Quality Management System for Medical Products

Why is a Quality Management System needed?

- Improves a business' performance
- Ensures requirements & standards are maintained throughout product lifecycle.
- To meet FDA's Code of Federal Regulations for Quality Systems (21 CFR 820) (ISO 13485 for medical devices / ISO 9001 for others)

Objectives of Presentation

Objectives:

- What is a quality system?
- Who does it apply to?
- What are a company's responsibilities?
- What are the options?
- When & where within the development pathway do specific activities happen?

What is a Quality Management system?

A framework in support of planning, execution and monitoring of specific objectives of a company which is constantly evolving.

A framework includes:
Policies – guiding principles
Processes – high level architecture
Procedures – steps to be followed

Quality Systems included:

- **General controls**
- **Development planning**
- **Inputs and Outputs**
- **Review, Verification and Validation**
- **Transfer, changes and history**

What is a Quality Management system?

A company's quality system should be customized for its unique application and includes:

- **General controls**: Sec: 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions)
- **Development planning** – designating activities & implementation responsibility.
- **Inputs:** Ensure that the design requirements are appropriate and address the intended use of the device, including the needs of the user.
- **Outputs:** Defines the design output in terms that allow an adequate evaluation of conformance to design input requirements.
- **Verification**: Confirms that the design output meets the design input
- **Validation**: Evidence that device specifications conform with user needs and intended use.
- **Transfer, changes and history** – accurate record keeping; documenting decisions/changes

The above activities make up a Quality System Manual.

Who does it apply to?

Medical Device Companies:

- Who are developing a product regulated by the FDA.

Non-Medical Product or Service Companies desiring to:

- Consistently meet customer and regulatory requirements
- Improve system effectiveness and efficiency
- Ensure customer satisfaction

What are a Company's Responsibilities?

Medical device Co.:
FDA requires companies to establish and follow a quality system to ensure that the products consistently meet applicable requirements and specifications.

It is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. that meet the quality system requirements.

The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated.

Non-Medical Product or Service Co.:
Implementing a quality management system is a leadership decision and requires commitment and dedication throughout the organization. The company must provide sufficient training, resources and leadership to develop and sustain a high quality QMS system.

Management team is responsible for ensuring that the process is correct and is being followed

Employees' responsibility to ensure that they have processes that are well documented and are being followed.

What are my options?

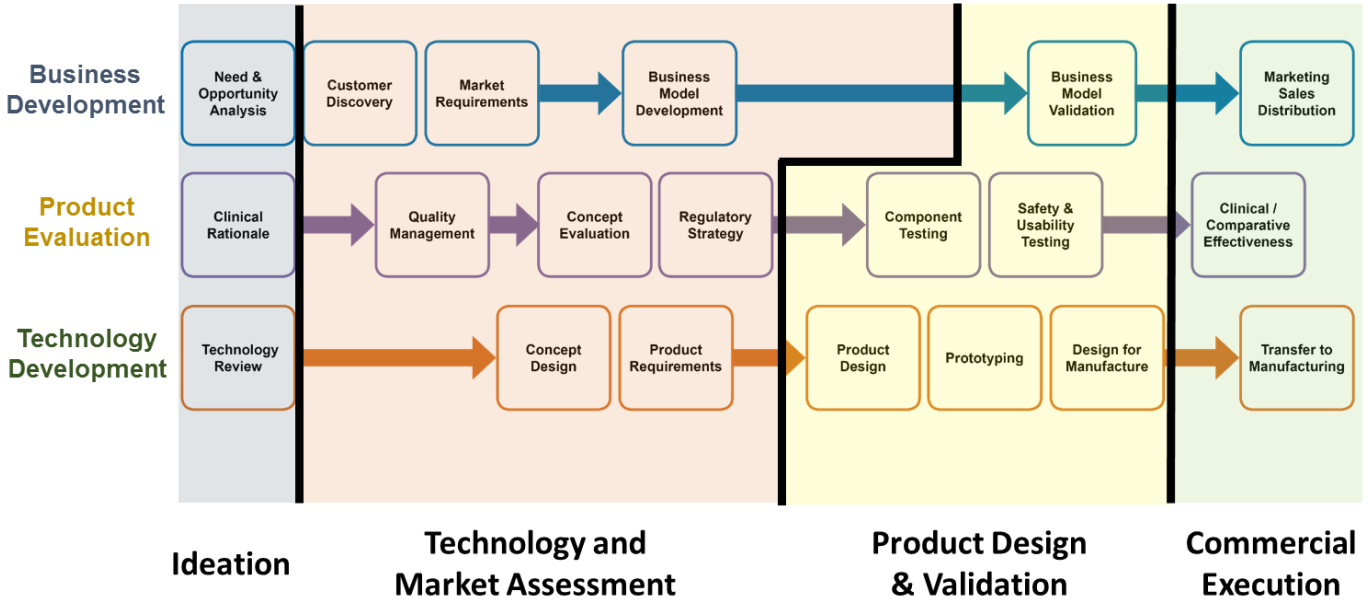
Method	Advantages	Disadvantages
Start from Scratch	Customized to meet individual needs	Slowest implemention time, requires skill set to develop and implement the QMS
Software (online or server based)	Little to no paper. Customized.	Fairly expensive up front and ongoing costs. Requires individual with moderate skill set to implement and develop the QMS
Templates (paper based)	Probably the fastest implementation of any method, no software to learn.	Will need individual with moderate skill set to implement and develop the QMS
Consultant	Relatively little up front effort by innovator or team. Customized QMS with only what's needed at this time.	Most expensive up-front cost.

What is the scope of a Quality Management System?

Requirements of a quality management system depend on several factors
21 CFR Part 820 - QUALITY SYSTEM REGULATION

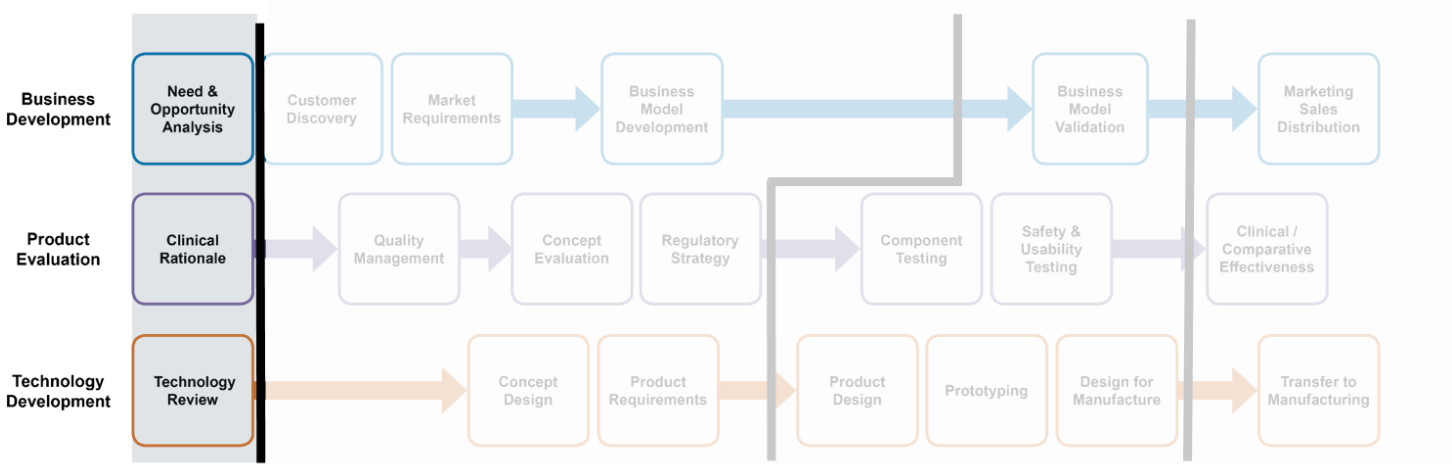
Subpart A - General Provisions (§§ 820.1 - 820.5)
Subpart B - Quality System Requirements (§§ 820.20 - 820.25)
Subpart C - Design Controls (§ 820.30)
Subpart D - Document Controls (§ 820.40)
Subpart E - Purchasing Controls (§ 820.50)
Subpart F - Identification and Traceability (§§ 820.60 - 820.65)
Subpart G - Production and Process Controls (§§ 820.70 - 820.75)
Subpart H - Acceptance Activities (§§ 820.80 - 820.86)
Subpart I - Nonconforming Product (§ 820.90)
Subpart J - Corrective and Preventive Action (§ 820.100)
Subpart K - Labeling and Packaging Control (§§ 820.120 - 820.130)
Subpart L - Handling, Storage, Distribution, and Installation (§§ 820.140 - 820.170)
Subpart M - Records (§§ 820.180 - 820.198)
Subpart N - Servicing (§ 820.200)
Subpart O - Statistical Techniques (§ 820.250)

When & Where Do I Need To Worry About This?



- **Ideation stage:** Documenting with emails and memos as appropriate
- **Technology and Market Assessment:** Formal documentation (Procedures and forms)
- **Product Design & Validation:** Formal documentation (Procedures and form)
- **Commercial Execution:** Formal documentation (Procedures and form)

Where in the Commercialization Pathway?



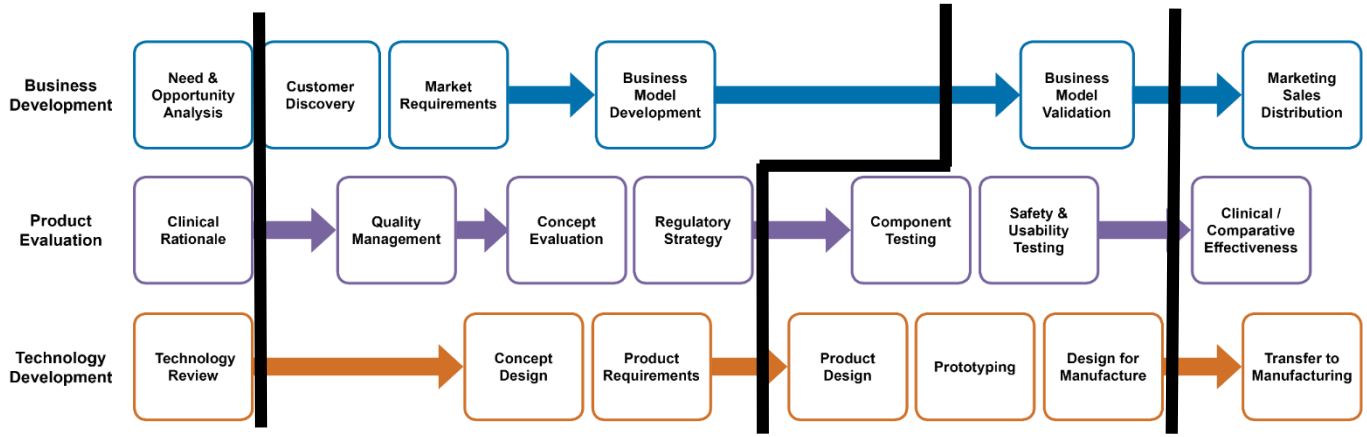
Ideation

Development phase	SOP's (SOP = Standard Operating Procedure)	Documentation (FRM = Form)
Pre-Development	None	Memo

Where in the Commercialization Pathway?

If Ideation phase shows:

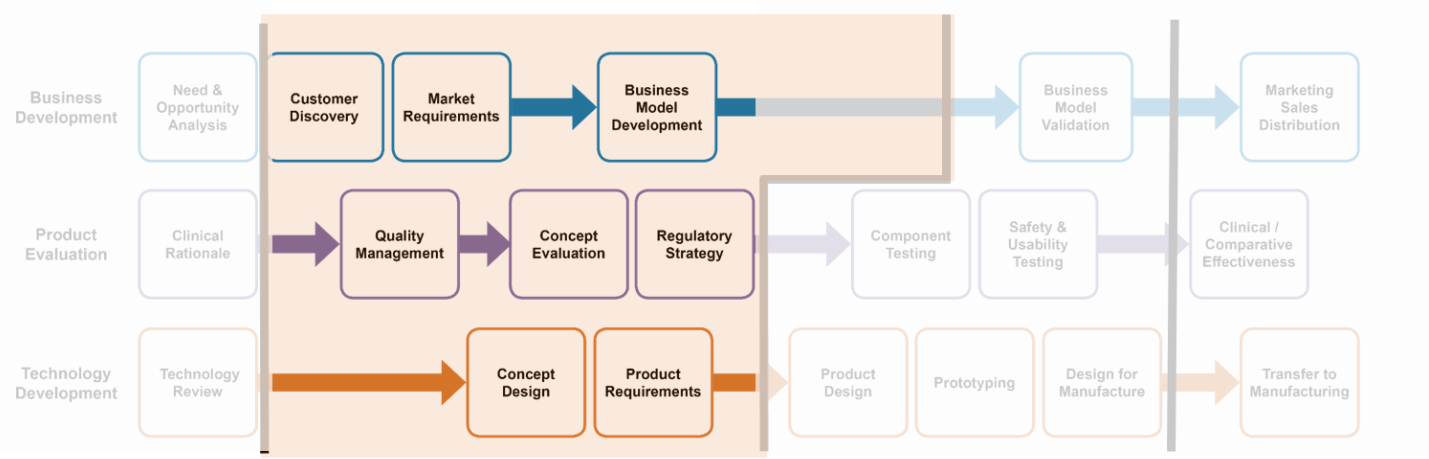
- Evidence of growing market which could provide adequate ROI
- Evidence that the problem is recognized as worth solving
- Lack of insurmountable hurdles which would prevent success



Foundational SOPs*

Quality Manual
Risk Management
Document Development
Control of Documents
Change Control
Deviations
Control of Records
Competency, Awareness, and Training
Corrective and Preventative Action

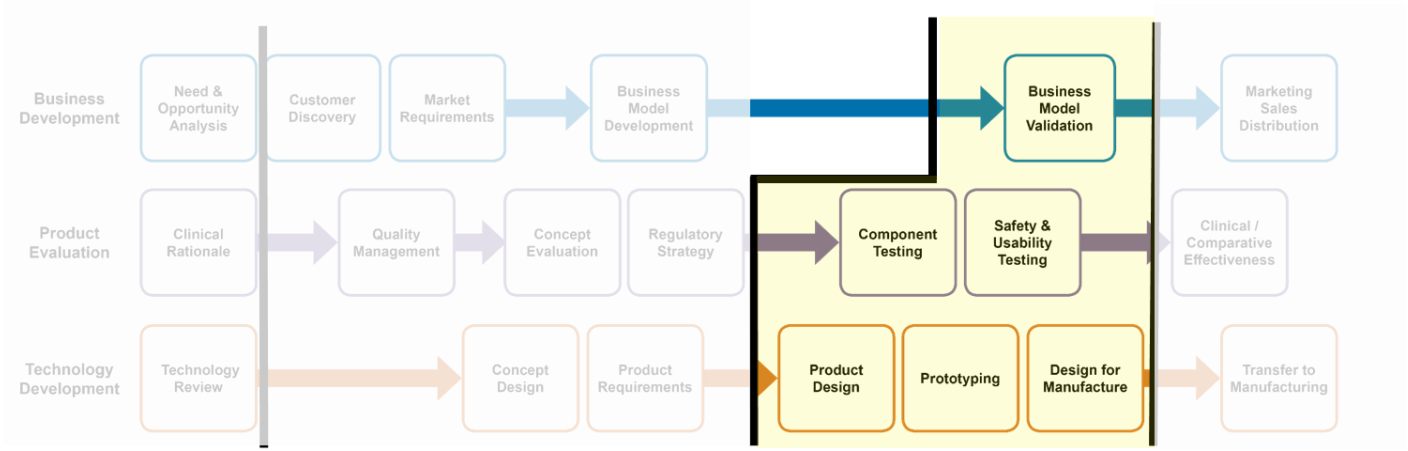
Where in the Commercialization Pathway?



Technology and Market Assessment

Development phase	SOP's*	Documentation* (FRM)
Pre-Development	Customer Related Processes (inputs) • Complaint Handling (Current complaints) • Identification of customer requirements • Review of product requirements • Design and /or development of inputs • Software Design and Development Planning of Product Realization Project Initiation	Market Requirements Document Product Requirements Document Quality Plan Software Requirements Document Quality Assurance Plan

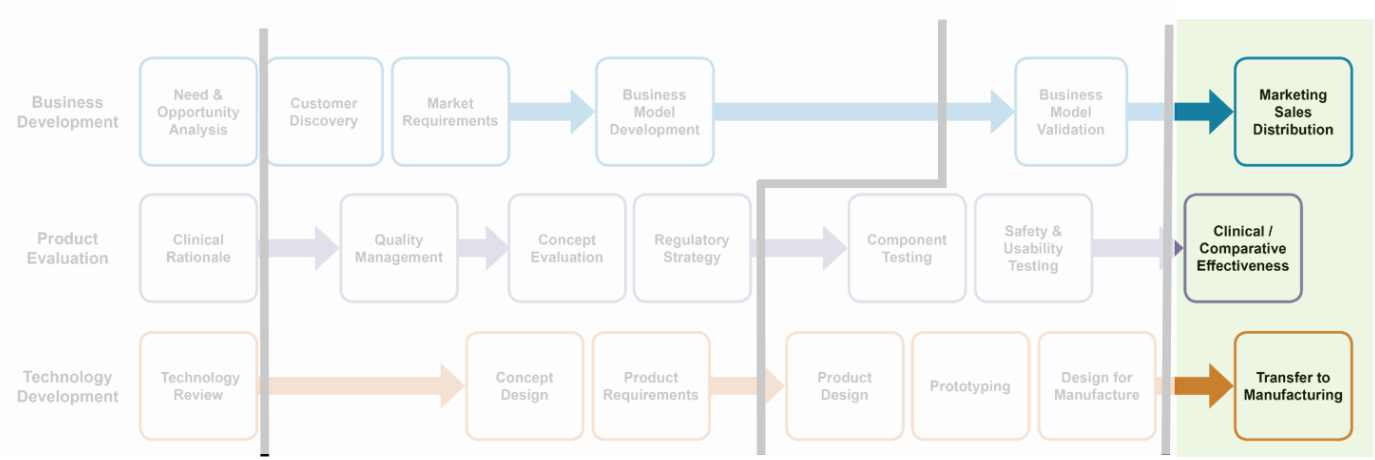
Where in the Commercialization Pathway?



Design & Development Verification

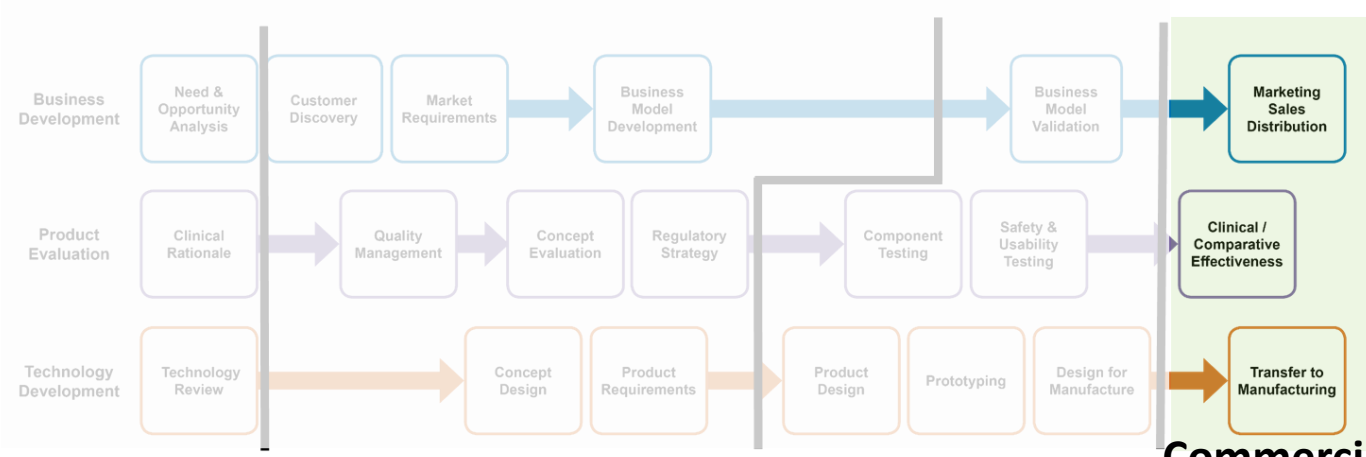
Development phase	SOP's*	Documentation* (FRM)
Alpha Beta Additional as needed	Design and/or development • Design and/or development outputs • Design and /or development review • Design and/or development verification Control of design and/or development changes	Development Memo Development Test Plan Device Test Plan Design Failure Mode and Effect Analysis Device Record
Pre-Production Production	Design and/or development Review Supplier Selection and Evaluation Inventory Parts & Assembly Numbering	Bill Of Materials Work In-Process

Where in the Commercialization Pathway?



Development phase	SOP's*	Documentation* (FRM)
Product Design & Validation		
Production	Design and/or development validation Design and/or development review Statistical techniques	Device Master Record Design History File Design Review Product Release checklist Regulatory Affairs Requirements Product Release checklist Regulatory Affairs Requirements

Where in the Commercialization Pathway?



Development phase	SOP's*	Documentation* (FRM)
Design Validation		
Production	Purchasing • Quoting • Purchasing • Supplier Selection and Evaluation • Inspection and Test Status Production • Control of Monitor & Measurement Equipment • Competency, awareness, and Training • Preservation of product • Monitoring and Measuring of Product • Control of Non-conforming Product • Identification and Traceability • Deviations • Order Fulfillment	Design History Record Declaration of Compliance Device Test Log Device Training Record Inspection and Test Procedures Inspection and Test Report Non-conformance Report Traveler Inventory Transfer Article Inspection Report

Example –

890.3475 Limb Orthosis (Brace)

Class 1 Exempt

FDA Quality Requirements - Example

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart D--Physical Medicine Prosthetic Devices

Sec. 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, regarding general requirements concerning records and 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

FDA Quality Requirements - Example

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, regarding general requirements concerning records and 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

General controls: Sec: 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions)

890.9 – Limitations of exemptions from section 510(k)

Exempt of good manufacturing practice and general controls except:

820.180 – Records – General requirements

820.198 – Compliant files

Resources

http://treatcenter.org/edu/commercialization-process/quality-management/

http://treatcenter.org/edu/commercialization-process/regulatory-strategy/

Quality System (QS) Regulation/Medical Device Good Manufacturing Practices

- https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/default.htm

Standards Stores: Paper Based Templates

- https://standards-stores.com/certification-products/