On-going Quality Management System Audits
- New QMSR risk-based inspection framework

FDA Office of Inspections and Investigations

The Consequences of not Complying

MEDICAL DEVICE LIFE CYCLE



(PREMARKET APPROVAL PHASE)

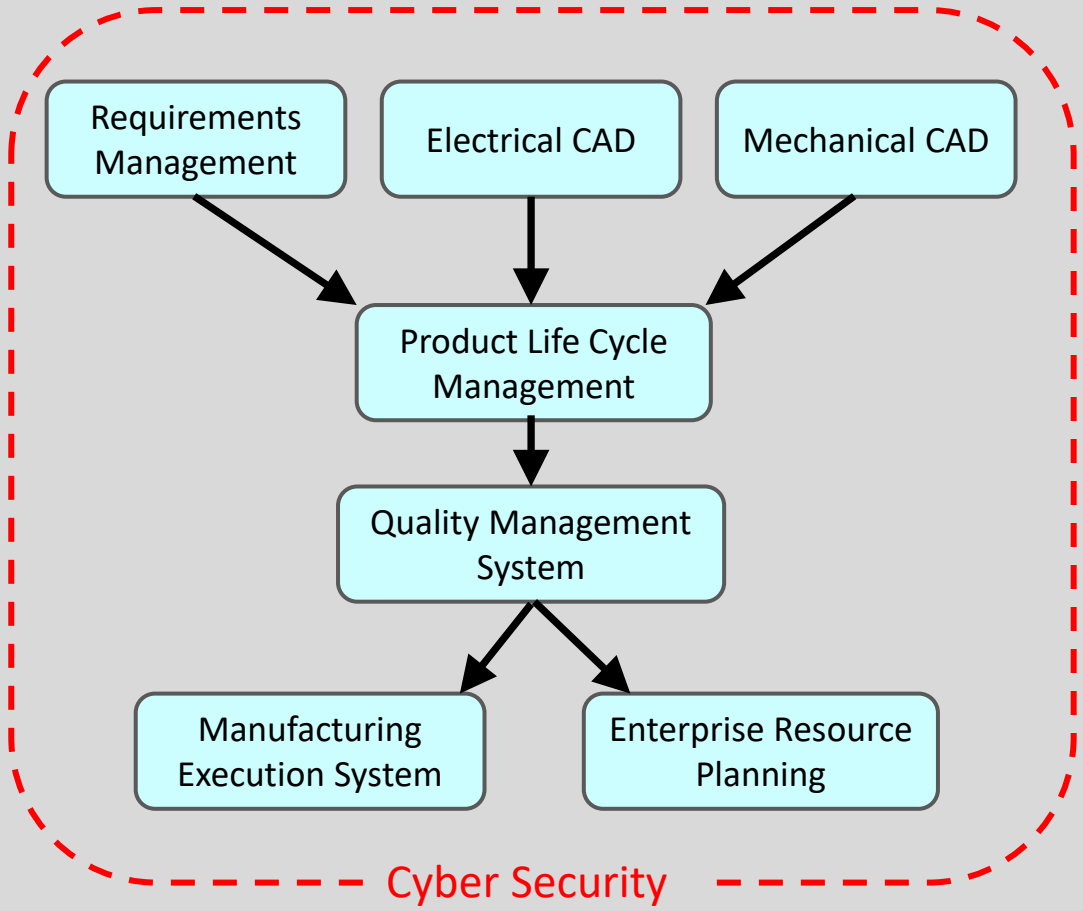
(POST MARKET SURVEILLANCE PHASE)

- Missing requirement(s) and/or Risk Analysis
  - Costly re-design and/or design modification(s)
- False capability claim(s)
  - Design cannot meet requirements
  - Jeopardize clearance, client and market
- Inadequate or unsafe design
  - Insufficient Risk Analysis
  - Costly re-design and verification testing
- Inability to demonstrate traceability
  - Costly and very difficult task to manually establish traceability amongst design inputs, risks and verifications
- 510K rejection
  - Costly corrections to achieve clearance
  - Late to market, missed revenue

- Standard Operating Procedures do not comply with 21 CFR 820
  - Business framework for Medical Device company is costly to correct later and “snowballs” fast
- Poor Quality Management System (QMS)
  - Gaps in QMS can lead to costly correction(s)
- Subject to 483 Warnings with one or more classification types
  - No Action Indicated (NAI)
  - Voluntary Action Indicated (VAI)
  - Official Action Indicated (OAI)
- 483 Warnings
  - Costly remediation plans requiring significant portion of staff
  - Official Action Indicated can lead to monetary penalties, seizures, withdrawal of product
  - Severity of warning can also lead to business freeze until remediation executed
- Severity of 483 Warning may require external guidance
  - Costly regulatory attorney

Business Systems & Compliance

- Quality Management System Regulation (QMSR) establishes the business framework for a Medical Device company to be compliant
- Given the volume of process and supporting documentation required to comply with QMSR, it is highly recommended that the business systems are designed or able to be configured to comply with as much of ISO 13485:2016 as possible
- FDA 21 CFR 11 and QMSR mandate that electronic records and signatures in business system software that are associated with the quality system must be validated. Validation must be performed with every revision or update.
- Validation ensures:
  - Data Integrity
  - Consistent Performance
  - Accuracy & Reliability
  - Compliance
- Most business system software specifically intended for Medical Device use, offer validation services
- Business software supporting multiple industries, typically do not have validation services and must be addressed internally (e.g., CAD design software)
- Computer operating system software must also be validated with every revision as it may/may not affect the performance of dependent software (e.g., CAD design software)



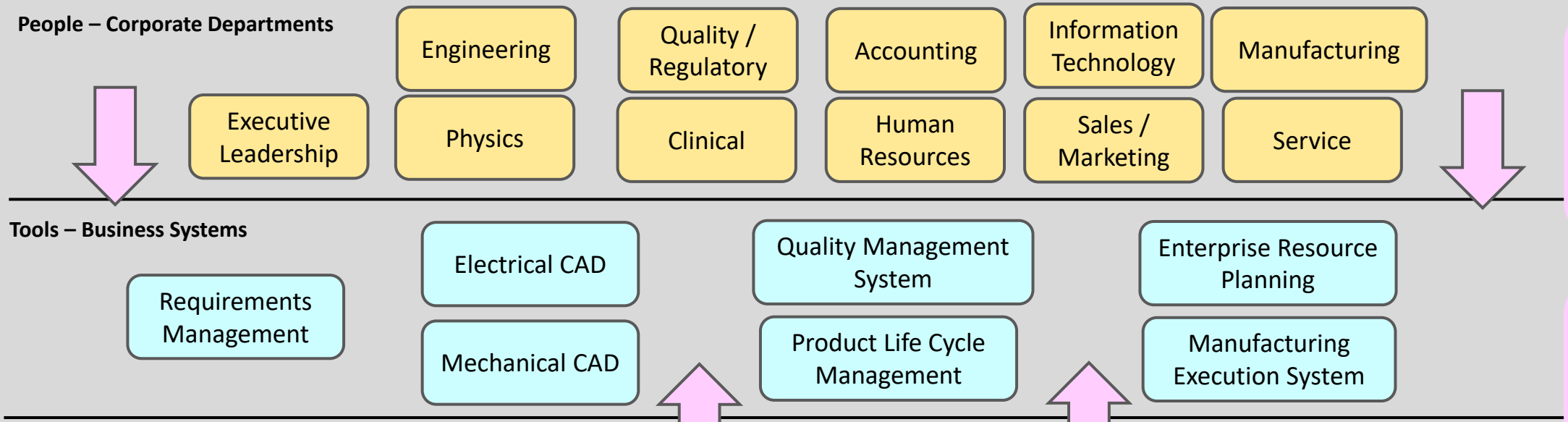
Medical Device Compliance

A brief pause...

…There are many moving parts and a lot to digest!

The overall goal,…….to establish and maintain the safety and efficacy of the Medical Device(s) throughout the defined life cycle

The “big picture” and breaking it all down – The foundation and corporate “building blocks”



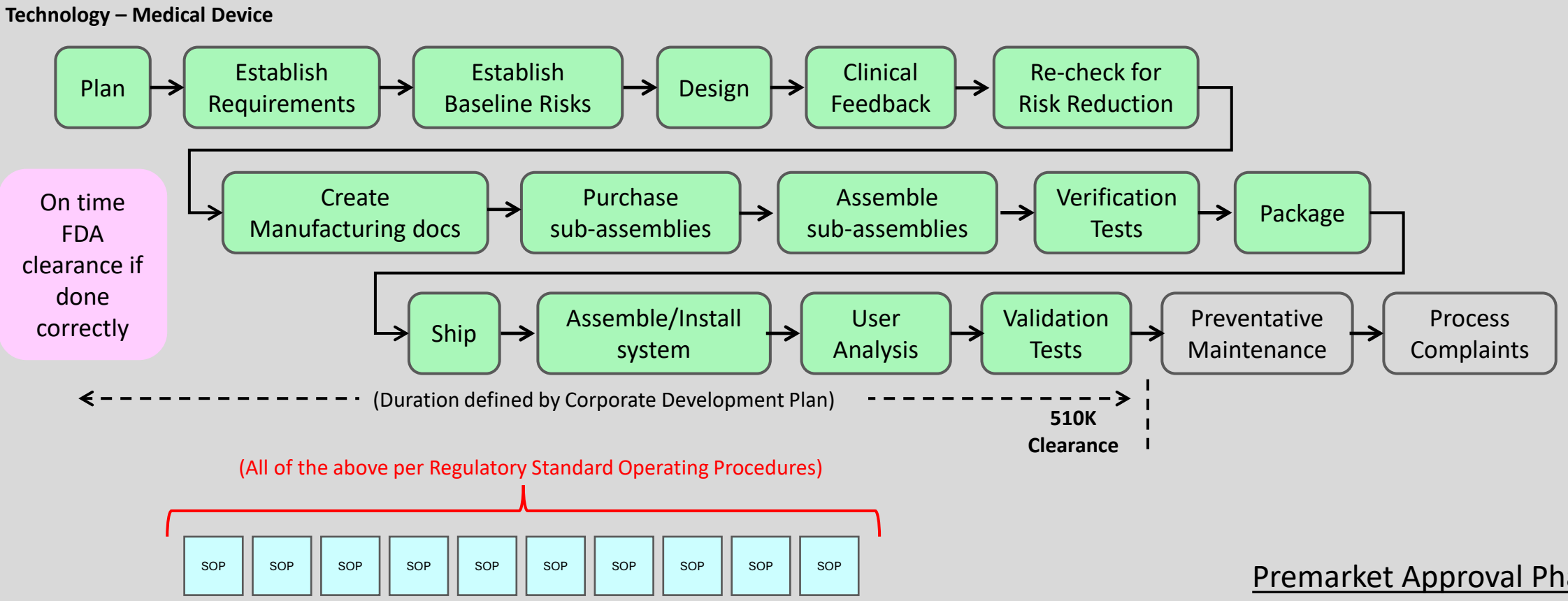
What essential, internal functions are required for the company to function?

What Business Systems are required to run the company and are capable of automating the regulations?

21 CFR 820

ISO 13485

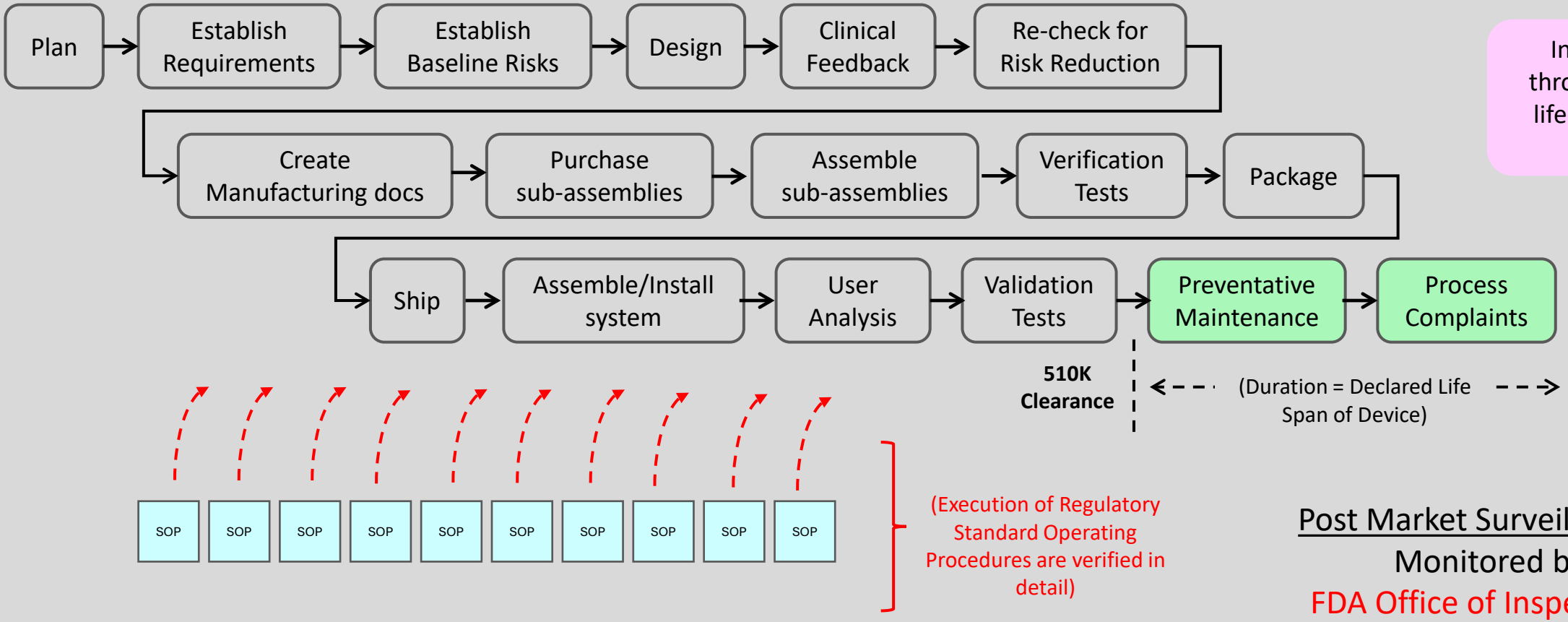
The Medical Device, Premarket Approval journey



Premarket Approval Phase
Submissions reviewed by the
FDA Center for Devices & Radiological Health

The Medical Device, Post Market Surveillance journey

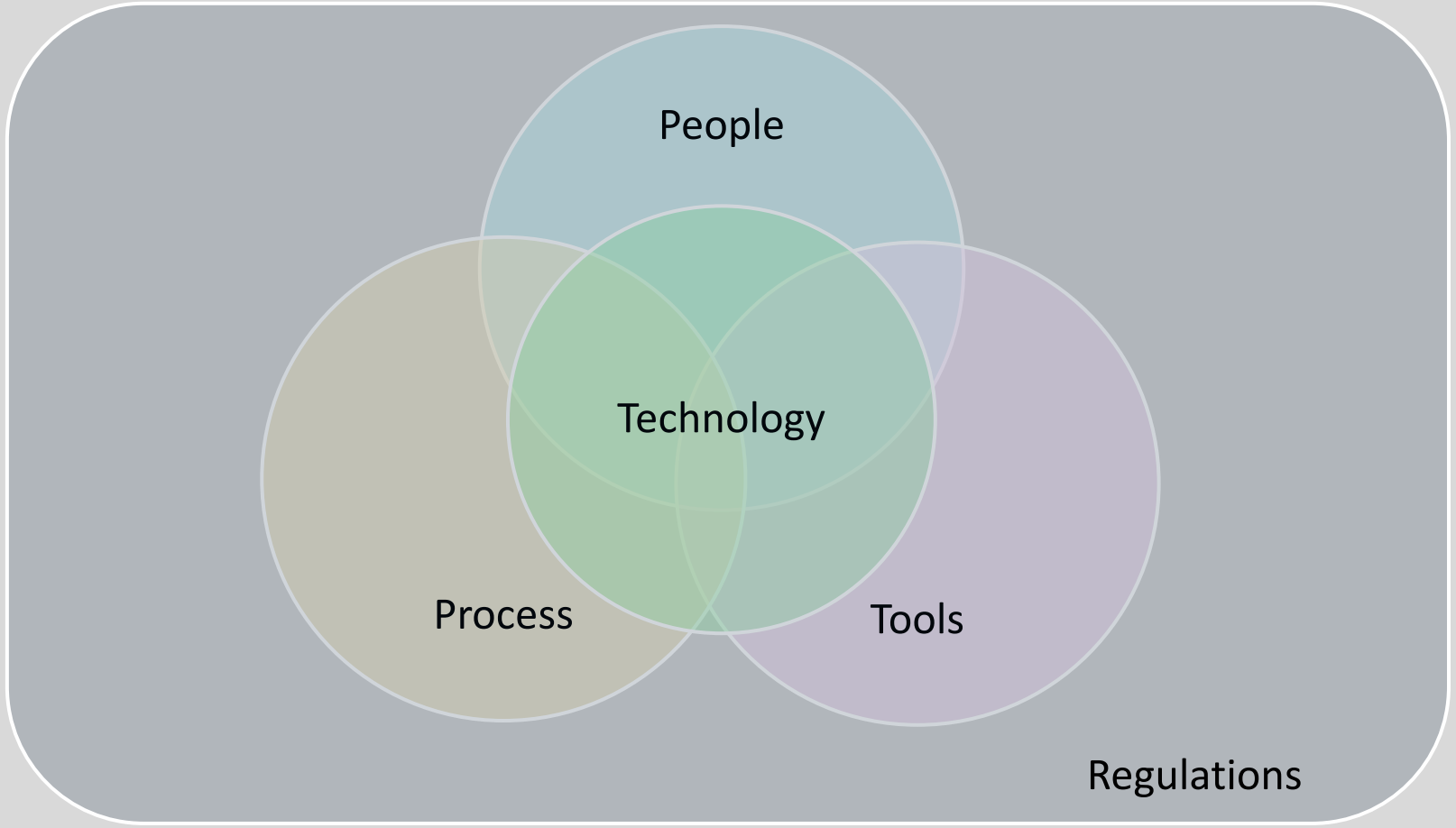
Technology – Medical Device



Inspections throughout the lifecycle of the device

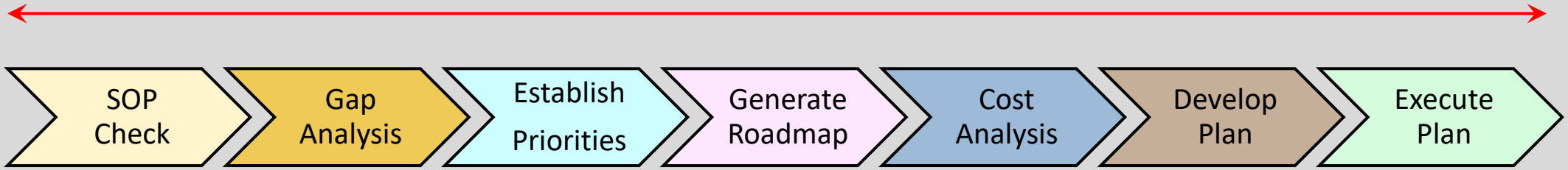
Post Market Surveillance Phase
Monitored by the
FDA Office of Inspections and Investigations

The “goal”: To Bridge People, Process, Tools, Technology with the regulations



Suggested Approach

Consider ISO 13485 Certification
(TUV SUD America)



Key points:

1. There must be support from the top.
2. Establishing a culture of compliance early on is critical.

Suggested Approach – SOP Check

SOP Check → Gap Analysis → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan

Considerations

- Check the Standard Operating Procedures (SOPs), as established for compliance with FDA 21 CFR 820 (and updated per ISO 13485).
- The SOPs must incorporate risk management.
- The SOPs are the business framework for the entire company.
- It is recommended to have a Regulatory Attorney perform this check.
- Compliance gaps in SOPs can be very expensive to fix later.

Foundation - Regulations

	SUBPART A – GENERAL PROVISIONS			SUBPART B – QUALITY SYSTEM REQUIREMENTS			SUBPART C – DESIGN CONTROLS		SUBPART D – DOCUMENT CONTROLS	SUBPART E – PURCHASING CONTROLS	SUBPART F – IDENTIFICATION	SUBPART G – PRODUCTION & PROCESS CONTROLS			SUBPART H – ACEPTANCE ACTIVITIES		SUBPART I – NONCONFORMING PRODUCT	SUBPART J – CORRECTIVE & PREVENTATIVE ACTION	SUBPART K – LABELING & PACKAGE CONTROL		SUBPART L – HANDLING, STORAGE, DISTRIBUTION, INSTALLATION				SUBPART M – RECORDS					SUBPART N – SERVICING	SUBPART O – STATISTICAL TECHNIQUES		
FDA 21 CFR 820	820.1	820.3	820.5	820.20	820.22	820.25	820.30		820.40	820.50	820.60	820.70	820.72	820.75	820.80	820.86	820.90	820.100	820.120	820.130	820.140	820.150	820.160	820.170	820.180	820.181	820.184	820.186	820.198	820.200	820.250	806	807
	SCOPE	DEFINITIONS	QUALITY SYSTEM	MANAGEMENT RESPONSIBILITY	QUALITY AUDIT	PERSONNEL	DESIGN CONTROLS	RISK MANAGEMENT	DOCUMENT CONTROLS	PURCHASING CONTROLS	IDENTIFICATION	PRODUCTION & PROCESS CONTROL	INSPECTION MEASURING & TEST EQUIPMENT	PROCESS VALIDATION	RECEIVING IN-PROCESS FINISH DEVICE ACCEPTANC	ACCEPTANCE STATUS	NON-CONFORMING PRODUCT	CORRECTIVE & PREVENTATIVE ACTION	DEVICE LABELING	DEVICE PACKAGING	HANDLING	STORAGE	DISTRIBUTION	INSTALLATION	GENERAL RECORDS & REQUIREMENTS	DEVICE MASTER RECORD	DEVICE HISTORY RECORD	QUALITY SYSTEM RECORD	COMPLAINT FILES	SERVICE	STATISTICAL TECHNIQUES	REPORTS OF CORRECTIONS & REMOVALS	ESTABLISHMENT REGISTRATION & DEVICE LISTING
ISO 13485	1	3	4	5	8.2.4	6.2	7.3		4.2.3	7.4	7.5.8	7.5.1	7.6	7.5.6	7.1 7.4.3 7.5.1	7.5.8	8.3	8.5.2 8.5.3	7.5.8	7.5.11	7.5.1	8.3	7.2.1 7.5.1 7.5.3 7.5.8 7.5.11	7.5.1 7.5.3	4.2.5	4.2.3	4.2.5	4.2.3 4.2.5	8.2.2	7.5.1	8.4		

FDA 21 CFR 820

ISO 13485

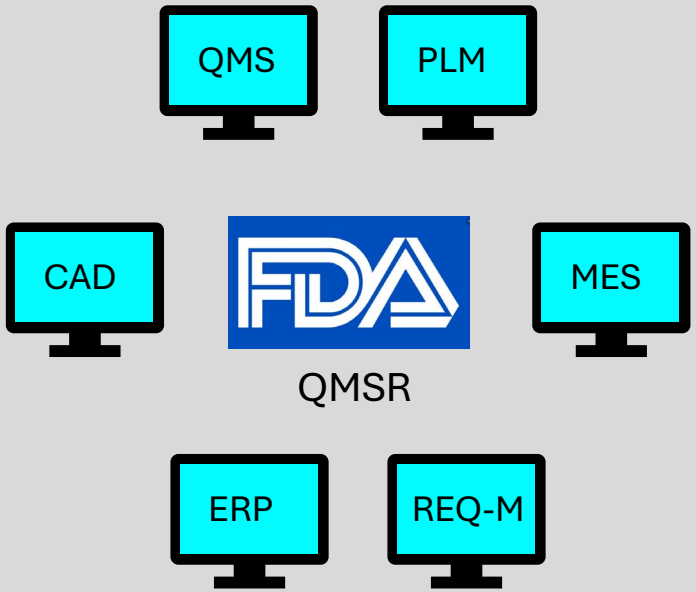
Suggested Approach – Gap Analysis

SOP Check → **Gap Analysis** → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan

1. **People Considerations**
   - What cross-functional core employee functions are required to comply with each SOP of the regulations and operate the business?
   - What cross-functional core competencies do we have and what cross-functional core competencies are missing?
   - Is our organization construct scalable?
   - Do we have sufficient job descriptions for all employee functions?
   - What parts of the premarket approval phase are going to require external resources?
   - What parts of the post market surveillance phase are going to require external resources?
   - How often do we conduct compliance training for all employees?

Suggested Approach – Gap Analysis

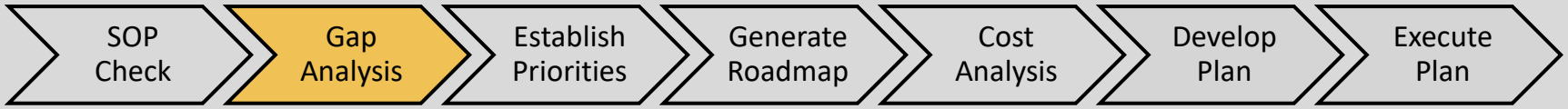
SOP Check → **Gap Analysis** → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan

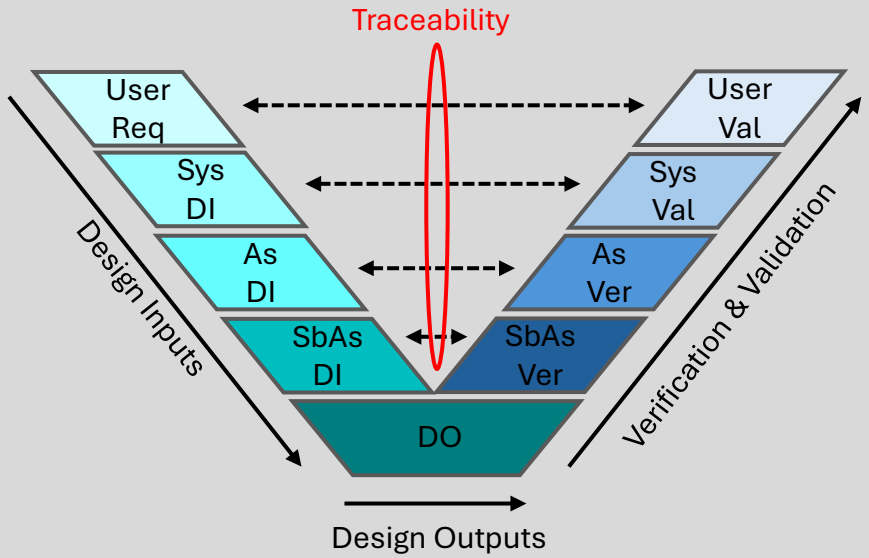


2. Tools Considerations

- Do our combined business systems address, or are capable of addressing all parts of the regulations?
- How well do our business systems integrate with one another for data exchange?
- Can our business systems scale with the company?
- Can our business systems be upgraded with or interfaced with Artificial Intelligence agents (future proofing)?
- How difficult are our business systems to validate with upgrades?
- How well are our business systems supported?
- Are our business system configurations and data backed up?
- Do we have cyber security measures in place?

Suggested Approach – Gap Analysis





Requirements Management, the Cornerstone for Medical Device

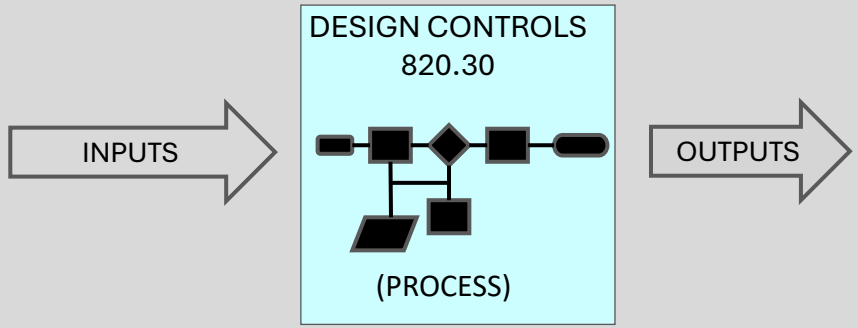
2. **Tools Considerations (cont'd)**
   - Specific to Requirements Management:
     - How are User Requirements captured and transposed to Design Inputs?
     - How are regulatory standards captured and accounted for in Design Inputs?
     - How are Risk Analysis captured and accounted for (Hazard Analysis, DFMEA, PFMEA, UFMEA)?
     - Do we incorporate Human Factors input from the end user(s) into our Design Inputs?
     - How are Verification and Validation tests captured and accounted for?
     - How is traceability amongst the above accomplished?

Suggested Approach – Gap Analysis

SOP Check → **Gap Analysis** → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan

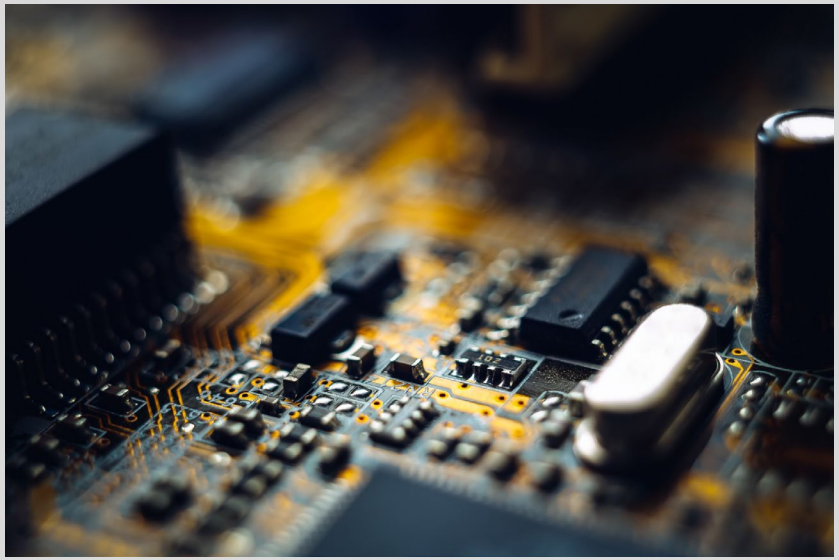
3. Process Considerations

- Do we have processes for as many of our SOPs that warrant process?
- Do our processes take into account input from preceding processes?
- Do our processes take into account reaching back into preceding processes?
- Do our processes take into account all required stakeholders and stakeholder approvals?
- Do our processes incorporate risk management within the process, as well as risk management to advance to the next process?
- What processes or parts of our processes have inefficiencies?
- Have we validated our processes?



Suggested Approach – Gap Analysis

SOP Check → **Gap Analysis** → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan



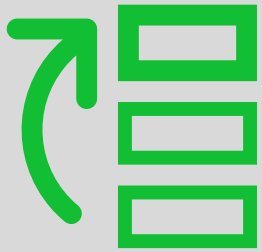
4. **Technology Considerations**
   - What parts of our Medical Device did we develop the technology in-house?
   - Are there any gaps in our technical core competency associated with the in-house technology?
   - Have any risks been identified with the in-house technology and if yes, have they been mitigated?
   - What parts of our Medical Device was the technology developed from external resources (supplier)?
   - Has the technology supplier been defined as critical and has there been an extensive qualification performed?
   - Who has responsibility for verification of external technology?

Suggested Approach – Establish Priorities

SOP Check → Gap Analysis → **Establish Priorities** → Generate Roadmap → Cost Analysis → Develop Plan → Execute Plan

Considerations

- Were there any compliance gaps from the preceding SOP check and if yes, how are they prioritized?
- Were there any "people" gaps from the preceding gap analysis and if yes, how are they prioritized?
- Were there any "tools" gaps from the preceding gap analysis and if yes, how are they prioritized?
- Were there any "process" gaps from the preceding gap analysis and if yes, how are they prioritized?
- Were there any "technology" gaps from the preceding gap analysis and if yes, how are they prioritized?
- What are the priorities of the different gap analysis categories (people, tools, process, technology)?
- Do we have multiple Medical Devices that are in both the premarket approval and post market surveillance phases that have competing priorities?
- Has the company been inspected by the FDA?
- Does the company have FDA warnings that must be addressed?



Suggested Approach – Generate Roadmap

SOP Check → Gap Analysis → Establish Priorities → **Generate Roadmap** → Cost Analysis → Develop Plan → Execute Plan

Business Roadmap (the strategic plan)

	Year 1				Year 2			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SOPs	▼							
People		▼						
Tools		▼	▼					
Process			▼	▼				
Technology			▼	▼	▼		▼	

▼ = Milestone

Suggested Approach – Cost Analysis

SOP Check → Gap Analysis → Establish Priorities → Generate Roadmap → **Cost Analysis** → Develop Plan → Execute Plan

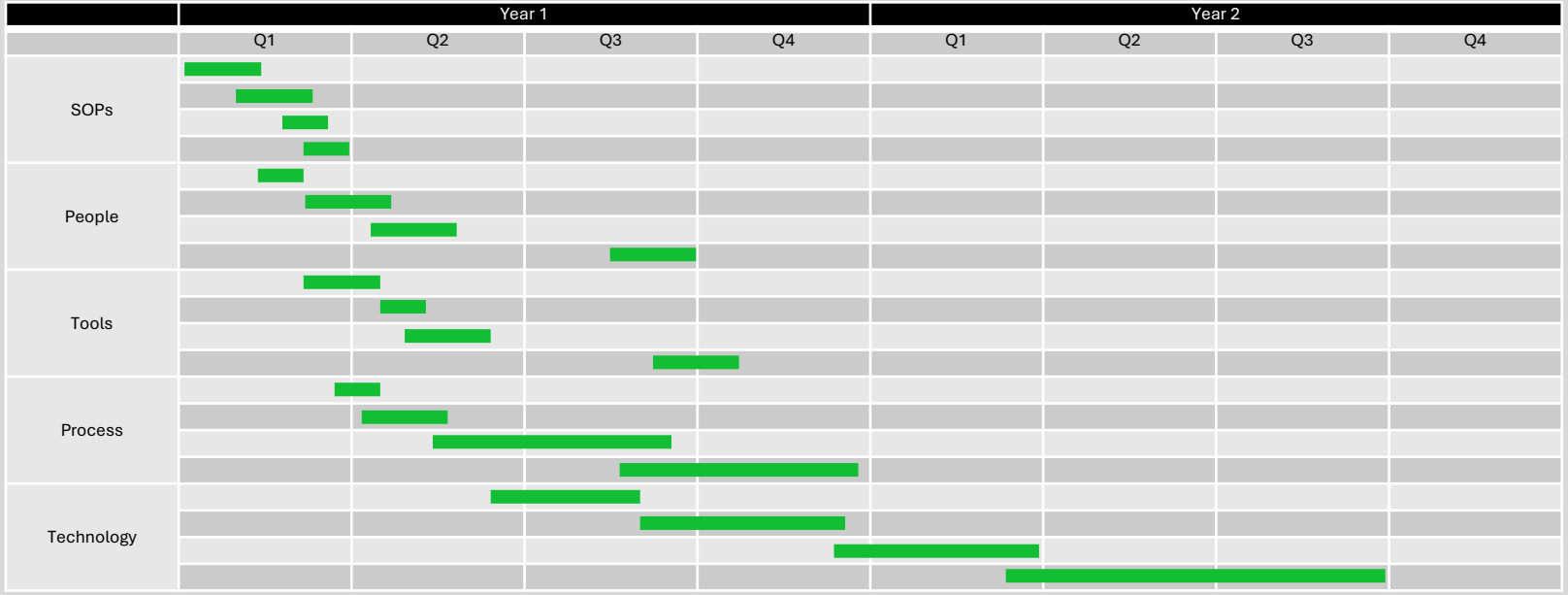
Considerations

- Structure cost analysis around the two main phases of the Medical Device Lifecycle
- Use high level gap analysis cost categories (i.e., People, Tools, Process, Technology)
- Assuming gaps were previously discovered:
  - Establish current "Premarket Approval", costs as a "baseline"
  - Establish current "Post Market Surveillance", costs as a "baseline"
- Estimate the percentage of costs directly associated with Medical Device compliance in the two main phases
- Identify current process inefficiencies and/or opportunities to improve processes
- Estimate additional costs to mitigate gaps in "Premarket Approval" phase
- Estimate additional costs to mitigate gaps in "Post Market Surveillance" phase
- Establish ROI target(s)

Suggested Approach – Develop Plan

SOP Check → Gap Analysis → Establish Priorities → Generate Roadmap → Cost Analysis → **Develop Plan** → Execute Plan

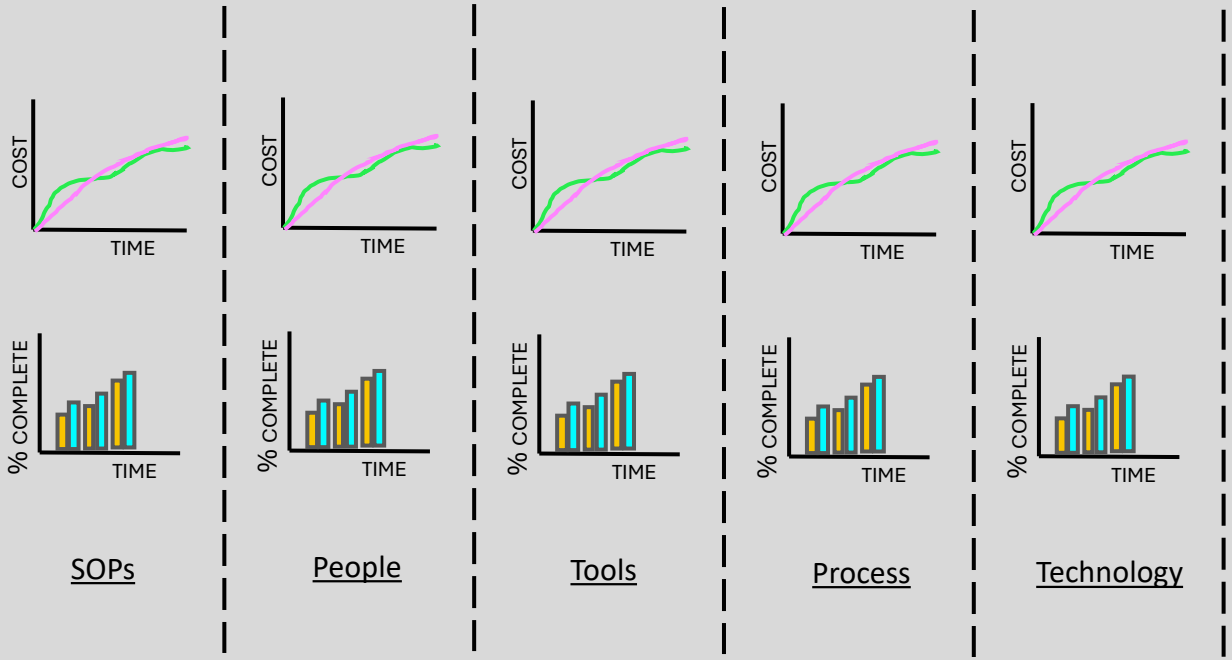
Detailed Project Plan (the tactical plan)



- ✓ Create a plan or plans that make sense
- ✓ Keep the plan(s) simple with logical flow
- ✓ Create work breakdown groups that make sense for summarized “roll-up”
- ✓ Develop work breakdown structures within groups with cross-functional input

Suggested Approach – Execute Plan

SOP Check → Gap Analysis → Establish Priorities → Generate Roadmap → Cost Analysis → Develop Plan → **Execute Plan**



- ✓ Establish Key Performance Indicators (KPIs)
- ✓ Create KPI Metrics Dashboards
- ✓ Execute Plan(s)
- ✓ Monitor and Adjust as necessary

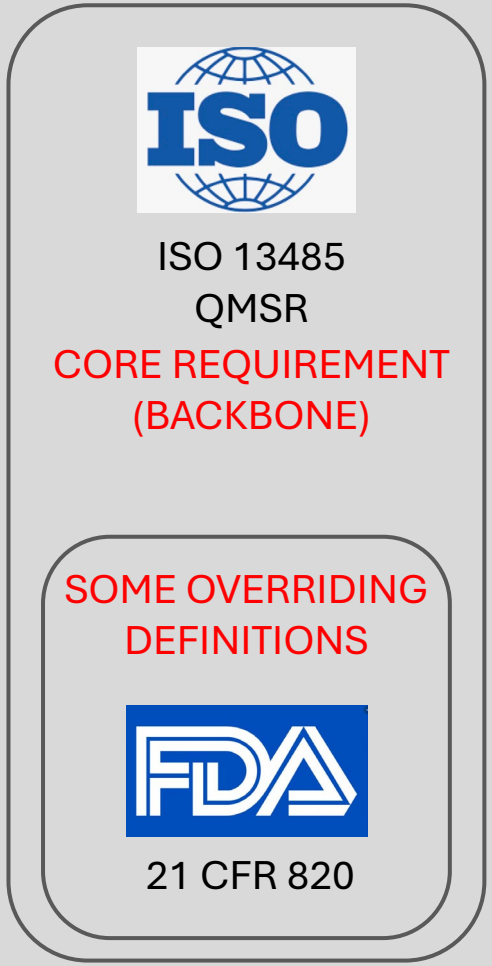
What's New – Regulations

✓The FDA has harmonized 21 CFR 820 (quality system regulation (QSR)) with ISO 13485:2016 (quality management system regulation (QMSR))

- **Structure:** Part 820 is updated, but it is not going away.
- **Incorporation by Reference:** ISO 13485:2016 requirements are now part of 21 CFR Part 820.
- **Retained FDA Requirements:** Specific 820 sections remain for areas where FDA requirements go beyond ISO 13485, such as control of records (§820.35), device labeling/packaging (§820.45), and specific definitions.
- **Terminology:** The old QSR is replace by the new QMSR.

✓The new QMSR took effect on February 2, 2026

✓Benefits compliance in multiple jurisdictions



What's New - Inspections

Diagram 1: FDA Medical Device Risk-Based Inspections [3]

"The QMSR maintains a focus on risk and describes a QMS as a set of linked processes. [4]"

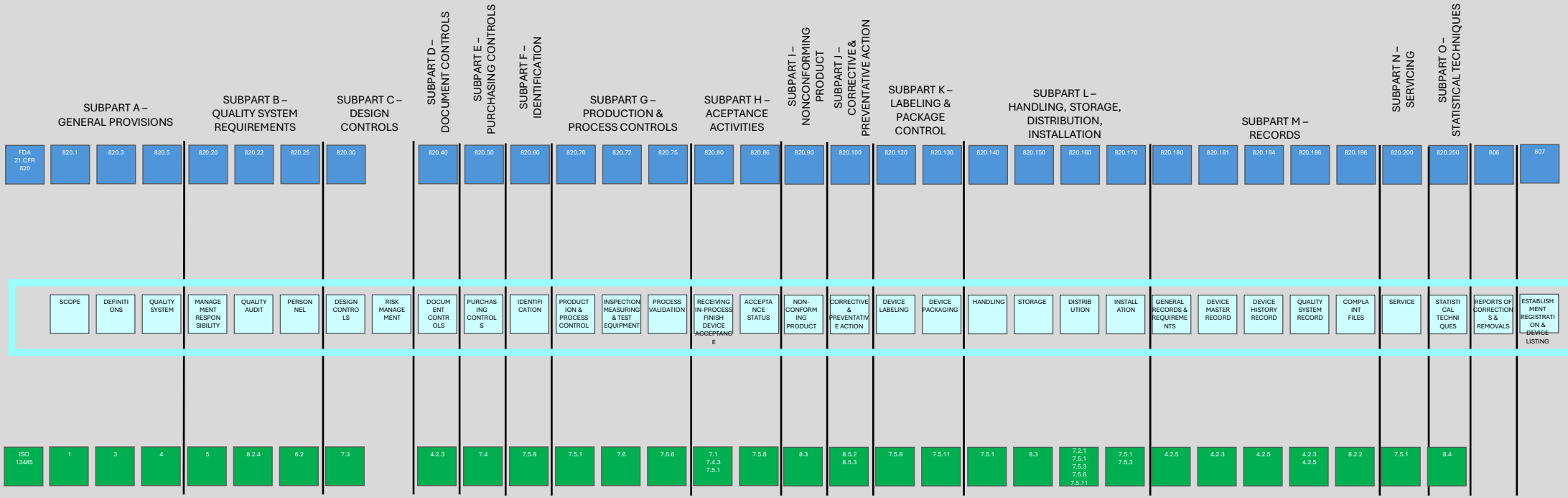
21 CFR 820

"FDA expects top management to ensure applicable regulatory requirements are met through integrating QMS processes and embracing a culture of quality.[5]"

ISO 13485

What's New – Your SOPs

MEDICAL DEVICE REGULATIONS



21 CFR 820

SOP Updates MANDATORY

ISO 13485

Thank You

For more information

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References

1. Complizen (October 17, 2025). How Much Does It Cost to Bring a Medical Device to Market? 2025 Budget Guide. https://www.complizen.ai/post/medical-device-development-costs-2025-budget-guide
2. Tracekey Solutions (June 14, 2024). Post-Market Surveillance and its Costs. https://www.tracekey.com/en/pms-costs/
3. illustration from FDA Program Document 7382.850, p. 20 of 78
4. ISO 13485:2016 Clause 0.3 Process approach
5. FDA's response to QMSR preamble comment 27 discusses top management and culture of quality. It reads in part, "…FDA expects medical device manufacturers, led by individuals with executive responsibilities, to embrace a culture of quality as a key component in ensuring the manufacture of safe and effective medical devices that otherwise comply with the FD&C Act. A culture of quality meets regulatory requirements through a set of behaviors, attitudes, activities, and processes. Top management ensures that applicable requirements are met through integration of QMS processes…" 89 FR 7496, 7506 (Feb. 2, 2024).