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

<table>
<thead>
<tr>
<th>Development phase</th>
<th>SOP’s (SOP = Standard Operating Procedure)</th>
<th>Documentation (FRM = Form)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Development</td>
<td>None</td>
<td>Memo</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Development phase</th>
<th>SOP’s*</th>
<th>Documentation* (FRM)</th>
</tr>
</thead>
</table>
| 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?

![Commercialization Pathway Diagram]

### Design & Development Verification

<table>
<thead>
<tr>
<th>Development phase</th>
<th>SOP’s*</th>
<th>Documentation* (FRM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha</td>
<td>Design and/or development</td>
<td>Development Memo</td>
</tr>
<tr>
<td></td>
<td>• Design and/or development outputs</td>
<td>Development Test Plan</td>
</tr>
<tr>
<td></td>
<td>• Design and/or development review</td>
<td>Device Test Plan</td>
</tr>
<tr>
<td></td>
<td>• Design and/or development verification</td>
<td>Design Failure Mode and Effect Analysis</td>
</tr>
<tr>
<td></td>
<td>Control of design and/or development changes</td>
<td>Device Record</td>
</tr>
<tr>
<td>Beta</td>
<td>Design and/or development Review</td>
<td>Bill Of Materials</td>
</tr>
<tr>
<td>Additional as needed</td>
<td>Supplier Selection and Evaluation</td>
<td>Work In-Process</td>
</tr>
<tr>
<td>Pre-Production</td>
<td>Design and/or development Review</td>
<td></td>
</tr>
<tr>
<td>Production</td>
<td>Inventory Parts &amp; Assembly Numbering</td>
<td></td>
</tr>
</tbody>
</table>
Where in the Commercialization Pathway?

Commercial Execution

<table>
<thead>
<tr>
<th>Development phase</th>
<th>SOP’s*</th>
<th>Documentation* (FRM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Design &amp; Validation</td>
<td>Design and/or development validation</td>
<td>Device Master Record</td>
</tr>
<tr>
<td></td>
<td>Design and/or development review</td>
<td>Design History File</td>
</tr>
<tr>
<td></td>
<td>Statistical techniques</td>
<td>Design Review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product Release checklist</td>
</tr>
<tr>
<td>Production</td>
<td></td>
<td>Regulatory Affairs Requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product Release checklist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Regulatory Affairs Requirements</td>
</tr>
</tbody>
</table>

Center for Translation of Rehabilitation Engineering Advances and Technology
Where in the Commercialization Pathway?

<table>
<thead>
<tr>
<th>Development phase</th>
<th>SOP’s*</th>
<th>Documentation* (FRM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Validation</td>
<td>Purchasing</td>
<td>Design History Record</td>
</tr>
<tr>
<td></td>
<td>• Quoting</td>
<td>Declaration of Compliance</td>
</tr>
<tr>
<td>Production</td>
<td>• Purchasing</td>
<td>Device Test Log</td>
</tr>
<tr>
<td></td>
<td>• Supplier Selection and Evaluation</td>
<td>Device Training Record</td>
</tr>
<tr>
<td></td>
<td>• Inspection and Test Status</td>
<td>Inspection and Test Procedures</td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td>Inspection and Test Report</td>
</tr>
<tr>
<td></td>
<td>• Control of Monitor &amp; Measurement Equipment</td>
<td>Non-conformance Report</td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td>Traveler</td>
</tr>
<tr>
<td></td>
<td>• Competency, awareness, and Training</td>
<td>Inventory Transfer</td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td>Article Inspection Report</td>
</tr>
<tr>
<td></td>
<td>• Preservation of product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Monitoring and Measuring of Product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Control of Non-conforming Product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Identification and Traceability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Deviations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Order Fulfillment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production</td>
<td></td>
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</tbody>
</table>
Example –

890.3475 Limb Orthosis (Brace)

Class 1 Exempt
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.

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/