If you see this icon by the AdvaMed logo on the page, that means this slide contains interactive, live links.

If you see text in bold blue on the page, that means this text is an interactive link that will take you to another place in the library.

If your computer mouse turns into a white pointed hand when you pass over a text or image on the page, that means that text or image has an interactive link that will take you to another place in the library.

If you see this pointer finger icon by a text or image on the page, clicking on the pointer finger icon will take you to the related interactive link in another place in the library.

Clicking on the YELLOW arrow icon will take you BACK to the last page you were on.

Clicking on the GREEN arrow icon will take you to the NEXT sequential page from where you were on.

Clicking on the BLUE arrow icon will take you to the MAIN Table of Contents page in the current library area that you are in.

Clicking on the PURPLE location marker icon will take you to the Table of Contents (TOC) for the particular company presentation that you are in.

Clicking on the BLUE house icon will take you to the MAIN library page for the Case of Quality where you can access other library areas.
Category A:
How Do You Determine Customer Requirements?
Practices To Determine Customer Requirements

Table of Contents
Practices To Determine Customer Requirements

1. Cascade Method
2. Common Practices
3. Key Tools Used
4. Quality Systems Process Approaches
   a. Superstructure Model
   b. Value Stream Model
   c. Product Development Model
   d. Critical Parameter Management Model
Cascade Method
Tool/Method/Example Summary

- **Tool/Example Name:** Requirements Cascade (Radar Diagram, QFD, Pugh Matrix)
- **General Description:**
  Process by which requirements are gathered, translated into a design, and device is developed
- **Glossary of terms:**
  - **Radar Diagram:** Is a graphical representation of the relationship between the importance of a customer need, the current satisfaction and planned satisfaction for new design
  - **Pugh Matrix:** Is a quantitative technique used to rank the multi-dimensional options of an option set, e.g. is concept ‘a’ better than concept ‘b’ or ‘c’.
  - **Transfer Function:** Is a mathematical representation of the relationship between a set of design factors and output variables.
  - **House of Quality:** Also called QFD [Quality Function Deployment] is a tool used to systematically translate customer requirements into quantitative parameters that can be used to develop a concept and select a product solution.
- **Typical Uses:**
  - Requirements cascade is used throughout the design and development of the product and is critical in post-mkt product support
- **Relevant FDA Regulations:**
  - Applicable to all stages of design control (21 C.F.R. § 820.30)
EVERY REQUIREMENT is fully traced
Design Inputs

• 4 sources
  – VOC – Identifies customer preferences
  – VOB – Identifies internal stakeholder preferences
  – Application – Identifies needs and risks of clinical practice
  – Standards – Identifies applicable standards and statutes

• NO PERSON within the company represents the customer
  – Marketing, sales, medical affairs, and clinical affairs personnel provide access and interpretation, but are not surrogates

• Every input must be validated and a measurement method defined.

• Every requirement must trace to either a Design Input or an intermediate design input that results from concept refinement.
Design Inputs – Preference Criteria

In this example, 1, 13, 8, 7, 12, 3 drive highest satisfaction

Charts are created for each actor type
Scores are combined based on actor importance

- Normalized Importance
- Current Satisfaction
- Planned Satisfaction

Company: A
- Medical Devices
- 1001-5000 employees
- North America
Quality Function Deployment

Weighted Customer and Business needs ("whats")

Product Requirements ("hows")

These should still be "solution free"

Product Requirements ("hows")

Weighted Selection Criteria

QFD House of Quality is a form of transfer function used to translate subjective ideas such as needs statements into hard, measureable requirements.
Practices To Determine Customer Requirements

Concept Development & Selection

- CTQs and weights are deliverables from the design input efforts (QFD-HOQ)
- A minimum of 3 valid concepts are developed for each iteration
- Each iteration brings improved alignment on requirements, concurrence on best features and eventual convergence
- Final deliverable contains the chosen concept, why it was selected, and what else was considered

The winning concept is then analyzed for requirements decomposition and to define structural architecture
Common Practices for Determining Customer Requirements
Tool/Method/Example Summary

- **Tool/Example Name:** Four Voices

- **General Description:**
  Determining Customer Requirements

- **Glossary of terms:**
  - Voice of Customer,
  - Voice of Business
  - Voice of Technology
  - Voice of Regulatory

- **Typical Uses:**
  - Identifying and determining customer requirements

- **Relevant FDA Regulations:**
  - 21 C.F.R. § 820.30
CTQ Practice Name:
List of Practices for Developing Design CTQs

• Integrated Global Quality System utilizing Product Life Cycle Process’s “Four Voices” using Series of guided questions according to Categories:
  ○ Voice of Customer
  ○ Voice of Business
  ○ Voice of Technology
  ○ Voice of Regulatory

• Questions are answered in structure format that is consistent across all projects.
  ○ Relevancy (y/n)
  ○ Current knowledge level (R/Y/G)
  ○ Open Response to question
  ○ How would you increase the level of knowledge (if not green)
How Do You Determine Customer Requirements?

Utilize Four Voices

<table>
<thead>
<tr>
<th>Four Voices</th>
<th>Leadership</th>
<th>Purpose</th>
<th>Guided Question Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voice of Customer</td>
<td>Led by Marketing</td>
<td>Refine &amp; capture VOC to obtain level of detail to identify user needs</td>
<td>Categories: Who is customer, customer needs, reimbursement, Regions,</td>
</tr>
<tr>
<td>Voice of Business</td>
<td>Led by Project Mgr</td>
<td>Refine &amp; capture VOB to obtain detail needed to create a detailed Project Plan</td>
<td>Categories: Financials, Capacity, supply chain, equipment, COGS, Site selections, relevant standards, complaints, CAPAs, Sustaining, Service burden, exit strategy</td>
</tr>
<tr>
<td>Voice of Technology</td>
<td>Led by R &amp; D</td>
<td>Previously identified knowledge gaps addressed so Global Regulatory Strategy be developed for selected design concept. Risks well characterized</td>
<td>Concept, Risks, Knowledge gaps, confidence in closing knowledge gaps, competitive landscape, leveragability, Strategy &amp; investment plans, time &amp; money estimates,</td>
</tr>
<tr>
<td>Voice of Regulatory</td>
<td>Led by RA</td>
<td>Ensure we ask right technical questions, see strong connection between needs and technical solutions, visibility to technology knowledge gaps and technical options</td>
<td>Categories: Intended use, Indications of Use, desired Market claims, mode of action, clinical evidence / success, device class, product description, Supporting data requirements, Materials, Sterilization, Standards /guidance, labeling, manufacturing, Post Market</td>
</tr>
</tbody>
</table>

You are currently viewing a featured section of AdvaMed’s Case for Quality Library. To view AdvaMed's Case for Quality website, click HERE. To view the full slide deck of AdvaMed's Design Control recommendations, click HERE.
Key Tools Used for Determining Customer Requirements
Key Tools Used

- Design for Six Sigma
- Voice of Customer
  - Qualitative & Quantitative methods
- Quality Function Deployment (House of Quality)
- KJ Analysis / Affinity Diagram
- Kano Satisfaction model
- Pugh Matrix
- Critical Parameter Management
- Clinical Opinion (with expertise in the area of interest)
- Risk Analysis
- Pairwise Analysis
Additional Tools for VOC Gathering and Analysis

- Qualitative methods
  - Focus Groups
- Quantitative methods
  - Surveys
  - Contextual Inquiry
  - Conjoint Analysis
  - Concept testing
Tool/Method/Example Summary

- **Tool/Example Name:** CTQ Flow Down

- **General Description:**
  Graphical representation to show how Voice of the customer translates to CTQ characteristics. Inputs and Output from marketing standpoint at various stages of product cycle.

- **Glossary of terms:**
  - **CTQ:** Critical to quality; **VOC:** Voice of customer
  - **DFMEA:** Design failure mode effect analysis
  - **PFMEA:** Process failure mode effect analysis

- **Typical Uses:**
  - CTQ cascade applies throughout the entire design process.

- **Relevant FDA Regulations:**
  - Applicable to all stages of Design Controls: 21 C.F.R. § 820.30
Practices To Determine Customer Requirements

CTQ Flow Down

Post Market Surveillance | Clinical | Marketing | Focus Groups | Repairs | Complaints | Regulatory

Voice of the Customer (User needs)

Therapy system shall deliver the prescribed negative pressure to the wound site when powered on

Technical Requirements

Therapy unit shall maintain pressure within ±x mmHg of target pressure

Part Drawings – (Link to DFMEA for Risk)

Therapy Unit, Canister, Dressing (e.g. drape), System Interactions (sub-assembly)

CTQ Characteristics

Pump Flow rate
Pump Diaphragm characteristics
Drape adhesive properties
Canister – Unit interface

Access Risk level from Top Down* and Usability * perspective

Link to DFMECA for Risk

Carry over to PFMEA

Link CTQs identified to Risk

Top Down: evaluates the potential risks from the system level perspective, before finalizing the design. Mitigations from Top down should be used as an input to the design.

Usability risk analysis: evaluates the potential hazards related to the use or misuse of the product.

You are currently viewing a featured section of AdvaMed's Case for Quality Library. To view AdvaMed's Case for Quality website, click HERE. To view the full slide deck of AdvaMed's Design Control recommendations, click HERE.
# Collecting Customer Inputs

<table>
<thead>
<tr>
<th>Concept</th>
<th>Planning</th>
<th>Development</th>
<th>Commercialization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Market Needs</strong></td>
<td><strong>Value Proposition</strong></td>
<td><strong>Product Requirements</strong></td>
<td><strong>Market Position</strong></td>
</tr>
<tr>
<td>Confirm level of unmet needs in market, multiple voice of customer avenues</td>
<td>Validate unmet needs, and provide initial forecast</td>
<td>Confirm customer product requirements and lock design.</td>
<td>Identify target market opportunities, confirm market plan including pricing.</td>
</tr>
<tr>
<td>Approach: VOC</td>
<td>Approach: Qualitative and Quantitative Concept Testing Early Product Usability studies</td>
<td>Approach: Conduct user research, employing appropriate market research methods, to identify required product attributes</td>
<td>Approach: Conduct customer market research to confirm product position, branding, pricing, distribution/packaging</td>
</tr>
<tr>
<td>- 3rd party reports</td>
<td>- Internal/External Interviews</td>
<td>- Primary &amp; Secondary Market research</td>
<td>- Various Databases</td>
</tr>
<tr>
<td>- Various Databases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output: Qualitative Assessment Reports Prototype development</td>
<td>Output: Qualitative and Quantitative Assessment Reports Concept Testing Reports</td>
<td>Output: Qualitative and Quantitative Assessment Reports Product Attributes Valuation</td>
<td>Output: Qualitative and Quantitative Assessment Reports Establish Global Pricing Bands</td>
</tr>
</tbody>
</table>
Tool/Method/Example Summary

- **Tool/Example Name:** Four Voices Guiding Questions

- **General Description:**
  Determining Customer Requirements by asking questions from different perspectives.

- **Glossary of terms:**
  - Voice of Customer,
  - Voice of Business
  - Voice of Technology
  - Voice of Regulatory

- **Typical Uses:**
  Identifying and determining customer requirements

- **Relevant FDA Regulations:**
  21 C.F.R. § 820.30
Guiding Questions

Voice of Customer
- Who makes or influences buying decision?
- Who received benefits articulated by the product iteration (clinician, patient, hospital)?
- Which physicians are important for this insight?
- How well are customers needs understood and defined?
- How will reimbursement be pursued by region?
- What if any are risks to reimbursement?
- How different is the job this product does from those of other products currently in use by customers?
- Is the project designed for specific regional needs that may not be present to the same degree in every market?

Voice of Business
- What strategic objectives does this investment satisfy and how likely is success?
- What are the cost constraints and how confident are we in staying within those constraints?
- What are the schedule constraints and how are we managing critical path?
- What are the minimum performances, claims, and competitive positioning’s?
- How complete is our project resourcing?
- How does this investments risk-weighted return on investment rank against other opportunities?
- Who makes or influences buying decision?
Guiding Questions

Voice of Regulatory

• What is the body system, condition or disease state that this device will treat?
• What specific indications will be pursued for this product (patient population, treatment locations?)
• What are the plans for different indications by region?
• What specific expanded indications will be pursued for this product?
• What are the plans for expanded indications by region?
• How will any market claims be supported by pre-clinical, clinical, and/or bench data?
• How do these claims impact indications for intended use?
• How novel or revolutionary is the technology to the therapy?
• How is mode of action defined?

Voice of Technology

• What is the technology idea or concept?
• What four voices are being satisfied, and the level of satisfaction if this technology is successful?
• What are the risks (technical, clinical, regulatory, reimbursement, business)
• How thoroughly have technical knowledge gaps been identified and how large are these?
• What is the confidence in closing these knowledge gaps?
• How leveragable is the technology across the company?
• What is the IP landscape surrounding this technology concept or Four Voices need?
• What is the status of the company’s filings for this concept?
• Is the company free to operate with this technology concept?
• What are the competing technology options and their likelihood of success?
Practices To Determine Customer Requirements

Tool/Method/Example Summary

- **Tool/Example Name:** NPD [New Product Development] CTQ [Critical to Quality] Cascade Tools
- **General Description:**
  Once a product or process characteristic is identified as being important to meeting a customer requirement, there is a need to ‘translate’ that item into a parameter that can be used to produce the product. There are various tools that can used to accomplish this.

- **Glossary of terms (specific to this tool/example):**
  - **Critical to Quality (CTQ):** A product or process characteristic, which is quantifiable and measurable, that has been determined to be critical to meeting customer requirements and to the proper functioning of the device.
  - **Pugh Matrix:** Is a quantitative technique used to rank the multi-dimensional options of an option set, e.g. is concept ‘a’ better than concept ‘b’ or ‘c’.
  - **DOE:** Design of Experiment is a statistical tool used to evaluate impact of multiple factors on a set of output variables. **Robust Design [Taguchi Method]** is a subset of DOE designed to find the optimum settings for given parameters. **Transfer Function** is a mathematical representation of the relationship between a set of design factors and output variables.
  - **House of Quality:** Also called QFD [Quality Function Deployment] is tool used to systematically translate customer requirements into quantitative parameters that can be used to produce a given product.
  - **DFSS [Design for Six Sigma] Scorecard:** Tool used to capture optimum parameters for producing a given product at high quality levels [6 sigma].
  - **Requirements Document:** Document used at various stages of the design process to identify product requirements starting with the customer and then honing in on detailed requirements for production.
  - **Sub-Team Interaction Management:** Graphical tool to allow a team to identify potential interaction and manage them

- **Typical Uses:**
  - CTQ cascade applies throughout the entire design process, use of tools typically go from qualitative to very quantitative as designs are finalized and ready for production.

- **Relevant FDA Regulations (specific 21CFR sections):**
  - Applicable to all stages of 820.30 Design Controls
Tool/Method/Example Summary

- **Tool/Example Name:** Pairwise Comparison Chart

- **General Description:**
  Chart is used to graphically show how specific customer input would rank features or requirement just two at a time. Then the resulting Pareto chart show the relative preferences for ranking overall customer needs/requirements.

- **Typical Uses:**
  - Multi-varied language; used to articulate the detailed functional customer needs

- **Relevant FDA Regulations:**
  - CFR §§ 820.30(B), and 820.30(C)
## Determining Key Customer Requirements

### Tool example

**Pairwise Comparison Chart**

<table>
<thead>
<tr>
<th></th>
<th>functionality</th>
<th>durability</th>
<th>quality</th>
<th>affordability</th>
<th>fabricability</th>
<th>usability</th>
<th>maintainability</th>
<th>safety</th>
<th>marketability</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
<tr>
<td>functionality</td>
<td>A</td>
<td>-</td>
<td>A</td>
<td>C</td>
<td>D</td>
<td>A</td>
<td>F</td>
<td>A</td>
<td>AH I</td>
</tr>
<tr>
<td>durability</td>
<td>B</td>
<td>-</td>
<td>-</td>
<td>C</td>
<td>D</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>H BI</td>
</tr>
<tr>
<td>quality</td>
<td>C</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>D</td>
<td>C</td>
<td>F</td>
<td>C</td>
<td>H C</td>
</tr>
<tr>
<td>affordability</td>
<td>D</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>D</td>
<td>F</td>
<td>D</td>
<td>D I</td>
</tr>
<tr>
<td>fabricability</td>
<td>E</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>F</td>
<td>E</td>
<td>H E</td>
</tr>
<tr>
<td>usability</td>
<td>F</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>F</td>
<td>FH</td>
<td>I</td>
</tr>
<tr>
<td>maintainability</td>
<td>G</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>H</td>
<td>I</td>
</tr>
<tr>
<td>safety</td>
<td>H</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>H</td>
</tr>
<tr>
<td>marketability</td>
<td>I</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

1. Each requirement is ranked against all others
2. The superior requirement letter is recorded in the box
3. Count the number of occurrences of each requirement
4. Pareto the results

### Total Counts

|          | 4 | 4 | 5 | 6 | 2 | 6 | 0 | 7 | 5 |

---

**Company:**

- Medical Devices
- 10,001 + employees
- Global
## Pairwise Comparison - Example

<table>
<thead>
<tr>
<th></th>
<th>Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Safety</td>
</tr>
<tr>
<td>B</td>
<td>Affordability</td>
</tr>
<tr>
<td>C</td>
<td>Usability</td>
</tr>
<tr>
<td>D</td>
<td>Quality</td>
</tr>
<tr>
<td>E</td>
<td>Marketability</td>
</tr>
<tr>
<td>F</td>
<td>Functionality</td>
</tr>
<tr>
<td>G</td>
<td>Durability</td>
</tr>
<tr>
<td>H</td>
<td>Fabricability</td>
</tr>
<tr>
<td>I</td>
<td>Maintainability</td>
</tr>
</tbody>
</table>

### Pareto Chart: Customer Requirements (Counts)

- **Safety**: 7
- **Affordability**: 6
- **Usability**: 6
- **Quality**: 5
- **Marketability**: 5
- **Functionality**: 4
- **Durability**: 4
- **Fabricability**: 2
- **Maintainability**: 0
Customer Requirements Translation Guidelines

• 1. Identify the functional need
  • What the customer would like to be able to do (Avoid statements of means = no solutions!)

• 2. Make it as specific as possible
  • Avoid abstract terms

• 3. Use multi-valued language
  • Articulate the degree of functionality needed

Tips:
• Use an action verb: this identifies the functionality that’s missing for the customer (the multi-valued part identifies the degree that’s missing)
• Put statements in positive form
Roles for Determining and Analyzing Customer Requirements

Day to Day Role & Responsibilities

- Gathering requirements (inputs) for local projects prior to approval including:
  - Device requirements from business
  - Additional Component Inputs (CAPA, Standards, etc.)
  - Business Inputs (PSD, Manufacturing, HVF, Component Eng, etc.)
- Entering local inputs and requirements into project tool (OR managing on paper)
- Owning project deliverable for requirements flow down (trace)
- Owning overall metrics associated with technical rigor and maturity of requirements
- Ensuring all requirements have proper verification and validation
- Providing enhancement requests to configuration resource

Required Skills

- Technically competent, confident voice at business unit for early design decisions
  - Participant in technical reviews at
  - Note: quality agreement currently states supplier will review customer’s Design Inputs
- Blackbelt / six sigma expertise.
- Average User knowledge of ARM
Manage Various NPD CTQ Cascade Tools

- Pugh Matrix
- DOE's
- DFMEA
- PFMEA
- Robust Design

Transfer Functions (Minitab, Matlab, Excel, etc)

DFSS Scorecards

Sub-Team Interaction Management

Company:
- Hospital & Health Care
- 10,001+ employees
- Global

“Source: Cognition Corporation”
Tool/Method/Example Summary

- **Tool/Example Name:** Unified Model
- **General Description:**
  This systematic approach captures the requirements to ensure that information is traced and maintained throughout the product development process. This also provides a mechanism to document relationships (conflicting or associated), specifications, test methods and capability metrics. Once the vital few characteristics are identified, the CTQs will be documented on the CTQ Scorecard.

- **Glossary of Terms:**
  - **KJ Analysis** – a group consensus technique that allows groups to quickly reach a consensus on priorities of subjective, qualitative data.

- **Typical Uses:**
  - This tool is utilized throughout the product development process.

- **Relevant FDA Regulations:**
  - 21 C.F.R. § 820.30 design controls
• **Templates:**

As you use the templates, your product data is being captured and a Unified Model is being created.

- Templates distill best practices into “TurboTax-like” process steps
  ↓
  Standardized deliverables from project to project.

- Product data flows from one template to the next, resulting in improvement to efficiency and user adoption.

• **End-to-End Connectivity and Traceability:** A system for capturing, tracing, and managing all the product development data
  – One environment
  – One database
  – One user interface
  – One installation
    (lean Web deployment)

  – One system that combines:
    • VOC Management
    • Requirements Management (INCOSE)
    • Risk Management
    • Test Management
    • Critical Parameter Management (DFSS)
    • Meeting and Action Management
    • DTV
    • Test method links
    • Flow up and flow down
    • Relationship reliability
    • Transfer functions if they exist

• **Indexed**
Activity Templates to Match Your Product Development Process

– Each level of Flow down reflects:
  • Relationships with parent, child and sibling requirements (multiple views)
  • Justification of stated relationships
  • Specifications
  • Test Methods
  • Capability metrics

– Risks
  • Relationships with parent and child risks

Needs/Voice Collection Capabilities

– Word templates for automatic interview and survey imports
– Interview and Survey results summary automatically generated
– KJ Analysis to organize raw voice inputs
– Affinity diagrams with red and blue groupings sort inputs
Requirements Scorecard

• Scorecard to report capability and capability growth
  – Initial capability listed under **Design**
  – Make a change; new capability under **Test**
**Template Example of CTQ Scorecard**

<table>
<thead>
<tr>
<th>System Name</th>
<th>Product Code</th>
<th>Owner</th>
<th>Date</th>
</tr>
</thead>
</table>

**Performance Level CTQ Scorecard**

<table>
<thead>
<tr>
<th>(VOC)</th>
<th>Product Level Requirement CTQ</th>
<th>Target Value</th>
<th>Design Prediction</th>
<th>Prototype Results (Including Engineering Builds)</th>
<th>Design Verification</th>
<th>Process Validation Data</th>
</tr>
</thead>
</table>

**Company:**
- Hospital & Health Care
- 10,001+ employees
- Global

---

“Source: Cognition Corporation”
Quality System Process Approaches:

*Superstructure Model*
Tool/Method/Example Summary

- **Tool/Example Name:** Global Quality System Architecture

- **General Description:**
  Global Quality System Superstructure

- **Glossary of terms:**
  - Global Quality System
  - ISO 13485 Process Based Model
  - Simplicity and Agility.

- **Typical Uses:**
  - Quality System Architecture

- **Relevant FDA Regulations:**
  - 21 C.F.R. Part 820
Global Quality System Superstructure

**Integrated REQUIREMENTS**

- **Single Global Quality Manual**
- **8 Global Process Policies**
- **38 Global Sub-Process SOPs**

**Global SOP’s & WI wherever feasible**

**EXECUTION**

- **Global SOP’s & Work Instructions**
- **Site/Div. SOP’s & Work Instructions**

**Global Quality Process Map**

- Global structure facilitates compliance to universal policy level requirements by establishing Global Sub-Process SOPs
- Global Sub Process SOPs either provide standardized approach for all business units or serves as bridge document to existing SOP structure during transition period
## Global Quality System

### Quality System Globalization

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>TYPES OF INFORMATION</th>
<th>CURRENT STATE</th>
<th>FUTURE STATE</th>
<th>EXAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEVEL 1</strong></td>
<td><strong>Global Quality Manual</strong></td>
<td>The Global Quality Manual describes the Quality System architecture and provides the description and scope of each BSC Quality System sub-process</td>
<td>Global</td>
<td>Global</td>
</tr>
<tr>
<td><strong>LEVEL 2</strong></td>
<td><strong>Global Policies</strong></td>
<td>Global Policies identify the Quality System requirements based on established interpretation of applicable regulations, standards and guidelines</td>
<td>Global</td>
<td>Global</td>
</tr>
<tr>
<td><strong>LEVEL 3</strong></td>
<td><strong>Standard Operating Procedures</strong></td>
<td>Standard Operating Procedures identify business requirements, processes, systems and procedures established to meet applicable Policy requirements.</td>
<td>Mix of Global and Local SOPS</td>
<td>Global</td>
</tr>
<tr>
<td><strong>LEVEL 4</strong></td>
<td><strong>Work Instructions</strong></td>
<td>Work Instructions identify task based actions for executing the requirements in the SOPs</td>
<td>Mix of Global and Local SOPS</td>
<td>Global, where appropriate</td>
</tr>
</tbody>
</table>

Driving towards “**Level 4** Global standards” to enable *simplicity and agility* in our Global Quality System.
Quality System Process Approaches:

Value Stream Model
**Tool/Method/Example Summary**

- **Tool/Example Name:** Value Stream Map

- **General Description:**
  Graphically illustrates a high level process flow from suppliers to the customer(s)

- **Glossary of terms (specific to this tool/example):**
  - Value Stream Map; Lean Six Sigma term meaning to show how value flows to the customer by showing key value adding processes and sequences.

- **Typical Uses:**
  - For any process mapping needs where customer value flow needs to be identified.

- **Relevant FDA Regulations (specific 21CFR sections):**
  - All 21 C.F.R. § 820.30 sections but primary uses in §§ (b), (c), (d), (e)
Medical Device Product Life Cycle
Macro Value Stream Map
### Deliverables by Stage

<table>
<thead>
<tr>
<th>Concept</th>
<th>Feasibility</th>
<th>Development</th>
<th>Qualification</th>
<th>Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Identify high level customer Requirements</td>
<td>✓ Complete a Design Concept</td>
<td>✓ Complete Product Specifications (parameter design)</td>
<td>✓ Identify Process CTQs / Controls</td>
<td>✓ Reconcile product/process performance against project scope</td>
</tr>
<tr>
<td>✓ Develop a Business Plan</td>
<td>✓ Technical Feasibility</td>
<td>✓ Design for Assembly &amp; Cost</td>
<td>✓ Complete Validation and Validate CTQ’s</td>
<td>✓ Ensure Future Success</td>
</tr>
<tr>
<td>✓ Develop high level Functional Requirements (performance CTQs)</td>
<td>✓ Define Design Parameters and Product Design CTQs</td>
<td>✓ Design Risk Assessment</td>
<td>✓ Design Transfer Review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Design Risk Assessment</td>
<td>✓ Complete Design Verification Tests</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Quality System Process Approaches:

Product Development Model
Tool/Method/Example Summary

- **Tool/Example Name:** Scope of CTQ Cascade

- **General Description:**
  Once a product or process characteristic is identified as being important to meeting a customer requirement, there is a need to ‘translate’ that item into a parameter that can be used to produce the product. The ‘Cascade’ refers to the action of taking customer insights and translating them into parameters that can be used to design and produce the device from various stakeholder perspectives, including regulatory requirements globally. Often times the cascade takes into account ‘Total Cost of Ownership’ of the devices with items such as training, after sales servicing and end of life disposal. There are various tools that can used to accomplish this.

- **Glossary of terms:**
  - **HOQ [House of Quality]:** Also called QFD [Quality Function Deployment] is tool used to systematically translate customer requirements into quantitative parameters that can be used to produce a given product.
  - **Pugh Matrix:** Is a quantitative technique used to rank the multi-dimensional options of an option set, e.g. is concept ‘a’ better than concept ‘b’ or ‘c’.
  - **Mind Mapping:** Use of a drawing or diagram to visually represent a concept or idea and associated ideas.
  - **DTV [Design to Value]:** A multifaceted approach to design which considers customer insights, quality, cost, knowledge management, & governance.

- **Typical Uses:**
  CTQ cascade applies throughout the entire design process, use of tools typically go from qualitative to very quantitative as designs are finalized and ready for production.

- **Relevant FDA Regulations:**
  Applicable to all stages of 21 C.F.R. § 820.30 Design Controls.
Key Activities in a Product Development Process

CTQ Cascade Scope: End-to-End

Silos of Knowledge

VOC/B/T/R*
- Customer Interviews
- HOQ
- Affinitize

Concept Exploration
- Pugh
- HOQ
- Concept Selection

Requirements Definition
- HOQ
- Rationale
- Risks
- Multi Target Goals
- Mind Mapping

Requirements Management
- Analytical based Active RM (includes CPM with transfer functions)

Validation & Verification
- Scorecards
- Flow Up Variation
- Risk Management (HA/DFMEA/PFMEA/Controls)
- Test Feedback
- Supplier Proc. Cap.
- Transfer Functions

DTV: Cost Management, Tracking, & Cost Reduction Initiatives

*Voice of Customer, Business, Technology, Regulatory, etc.
### Practices To Determine Customer Requirements

**Understand Consumer Requirements**

**Define Technical Requirements**

**What Parts are Affected**

**CTQ Characteristics (How are they affected)**

**Are we capable**

<table>
<thead>
<tr>
<th>Understand Consumer Requirements</th>
<th>Customer Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define Technical Requirements</td>
<td>Establish measureable testing methods</td>
</tr>
<tr>
<td>What Parts are Affected</td>
<td>Determine parts affected</td>
</tr>
<tr>
<td>CTQ Characteristics (How are they affected)</td>
<td>Establish dimension of part that effect the Technical requirements (Y)</td>
</tr>
<tr>
<td>Are we capable</td>
<td>Measure parts; establish Capability, Calculate Z-score</td>
</tr>
</tbody>
</table>

**Driving decisions with data, not Opinion**
Practices To Determine Customer Requirements

Managing Requirements

Design Inputs Requirements

1. OUTPUT (e.g. System Requirements) becomes an INPUT to next level flow down
2. OUTPUT (e.g. Hardware Specification) becomes an INPUT to next level flow down

Component Reqs

Design Review

100% Traceable
with Verification that Outputs satisfy Inputs at every level

Final Design Outputs

1. Product Design
   - Drawings
   - Material Specs
   - etc.
2. Process Controls
   - Work Instructions
   - Control Plan
   - etc.

Trace to Design Outputs

Process Planning Matrix
Quality System Process Approaches:

Critical Parameter Management Model
Tool/Method/Example Summary

- **Tool/Example Name:** CTQ Lifecycle Model

- **General Description:**
  This Critical to Quality lifecycle model shows the derivation of critical characteristics and the tools and processes used to capture, determine capability, and drive continuous improvement feedback loops.

- **Glossary of terms:**
  - CTQ, DFSS, Deployment

- **Typical Uses:**
  - Used as a descriptor of how critical to quality parameters are captured and managed throughout the product lifecycle

- **Relevant FDA Regulations:**
  - 21 C.F.R. §§ 820.20, 820.30, 820.70, 820.75, and 820.100

- **Notes:**
  - This is a conceptual high level CtQ deployment model showing the touch points for CtQ parameters throughout the Quality Management System
Critical Parameter Management Process Model

Practices To Determine Customer Requirements