CtQs in Design Controls

Company Presentations

Individual presentation from member companies on how they use CtQs in design controls.
If you see this icon by the AdvaMed logo on the page, that means this slide contains interactive, live links.

**Text In Blue**

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 to the previous sequential page from where you are 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.
Navigating The Main Table Of Contents Page For Company Presentations

Click on the letter to go to that company’s CtQ in Design Controls Presentation

Navigating Within A Company's Presentation Slides

Takes you to Table of Contents for that company’s presentation

Takes you back to the Case for Quality Library main page

Takes you to the Main Table of Contents where you can select other company presentations
CtQs in Design Controls Company Presentations

Individual presentation from member companies on how they use CtQs in design controls.

Company: A
- Medical Devices
- 1001-5000 employees
- North America

Company: B
- Medical Devices
- 10,001 + employees
- Global

Company: C
- Medical Devices
- 10,001 + employees
- Global

Company: D
- Medical Devices
- 10,001 + employees
- Global

Company: E
- Medical Devices
- 1001-5000 employees
- Global

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

Company: G
- Medical Devices
- 5001-10,000 employees
- Global

Company: H
- Medical Devices
- 10,001 + employees
- Global

Company: I
- Medical Devices
- 10,001 + employees
- Global

Company: J
- Medical Devices
- 10,001 + employees
- Global

Company: K
- Medical Devices
- 10,001 + employees
- Global
CtQs in Design Control

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9. Bill of Documents – A Configuration
10. Design Worksheet: Robustness vs. Undesired Variation
11. Design Worksheet: Reliability
12. V-Model
13. The 5 Core Principles
14. Impact of Embracing the 5 Core Principles
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.**
CtQs in Design Control

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
CtQs in Design Control

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.
CTQs in Design Control

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
Requirements Cascade

3 elements of a cascade
- Parent requirement \([y]\)
- Child requirement \([x]\)
- Transfer function \([f()]\)

- \(Y\) Requirements guide concept development and selection
- Concepts dictate transfer functions
- Design worksheets determine \(Xs\)
Ishikawa

An Ishikawa is just a requirements cascade done to discover relationships that should (and may) have already been known.
Mental Model #3: The Three Building Blocks

#1: Identify & Design Requirements
ACCOUNTING & PLANNING

#2: Develop & Select Concepts
INNOVATION & CREATIVITY

#3: Identify Transfer Functions & Deploy
ENGINEERING & SCIENCE

These three steps are repeated at successive levels until the design is complete.
The collection of all BOD configurations for a product is the DHF
CtQs in Design Control

Design Worksheet: Robustness vs. Undesired Variation

Nominals and tolerances are consciously selected to ensure the design and its processes are capable.
Design Worksheet: Reliability

CtQs in Design Control

Individual contributors are much easier to estimate reliability than complex systems.

Infant mortality is a failure rate that decreases with time.

Reliability is a failure rate that increases with time.

Robustness is a failure rate that is constant with time.
CtQs in Design Control

V-Model

User Needs

System Requirements

L2 Requirements

MFG Processes

Process Validation

Validation

System verification

L2 verification

…

…
The 5 Core Principles

1. **Product design is simply the successive refinement of requirements**
   All specifications are simply means to communicate requirements to the next level of hierarchy through an unbroken cascade.

2. **Nothing is more important to success than managing requirements**
   Requirements must be complete, concise, unambiguous, measurable and wholly transparent to all participants. They are the basis for schedules, reviews, testing, metrics, regulatory submissions, customer satisfaction, and continuous improvement.

3. **Mitigations and residual risks are requirements that must be managed**
   All failure modes, including use error & foreseeable misuse, must be traced to hazardous situations & all hazardous situations must be traced to potential harms.

4. **Evidence of conformance must identify the design configuration**
   Prototypes are cost, not progress. *Learning* is progress. Configurations used for verification must include assessments showing the configuration tested is equivalent to the design being released.

5. **Program Management relies on standard work and objective metrics**
   # +Δ requirements, # +Δ protocols w/GR&R, # +Δ protocols run, % +Δ req verified, % +Δ processes w/capability estimated, % +Δ processes w/capability verified. Chronological hours since last formal customer feedback, fever chart $$ vs plan.
Impact of Embracing the 5 Core Principles

1. **All activities are driven from requirements**
   All design documents, regulatory submission elements, promotional materials, complaint files, clinical studies, labeling and other product related artifacts are either requirements or controlled translations of requirements.

2. **Collaboration increases exponentially**
   The common language and transparency of the cascade vaccinates organizations against parochialism by making information universally available, providing forums for discussion and standardizing work systems.

3. **Systems Engineering becomes a critical competency**
   Systems Engineers ensure all a product’s transfer functions are solved simultaneously. This is true during initial design and throughout the product lifecycle.

4. **Progress, and lack of progress, are transparent**
   Metrics are objective and standardized for every program.

5. **Onboarding and Knowledge Transfer are simplified**
   All product knowledge is recorded and linked by the requirements cascade.

6. **Cycle time for changes drops by 70% or more**
   The cascade simplifies impact analysis, reduces design iterations, and streamlines investigations.
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7. Common VOC Questionnaire  
8. Definition Phase  
9. House of Quality  
10. VOC Priorities and Classification (Kano Analysis)  
11. Kano Analysis  

## Company: B  
- Medical Devices  
- 10,001 + employees  
- Global
Background

- Global Product Development System (GPDS)
- Methodologies Used:
  - Design for Six Sigma (DFSS) and Critical Parameter Management (CPM)
  - Requirements Mgt. (RM) Process
- Nomenclature is Slightly Different:
  - CTQ Used Primarily in Six Sigma
  - Critical to Function, Critical Parameters Used in Product Development (DFSS)
  - Somewhat Synonymous
- GPDS, DFSS, CPM, RM aligned with 21CFR 820
Acronyms

- GPDS = Global Product Development System
- RM = Requirements
- DFSS = Design for Six Sigma
- CPM = Critical Parameter Management
- VOC = Voice of the Customer
- VOB = Voice of the Business
- VOP = Voice of the Process
- TDM = Technology Development Matrix
- Cp = Capability Index
- CTF = Critical to Function
- CFR = Critical Functional Response
- DOE = Design of Experiments
- MSA = Measurement System Analysis
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
## CtQs in Design Control

**Phase Gate Process – DFSS vs Design Control**

<table>
<thead>
<tr>
<th>Phase 0</th>
<th>Phase 1</th>
<th>Phase 2A</th>
<th>Phase 2B</th>
<th>Phase 3</th>
<th>Phase 4</th>
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<tr>
<td>Concept</td>
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<td>Development A</td>
<td>Development B</td>
<td>Qualification</td>
<td>Launch</td>
<td>Post Launch</td>
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</table>

**Design Reviews**
- Project Mgt.
- Project FMEA
- Monte Carlo
- Models
- Market Research
- VOC Gathering
- KJ Maps
- VOC Analysis
- Conjoint
- QFD & HRA
- Requirements
- Document
- Functional
- Modelling
- System
- Architecture
- 1st Principles
- Modelling
- Concept
- Generation
- Engineering
- Design Principles
- Concept
- Evaluation & Selection - Pugh
- Design Input
- Design Output
- Design Verification
- Design Transfer & Process Validation
- Design Review
- Design Change
- Design Change
- Design Change
- Risk Management (ISO 14971)

**DFSS Reviews**
- Critical Parameter Management
- DFx
- DOE
- Design for Manufacture and Assembly, Cost, Environment etc.
- D/A/FMEA
- DFMEA
- Measurement
- Systems Analysis
- Analysis
- Critical Parameter Management
- Advanced Design of Experiments
- Mixture Experiments
- Robust Design
- Taguchi Methods
- HAST
- HALT
- Response Surface
- Methodology
- Multiple Y Response Optimization
- Reliability Testing
- Noise
- Maps/Diagrams
- Lean Mfg

**CER Reviews**
- Six Sigma
- DMAIC
- Lean
- Lessons Learned
- Design Capability
- Assessment
- Mfg Capability Assessment
- Reliability Testing
- HAST
- HALT
- Multi-Vari
- Capability Analyses
- SPC
- Lean
- Mistake Proofing
- SS
- TPM
- SMED
- VSM

**Company:**
- Medical Devices
- 10,001 + employees
- Global
## Phase Gate Process – Key tools used @ Phase

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<thead>
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<th>Concept</th>
<th>Definition</th>
<th>Development</th>
<th>Qualification</th>
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<td>• Monte Carlo Models</td>
<td>• Critical Parameter Management</td>
<td>• Critical Parameter Management</td>
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<td></td>
<td>• KJ VOC Analysis</td>
<td>• Design / Application FMEA</td>
<td>• Design Capability Assessment</td>
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<tr>
<td></td>
<td>• QFD / HoQ</td>
<td>• Measurement Systems Analysis (MSA)</td>
<td>• Mfg Capability Assessment</td>
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<td></td>
<td>• Concept Eval &amp; Selection - Pugh Matrix</td>
<td>• Screening / Advanced DOE’s</td>
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<td>• Transfer Functions : Defined, Ranked &amp; Prioritized</td>
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<td></td>
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<td>• Monte Carlo simulations</td>
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</table>

**Company:**
- Medical Devices
- 10,001 + employees
- Global
Concept & Definition Phase: Multiple tools for VOC Gathering & Analysis

- Qualitative methods
  - Focus Groups
- Quantitative methods
  - Surveys
  - Contextual Inquiry
  - Conjoint Analysis
  - Concept testing
Common VOC Questionnaire

VOC Questions

ANSWERS

I like it that way
It must be that way
I am neutral
I can live with it that way
I dislike it that way

QUESTIONS

1a. If the delivery device is tamper evident, how would you feel?
1b. How would you feel if the delivery device was not tamper evident?

2a.
2b.

3a.
3b.

4a. If the delivery device had dead volume , how would you feel?
4b. How would you feel if the dead volume in the delivery device was more than ?

5a.
5b.

6a. If the delivery device was smaller than , how would you feel?
6b. How would you feel if the delivery device was larger than ?

7a. If the delivery device had the ability to be terminally sterilized after , how would you feel?
7b. How would you feel if the delivery device could not be terminally sterilized ?

8a.
8b.
9a.
9b.

Answers targeted to aid in creation of Kano Analysis
Definition Phase:

• House of Quality used to Cascade requirements
  – Customer requirements vs. Design requirements
  – Design requirements vs. Engineering design
  – Engineering design vs. Product Characteristics
  – Product characteristics vs. Manufacturing operations reqmts
  – Manufacturing operations requirements vs. Production/ controls
• Consider the “Other Voices” – Business & Process
## House of Quality

### Design Requirements

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</table>

**Customer Rank** | 0.48 | 3 | 2 |
**Our Performance** | 0.32 | 1 | 3 |
**Competitor Performance** | 0.15 | 0 | 4 |

### Weighted Importance Scores

| | 4.32 | 1.44 | 1.44 | 4.32 | 4.32 | 2.88 | 0 | 0 | 1.44 | 1.44 | 3.15 | 1.05 | 1.05 | 1.35 | 0.45 | 1.35 | 8.01 | 4.32 | 4.32 | 4.32 | 2.67 |

### Normalized Importance Scores

| | 8 | 3 | 8 | 8 | 6 | 0 | 0 | 3 | 3 | 6 | 2 | 2 | 3 | 1 | 3 | 16 | 8 | 8 | 8 |

### Units of Measure

| uL | uL | % | uL | uL | inches cubed | SAL | ratio | % | mm |
## VOC Priorities & Classification (Kano Analysis)

<table>
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<th>Top Priorities</th>
<th>Core team classification</th>
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<td>Device needs to be tamper evident prior to use.</td>
<td>Delighter</td>
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<td>Device needs to minimize size for storage.</td>
<td>Linear</td>
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<td>The device needs to be intuitive with minimal training.</td>
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<tr>
<td>the device must withstand extreme hot (60C) and cold temperatures (-78C)</td>
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<tr>
<td>device functionality has to be consistent and reproducible</td>
<td>Basic</td>
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<tr>
<td>Low cost device is important</td>
<td>Delighter</td>
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</table>

Company: B
- Medical Devices
- 10,001 + employees
- Global
## Kano Analysis

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</tbody>
</table>
Table of Contents

1. **Tool/Method/Example Summary**: Global Quality System Architecture
   - a. ISO 13485 Process Based Model / Process Approach
   - b. Global Quality System Superstructure
   - c. Global Quality System
   - d. Product Life Cycle Process

2. **Tool/Method/Example Summary**: Risk Management, CTQ monitoring program
   - b. CTQ Practice: Usage in Manufacturing
   - c. CTQ Monitoring
   - d. Translating User Needs Into Design Inputs
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
CtQs in Design Control

Global Quality System Overview

Construction Approach

ISO 13485 Process Based Model

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

<table>
<thead>
<tr>
<th>Quality System Globalization</th>
<th>TYPES OF INFORMATION</th>
<th>CURRENT STATE</th>
<th>FUTURE STATE</th>
<th>EXAMPLE</th>
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<td><strong>LEVEL 1</strong></td>
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<tr>
<td>Global Policies</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>
<td><img src="example2.png" alt="Example" /></td>
</tr>
<tr>
<td><strong>LEVEL 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Operating Procedures</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>
<td><img src="example3.png" alt="Example" /></td>
</tr>
<tr>
<td><strong>LEVEL 4</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work Instructions</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>
<td><img src="example4.png" alt="Example" /></td>
</tr>
</tbody>
</table>

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

• Utilize Global Quality System
  • Global Quality Manual
  • 8 Global Processes – Standardized at the Policy level
    o Quality System Management
    o Document & Records Control
    o Design Controls
    o Product Approvals
    o Material Controls
    o Production & Process Controls
    o Post Market Support
    o CAPA

• SOP/WI standardization - based on business needs
• Stewardship model – process ownership and communities of practice
• Utilize Product Life Cycle Process (PLCP) as a business practice for product development and managing the product lifecycle
CtQs in Design Control

Product Life Cycle Process

- The PLCP is a global process that integrates business, technical and quality system tasks to drive innovative product ideas from strategy through commercialization, to end-of-life.
  - Global
  - Web-based
  - Linkages to the Global Quality System
  - Use of Knowledge Sharing Documents (KSDs)
  - Reinforces behaviors by working together across BSC
  - Enables us to simplify/continuously improve processes and systems
Product Life Cycle Process

Model is Global Regulation Based and Integrated

- 8 Global Processes – Standardized at the Policy level
  - Quality System Management
  - Document & Records Control
  - Design Controls
  - Product Approvals
  - Material Controls
  - Production & Process Controls
  - Post Market Support
  - CAPA

- SOP/WI standardization - based on business needs
- Stewardship model – process ownership and communities of practice
- Alignment throughout the Product Life Cycle Process (PLCP) as a business practice for product development and managing the product lifecycle
Tool/Method/Example Summary

- **Tool/Example Name:** Risk Management, CTQ monitoring program

- **General Description:**
  CTQ monitor program to predict and prevent unfavorable behavior

- **Glossary of terms:**
  - Risk Management, Fault Tree Analysis, Design FMEA, Use FMEA, Critical To Quality, In Process Monitoring, Response Flow

- **Typical Uses:**
  - Patient Safety, Process Control, predict and prevent unfavorable behavior

- **Relevant FDA Regulations:**
  - 21 C.F.R. §§ 820.30 & 820.70
Risk Management is integrated into design and development process as part of the PLCP (Product Life Cycle Process).

Risk Analysis includes device specific hazards, harms and risks associated with the design, manufacture, distribution and use of the medical device.

Risk Evaluations drive quality acceptance test levels and criteria.

Level 3 represents unacceptable harm and level 0, 1, & 2 drive verification & validation confidence statements which must be met.
CTQ Practice: Critical to Quality Usage in Manufacturing

- CTQ selection leverages Risk based analysis processes to evaluate key processes and the impact on patient safety.

- Risk based acceptable/unacceptable levels are used to assess “Vulnerable” Processes with Failure Mode with high severity and RI (RI: 2 / Severity: 4/5).

- While not a Global standardized approach to CTQ implementation, easily scalable. Many facilities are utilizing the model depicted in the following slide.
Why? CTQ monitor program is recommended to predict and prevent unfavorable behavior

What? CTQ is a potentially vulnerable failure mode or process that is key to assure patient safety

CTQ Screening:
- Failure Mode with high severity and RI (RI: 2 / Severity: 4/5) –link to Risk Management processes.
- Vulnerable process - High Scrap, NCEPs and/or Complaints
- Potentially affects patient safety

1. Perform a failure mode screening according to the CTQ decision flow and create a preliminary list
2. Discard and select CTQs with proper rationale
3. Propose and analyze ideas for making more robust each selected CTQ
4. Create an implementation plan for the ideas selected
5. Follow up and update plan

Options

IPM
Response Flow
Translating User Needs into Design Inputs

- Translates User Needs into Design Inputs
  - Assess Risks
  - Initiate Market Specification
  - Develop product specifications
- Develop prototypes
  - Identify possible design concepts, Test methods, design prototypes, evaluate prototypes
- Develop equipment & process
  - Assess process technology, develop and execute equipment strategy
- Define Supply Chain
  - Define supplier plan, define concept builds, establish supply chain strategy
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3. **Critical to Quality Characteristics – Key Points**
4. **Tool/Method/Example Summary: Value Stream Map**
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   - b. Deliverables By Stage
   - c. Prioritizing Customer Requirements
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   - c. Selecting Your CtQs
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10. Tool/Method/Example Summary: Analytic Hierarchy Process Excel Tool
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Objectives

• Recommended Methods for Critical to Quality (CtQ) parameters development
  – Prioritizing customer requirements
  – Developing the flow-down of requirements
  – Quality Assurance planning

• Introducing methods to improve CtQ capabilities
Quality Variation Explained

• There are three basic types of variation that contribute to Quality Loss:
  – Condition of the customers use
  – Variation of the parts (process)
  – Wear and deterioration

• CtQ selection should consider all three types of variation, but CtQs are tested for variation of the part/product against specifications.

• Design specification should cover conditions of customer use, wear, and deterioration.
What Are the Customer Requirements?

• Critical to Quality Characteristics – Key Points
  
  – All new PDP projects shall select CtQ(s) based on critical customer requirements by the completion of the development stage.

  – Final CtQ(s) should be approved by the Project Manager, R&D Technical Leader, and the Design Quality Assurance representative for the project.
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

- Patient/Customer Needs
- Pre-Concept
- Concept
- Feasibility
- Development
- Qualification
- Launch
- Post Market Surveillance

Customer:
- Patient
- Regulatory Authorities
### CtQs in Design Control

#### Deliverables by Stage

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

---

**Company:** Medical Devices  
10,001 + employees  
Global
Prioritizing Customer Requirements

• Critical Customer Requirement(s) should be chosen to start constructing the Quality Tree.
• These are the most important requirements to the customer as prioritized by the team.
• Tools for choosing Critical Customer Requirement(s) include the following:
  – VOC and Language Processing
  – Survey results
  – Clinical opinion (with expertise in area of interest)
  – Risk analysis
  – Field complaints
  – Pairwise analysis

• The total number of Critical to Customer Requirements may vary by product.
Tool/Method/Example Summary

- **Tool/Example Name:** Quality Tree

- **General Description:**
  Shows the flow down of customer requirements into Functional requirements, Design, and Process requirements in a hierarchical graphic format to help identify CTQ’s.

- **Glossary of terms (specific to this tool/example):**
  - Functional Requirements – description or metrics that the device’s needs to perform (functional output needs).
  - Design Requirements – description or metrics that the device’s design to meet the functional requirements.
  - Process Requirements -description or metrics relative to how the device’s is manufactured to meet the design and functional requirements.

- **Typical Uses:**
  - To help identify the flow down of requirements into critical design or process outputs needed. CTQ’s and important aspects of the product are typically shown on this chart.

- **Relevant FDA Regulations:**
  - 21 C.F.R. §§ 820.30 (b), (c), (d), (e), (f)
Developing the Quality Tree

- Quality Tree should be developed by the team.
- The project customer requirements, engineering documentation, and knowledge of the team are key inputs.
- The following activities should occur in sequence:
  - Critical customer requirements are identified by the end of the Feasibility Stage.
  - Functional requirements are identified by the end of the Feasibility Stage.
  - Design requirements are identified in the Development Stage or earlier.
  - Process requirements are identified in the Development Stage or earlier.
CtQs in Design Control

Quality Tree Format

Critical Customer Requirement (s)

Key Requirement (s) - Functional

Key Requirements - Design

Sub System Requirement

Component Requirement

Design Requirement

Design Requirement

Design Requirement

Design Requirement

Key Requirements - Process

Process Requirement

Process Requirement

Process Requirement

Process Requirement

Process Requirement
Selecting your CTQs

• Once the full Quality Tree has been completed, the team needs to make intelligent choices on which characteristics should be labeled “CtQs.”

• The bottom line is **assurance of quality** as it relates to Critical Customer Requirement(s)

• American Society for Quality (ASQ) defines **assurance of quality** as the “planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled.”
CtQs in Design Control

Quality Tree Example

Critical Customer Requirement

Key Requirement - Functional

No Infection

No leak past device

Key Requirements - Design

Mistake proof – Mold die

CTQ

Key Requirement - Process

Temperature

Machine Speed

Inject direction

Company:

- Medical Devices
- 10,001 + employees
- Global
# Overview of Quality Assurance Strategy

<table>
<thead>
<tr>
<th>Goals</th>
<th>Focus Areas</th>
<th>Tools</th>
<th>Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clarify&lt;br&gt;• Technical&lt;br&gt;• Requirements</td>
<td>Plan</td>
<td>VOC, CE, QFD &amp; FTA</td>
<td>CTQ CTS</td>
</tr>
<tr>
<td>• Achieve&lt;br&gt;• Technical&lt;br&gt;• Requirements</td>
<td>Risk Mgmt</td>
<td>MSA &amp; FMEA</td>
<td>Gage R&amp;R FMEA</td>
</tr>
<tr>
<td>• Overcome&lt;br&gt;• Technical&lt;br&gt;• Issues</td>
<td>Enhance</td>
<td>Optimization Tools, DOE, Simulation</td>
<td>Cpk and Score-Card</td>
</tr>
<tr>
<td></td>
<td>Overcome</td>
<td>Hypothesis Testing, DOE &amp; Capability Analysis</td>
<td>Problem Resolution</td>
</tr>
</tbody>
</table>
Additional Examples and Tools for Developing CTQs
Two Tools to Identify Customer Needs:
Language Processing and the Value Curve

- Language Processing Chart
- Value Curve

The Language Processing Chart is rich with opportunities, and contains important images and issues from the customer. The Value Curve shows the data graphically and is easier to communicate.
Value Curve: Example
Tool/Method/Example Summary

- **Tool/Example Name:** Value Curve chart

- **General Description:**
  Graphically illustrates critical customer needs and the current state of meeting those needs to determine key gaps.

- **Typical Uses:**
  - for defining critical new design features/functionality or improving an existing design

- **Relevant FDA Regulations:**
  - All 21 C.F.R. § 820.30 sections but primary uses in §§ (b), (c), (d), (e), (f)
Utilizing the Value Curve Tool to Determine Top Customer Needs

• Benefits include:
  – Clear communication of customer’s top needs
  – Clear communication of prioritization
  – Shows value / gap where new product would have advantage.
  – Can be verified with customers
  – Can easily be changed to reflect new circumstances
  – Helps better manage risk of project
  – Builds trust if clear about needs
### Police Car Value Curves (Existing vs. New)

<table>
<thead>
<tr>
<th>No.</th>
<th>First Draft</th>
<th>Low Value to Sheriff’s Department</th>
<th>High Value to Sheriff’s Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Purchase Price</td>
<td>$K</td>
<td>$K</td>
</tr>
<tr>
<td>2</td>
<td>Procurement Cost</td>
<td>$K</td>
<td>$K</td>
</tr>
<tr>
<td>3</td>
<td>Operating Cost</td>
<td>$/mile; $/mile</td>
<td>$/mile; $/mile</td>
</tr>
<tr>
<td>4</td>
<td>Life Expectancy</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Administration Expense</td>
<td>$1M</td>
<td>$5M</td>
</tr>
<tr>
<td>6</td>
<td>Disposal Cost</td>
<td>$1K</td>
<td>$10K</td>
</tr>
<tr>
<td>7</td>
<td>Functionality of Base Vehicle</td>
<td>Hi, Med, Lo</td>
<td>Hi, Med, Lo</td>
</tr>
<tr>
<td>8</td>
<td>Officer Comfort</td>
<td>Hi, Med, Lo</td>
<td>Hi, Med, Lo</td>
</tr>
<tr>
<td>9</td>
<td>Communications</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>10</td>
<td>Registration Plate Recognition System</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>11</td>
<td>Suspect Transport Compartment</td>
<td>Hi, Med, Lo</td>
<td>Hi, Med, Lo</td>
</tr>
</tbody>
</table>

**Customer Metric on Value Curve (low to high)**

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### CtQs in Design Control

#### Elements Rank Ordered

<table>
<thead>
<tr>
<th>Rank</th>
<th>CtQ</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Purchase Price</td>
<td>Total Cost of Road Ready Vehicle ($K)</td>
</tr>
<tr>
<td>2</td>
<td>Procurement Cost</td>
<td>Total Cost to procure finished vehicle ($K)</td>
</tr>
<tr>
<td>3</td>
<td>Operating Cost</td>
<td>Fuel Cost, $/mile; Maint Cost $/mile</td>
</tr>
<tr>
<td>4</td>
<td>Life Expectancy</td>
<td>Miles</td>
</tr>
<tr>
<td>5</td>
<td>Administration Expense</td>
<td>Annual cost to manage fleet ($)</td>
</tr>
<tr>
<td>6</td>
<td>Disposal Cost</td>
<td>Cost to dispose of vehicle ($K)</td>
</tr>
<tr>
<td>7</td>
<td>Officer Safety</td>
<td>Annual Health care cost/office ($K)</td>
</tr>
<tr>
<td>8</td>
<td>Performance</td>
<td>Top Speed, mph; Breaking Distance (ft)</td>
</tr>
<tr>
<td>9</td>
<td>Functionality of Base Vehicle</td>
<td>Officer Survey (Hi, Med, Lo)</td>
</tr>
<tr>
<td>10</td>
<td>Officer Comfort</td>
<td>Officer Survey (Hi, Med, Lo)</td>
</tr>
<tr>
<td>11</td>
<td>Communications</td>
<td>Officer Survey (Hi, Med, Lo)</td>
</tr>
<tr>
<td>12</td>
<td>Registration Plate Recognition System</td>
<td>Level of sophistication (%)</td>
</tr>
<tr>
<td>13</td>
<td>Suspect Transport Compartment</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

#### Elements Measured

- Ford Crown Vic

#### “As Is” Value Curve

#### Elements of Performance
Language Process: Example
Tool/Method/Example Summary

- **Tool/Example Name:** Language Processing

- **General Description:**
  Shows a process to use customer input to refine and fully develop CTQs

- **Glossary of terms (specific to this tool/example):**
  - LP Image; the interviewer’s observation, describing the current environment of use – this tends to be a mental picture or impression

- **Typical Uses:**
  - To develop a deeper understand of those critical needs to drive the full development of correct CTQs.

- **Relevant FDA Regulations (specific 21CFR sections):**
  - All 21 C.F.R. § 820.30 sections but primary uses in §§ (b), (c), (d), (e), (f)
Language Processing: Discovering Customer Requirements / Needs

• **Purpose**
  – Discover what functionalities the customer is missing now
  – Identify what they want to be able to do that they cannot do now
  – Identify the functionalities customers have that they would like to keep

• **And/or:**
  – Discover how much of a current functionality is missing
Concept Engineering

Stage 1: Understanding the Customers’ Environment

Stage 2: Converting Understanding into Customer Requirements

Stage 3: Operationally Defining Requirements for Downstream Development

Step 4: Transform Voices into Customer Requirements

Step 5: Select Most Significant Requirements

Step 6: Develop insight into Customer Requirements

Purpose:
- Discover customer requirements
- Create clear and unrestrictive customer requirement statements
Customer Requirements
Translation Process

1. Collect scenes of using the product/service
2. Link voice with context
3. Extract the key item(s) = essences
4. Translate to requirements

Use Translation Guidelines to convert essence into concrete requirements
Translation Worksheet - Definitions

• **Customer Voice:**
  – The customer’s verbatim statement taken from the transcript.

• **LP Image:**
  – A customer’s voice, or the interviewer’s observation, describing the current environment of use – this tends to be a mental picture or impression.

• **Key Items:**
  – Words or phrases that come to mind when you link the voice to an image.

• **Customer Requirement/Need Statement(s):**
  – A one sentence statement of the customer need that incorporates one or more key items.
Translation Guidelines

• Identify the **functional need**
  – What the customer would like to be able to do (avoid statements of means = no solutions!)

• Make it as **specific** as possible
  – Avoid abstract terms

• 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**
CtQs in Design Control

Desired Customer Requirements Statements

Relative Requirement Clarity

Relative Design Freedom

Company: D
- Medical Devices
- 10,001 + employees
- Global
CtQs in Design Control

Language Process Example:
WHAT ARE THE KEY CUSTOMER REQUIREMENTS FOR THIS PRODUCT?
Perceived performance benefits are maximized.

My dealer and I value my purchase of this attractive, high-performance system that is a pleasure to operate.
Ease of system setup & expansion is maximized.

Once set up, the system is easy to live with.

System suits my environment.

System preserves room character.

System looks complete, not hodge-podge.

System components' cosmetics are well matched.

Visible system components evoke pride of ownership.

System operation is readily apparent.

Room alteration to accommodate system is minimized.

System blends into room unsobtrusively.

System operation is learned quickly.

System is easy to operate properly.

System maximizes speed of access to desired functions.

Reconfiguration of the system to desired settings is accommodated easily.

Primary remote provides maximum number of essential functions.

System maximizes AV performance.

DSS/HTS provides a high-quality video and audio performance.

Audio system minimally detracts from video system performance and flexibility.

System maximizes value throughout distribution chain.

Total system price, including all hardware and programming is minimized.

Fairness of dealer compensation is maximized.

System interconnections are minimized.

Quickness of installation is maximized.

Installer effort in preparing for installation is minimized.

System is easy to continue.

The system maximizes the ease of telephone support.

The system maximizes user that he is using properly.

Guidance for system setup & use is clear.

System integration is maximized over time.

At time of installation, integration is maximized.

Additional predominant components are easily accommodated.
Analytic Hierarchy Process Excel Tool: (to Determine Ranking of Needs)
Tool/Method/Example Summary

- **Tool/Example Name:** Analytic Hierarchy Process Excel Tool

- **General Description:**
  Data driven Excel based tool to determine top requirements from multiple inputs for rankings to determine top CTQs

- **Glossary of terms (specific to this tool/example):**
  - AHP; abbreviation for the Analytic Hierarchy Process Tool

- **Typical Uses:**
  - For more in depth data analysis of critical customer needs to help determine CTQs

- **Relevant FDA Regulations (specific 21CFR sections):**
  - All 21 C.F.R. § 820.30 sections but primary uses in §§ (b), (c), (d), (e), (f)
## Analytic Hierarchy Process: AHP Template

### AHP Analytic Hierarchy Process (EVM multiple inputs)


Only input data in the light green fields and worksheets!

- **n=3** Number of criteria (3 to 10)
- **N=5** Number of Participants (1 to 20)
- **p=0** selected Participant (0=consol.)

<table>
<thead>
<tr>
<th>Objective</th>
<th>Product Design characteristics</th>
</tr>
</thead>
</table>

| Author          |                                  |
| Date            |                                  |

<table>
<thead>
<tr>
<th>Table</th>
<th>Criterion</th>
<th>Comment</th>
<th>Weights</th>
<th>Rk</th>
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<tbody>
<tr>
<td>1</td>
<td>Ease of Use</td>
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<td>24.1%</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Effectiveness</td>
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<td>24.6%</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Patient Safety</td>
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<td>51.3%</td>
<td>1</td>
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for 9 & 10, unprotected the input sheets and expand the question section ("++ " in row 86)

<table>
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<th>Result</th>
<th>Eigenvalue</th>
<th>lambda:</th>
<th>Consistency Ratio</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>3.000</td>
<td>0.37 GCR 0.00 CR 0.1%</td>
</tr>
</tbody>
</table>
Table of Contents

1. Customer Requirements
2. CtQ Process
3. Translating Customer Requirements to CtQ
4. CtQ in the PDP
5. Customer Requirement Matrix
Customer Requirements:

- Voice of Customer:
- Product Review:
  - Competitive products
  - Complaints
  - Prior concession made on design
  - Field performance
CtQ Process:

Process:
- Customer Requirements
- Critical to Customer (CtC)
- Drivers
- Critical to Design (CtD)
- Critical to Process (CtP)

Key Activities:
- VOC
- Market Assessment
- KOL
- Review Procedures/Cases
- Prototype
- product
- QFD
- Design Specification
- Design Risk Assessment
- Design Verification
- Process Requirements
- Process Risk Assessment
- Process Validation

Company:
- Medical Devices
- 1001-5000 employees
- Global
Translating Customer Requirements to CtQ:

• The many customer requirements are distilled down to the Critical to Customer (CtC) – VoC, KOL, Market Assessments, product review

• The CtC are translated down to Key Drivers by the use of DFQ and ranking

• Drivers are translated into Product Requirements

• Product Requirements are translated into Product Specifications (Critical to Design – CtD).

• CtD are approved by the Project Approval Board and reviewed at Gates 2 through 4 and During Design Reviews

• CtD will drive the process development and the Critical to Process (CtP) parameters to assure product design
Translating Customer Requirements to CtQ:

- CtP are approved by the Project Approval Board and reviewed at Gates 3 through 4 and during Design Reviews
- CtQ is comprised of both CtD and CtP
## CtQ in the PDP

### CtQs in Design Control

**Company:**
- Medical Devices
- 1001-5000 employees
- Global

---

### Product Development Process

<table>
<thead>
<tr>
<th>Concept</th>
<th>Development</th>
<th>Commercialization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I: Technology</td>
<td>Phase II: Design</td>
<td>Phase III: Development</td>
</tr>
<tr>
<td>Critical to Quality (CtQ)</td>
<td>Critical to Design (CtD)</td>
<td>Critical to Process (CtP)</td>
</tr>
</tbody>
</table>

#### Processes

- **Gate 1: Opportunity Assessment**
  - Customer Requirements Developed
  - Critical to Customer (CtC) Developed

- **Gate 2: Concept Selection**
  - Design Control
  - Traceability Matrix – VOC/Design Input
  - Marketing Specification
  - Risk Management Plan
  - Use Risk Assessment
  - Design Reviews
  - Gate Review

- **Gate 3: Design Control**
  - Design Verification
  - Traceability Matrix (Design Output)
  - FMEA (Design and Process)
  - Control Plan
  - Design Reviews
  - Gate Review

- **Gate 4: Design Transfer**
  - Design Validation
  - Process Validation
  - Design Transfer (GMR)
  - Control Plan
  - Risk Management Report
  - Design Review
  - Gate Review

---

### Deliverables

- Project Proposal
- Customer Requirements
- Critical to Customer Requirements
- Traceability Matrix – VOC/Design Input
- Marketing Specification
- Risk Management Plan
- Use Risk Assessment
- Design Reviews
- Gate Review
- Design Verification
- Traceability Matrix (Design Output)
- FMEA (Design and Process)
- Control Plan
- Design Reviews
- Gate Review
- Design Validation
- Process Validation
- Design Transfer (GMR)
- Control Plan
- Risk Management Report
- Design Review
- Gate Review
### Customer Requirement Matrix

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>CSI</td>
<td>1</td>
<td>23456789</td>
<td>CS</td>
<td>Angle of Articulation</td>
<td>The articulation mechanism shall support righting in a range of angles -45°, -30°, -15°, 0°, +15°, and +30° relative to the main longitudinal axis of the system - 15° deg.: 12.7 deg., 30° deg.: 27.6 deg., 45° deg.: 43.6 deg.</td>
<td>95/95 Low</td>
<td>RUNS 1</td>
<td></td>
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</tbody>
</table>

**CSI ease of getting to target Area**

CSI 123456789

The articulation mechanism shall support righting in a range of angles -45°, -30°, -15°, 0°, +15°, and +30° relative to the main longitudinal axis of the system.

- 15° deg.: 12.7 deg.,
- 30° deg.: 27.6 deg.,
- 45° deg.: 43.6 deg.
## Customer Requirement Matrix

The fields below are to be presented at Gates 2 through 4 and each Design Review

<table>
<thead>
<tr>
<th>Critical To Customer (CTC)</th>
<th>CTC No.</th>
<th>Doc. Number</th>
<th>Product Code</th>
<th>Drivers</th>
<th>Product Requirement</th>
<th>CID (Product Specifications)</th>
<th>Reliability /Confidence Level</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSI ease of getting to target Area</td>
<td>1</td>
<td>23482A23</td>
<td>CSI</td>
<td>Angle of Articulation</td>
<td>The articulation mechanism shall be designed align the tip at discrete angles of $-45^\circ$, $-30^\circ$, $-15^\circ$, $+15^\circ$, $+30^\circ$, and $+45^\circ$ relative to the main longitudinal axis of the system—rotating on the transection</td>
<td>15 deg.: 12.7 deg., 30 deg.: 27.6 deg., 45 deg.: 43.6 deg.</td>
<td>95/95</td>
<td>Low</td>
</tr>
</tbody>
</table>
CtQs in Design Control

Table of Contents

1. Why CTQ Cascade?
2. The Environment
3. Key Activities in a Product Development Process
4. Translating or Cascading Customer Requirements in CTQ’s
   1. CTQ Cascade: Customer Needs and Requirements
   2. CTQ Cascade: Product Requirements
   3. CTQ Cascade: Process Requirements
   4. CTQ Cascade: Risk Mitigation Strategies and Controls
   5. CTQ Cascade: Verification and Validation
5. Requirements Management (RM) Tools to Support PDP
6. Tool/Method/Example Summary: Active Requirements Management (RM) Tool
CtQs in Design Control

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7. Tools for Capturing Customer Requirements and Developing CTQs
   1. Manage Various NPD CTQ Cascade Tools

   1. Unified Model
   2. Risk Flowdown
   4. Requirements Scorecard
   5. Product to Process Flown Down

9. CTQ Cascade Focus
Why CTQ Cascade?

What’s Our Job?

Creating and Delivering Functionality to Satisfy Customer/User Need(s)
CtQs in Design Control

The Environment

“Go To” place for Product Performance Knowledge

- Marketing
- Systems Engineering
- Subject Matter Experts
- Design
- Standards
- MFG
- Suppliers
- Partners

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

---

*Voice of Customer, Business, Technology, Regulatory, etc.*

---

**CtQs in Design Control**
Translating or cascading Customer Requirements in CTQ’s
**CTQ Cascade**

- **Customer Needs and Requirements**
  - User Issues
  - User Needs/Requirements
  - Functions to Meet User Needs
  - Concepts to Meet the Functions
CTQ Cascade

Customer Needs and Requirements

Product Requirements

Measureable Performance Requirements

Architecture: Subcomponents?

Attributes/ Properties/ Specifications

CtQs in Design Control
CTQ Cascade

Customer Needs and Requirements

Product Requirements

Process Requirements

- Raw Material Properties, Specifications, Sources of Variation
- Critical Process Variables, Requirements
- Equipment Requirements, Sources of Variation

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

Customer Needs and Requirements

Product Requirements

Process Requirements

Risk Mitigation Strategies and Controls

Risks

Mitigations, Controls

Improve Chances of Success Proactively
CTQ Cascade

- Customer Needs and Requirements
- Product Requirements
- Process Requirements
- Risk Mitigation Strategies and Controls
- Verification and Validation
- Specifications, Critical Testing
CTQ Cascade

Customer Needs and Requirements

Product Requirements

Process Requirements

Risk Mitigation Strategies and Controls

Verification and Validation
**Requirements Management (RM) Tools to Support PDP**

- **Active RM** allows flowing up process capability and predicted performance to customer requirements.

**CTQ Flow down/up:**
- **What**

**CTQ Flow down/up:**
- **What, Why, How, Cost?**
Tool/Method/Example Summary

- **Tool/Example Name:** Active Requirements Management (RM) Tool
- **General Description:**
  This tool is utilized to ensure that the various (inputs) requirements are translated into predictive, measurable performance values. These outputs can be tracked on the CTQ Scorecard. The Risk Flow Down model is utilized to ensure that risks associated with a specific requirement have the appropriate mitigations.

- **Glossary of terms (specific to this tool/example):**
  - None unique

- **Typical Uses:**
  - These tools can be utilized during the design process to ensure requirements are adequately translated to quantify performance values.

- **Relevant FDA Regulations:**
  - 21 C.F.R. §§ 820.30 design controls & FDA Preamble – comment 72.
Tools for capturing customer requirements and developing CTQs
Manage Various NPD CTQ Cascade Tools

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

Transfer Functions (Minitab, Matlab, Excel, etc)

CtQs in Design Control

DFSS Scorecards

Sub-Team Interaction Management

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

Req Doc

“Source: Cognition Corporation”
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
Unified Model

As you develop 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
  - Risk Management
  - Test Management
  - Critical Parameter Management (DFSS)
  - Test method links
  - Flow up and flow down
  - Relationship reliability
  - Transfer functions if they exist
  - Meeting and Action Management

- 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
CtQs in Design Control

Risk Flowdown

Requirement Flow Down

- VOICE OF CUSTOMER
- FUNCTIONS
- SYSTEM REQS
- SUBSYSTEM REQS
- SUBASSEMBLY REQS
- PROCESS & EQUIPMENT
- COMPONENT SPECS
- RAW MATERIALS

Risk Flow Down

- EFFECTS
- FAILURE MODES
- MITIGATIONS
- FAILURE MODES (CAUSES)
- MITIGATIONS
- FAILURE MODES (CAUSES)
- MITIGATIONS
- FAILURE MODES (CAUSES)
- MITIGATIONS

Uses Managed Libraries

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

- Scorecard to report capability and capability growth
  - Initial capability listed under **Design**
  - Make a change; new capability under **Test**

---

**Product Requirements Document**

<table>
<thead>
<tr>
<th>System Requirement</th>
<th>Owner</th>
<th>T/F</th>
<th>Units</th>
<th>Introduction</th>
<th>System Architecture</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Product to Process Flow Down, FMEA’s incorporated in end-to-end cascade

...Including Raw Materials

...all the way to the Equipment Requirements
CTQ Cascade Focus

• The CTQ Cascade Brings Three Main Breakthroughs:
  – Connectivity of What, Why, How and How Much?
  – Templates
  – Opportunity to Index Information for Searchability
# Table of Contents

1. How Do You Determine Customer Requirements?
2. Critical to Quality (CTQ) Flowdown
3. KPIV / KPOV
4. CTQ Flow Down
5. Quality / Engineering Tools
6. Collecting Customer Inputs
7. Cp, Cpk, Z-score
8. CTQ : What it is, What it is Not
9. Key Findings
How Do You Determine Customer Requirements?

• Step 1 - Understand Consumer & Technical Requirements

• Step 2 - Translate Technical Requirements to Part CTQ

• Step 3 - Determine how capable we are of meeting requirements
CtQs in Design Control

Understand Consumer Requirements

Define Technical Requirements

What Parts are Affected

CTQ Characteristics (How are they affected)

Are we capable

Customer Expectations

Establish measureable testing methods

Determine parts affected

Establish dimension of part that effect the Technical requirements (Y)

Measure parts; establish Capability, Calculate Z-score

Driving decisions with data, not Opinion

Company: G

- Medical Devices
- 5001-10,000 employees
- Global
CtQs in Design Control

Critical to Quality (CTQ) Flowdown

Voice of Customer
Function
Parts
Dimensions
Capability
Match Capability Vs. Goal
Launch

Company:
• Medical Devices
• 5001-10,000 employees
• Global
CtQs in Design Control

- **KPIV**
  - Key Process input variable
  - Associated with X’s

- **KPOV**
  - Key process output variable or Customer requirement
  - Associated with Y’s

\[ Y = f \left( x_1, x_2, \ldots, x_k \right) \]

Understand the X’s to control the Y’s
CTQ Flow Down

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.
<table>
<thead>
<tr>
<th>Quality/Engineering Tools</th>
<th>CtQs in Design Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>• FMEA (Design, Process, Top Down, Usability)</td>
<td>• Process Mapping</td>
</tr>
<tr>
<td>• Measurement Systems Analysis</td>
<td>• Process FMEA</td>
</tr>
<tr>
<td>• Capability Assessment</td>
<td>• Control Plans</td>
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<tr>
<td>• Stack-up Tolerancing</td>
<td>• Reliability Assessment</td>
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<tr>
<td>• Design for Manufacture</td>
<td>• Process Control</td>
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<tr>
<td>• Hypothesis Testing</td>
<td>Methods</td>
</tr>
<tr>
<td>• DOE</td>
<td>• Gage R&amp;R</td>
</tr>
<tr>
<td>• Robust Design Methodology</td>
<td>• 8D (for Root Cause</td>
</tr>
<tr>
<td></td>
<td>Analysis)</td>
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</tbody>
</table>

Company: Medical Devices
- 5001-10,000 employees
- Global
# Collecting Customer Inputs

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

## CtQs in Design Control

- Medical Devices
- 5001-10,000 employees
- Global
Cp
Answers the question “Are the specifications matched to the variation in the process?”
Formula: Upper Spec – Lower Spec / 6*Std Dev

Cpk
Answers the question “How well does the process meets the specification?”
Formula: Min of Lower Cpk & Upper Cpk
   Lower Cpk = Mean – Lower spec / 3*Std Dev
   Upper Cpk = Upper spec - Mean / 3*Std Dev

Pp and Ppk are calculated the exact same way, except for the standard deviation number.
They use an “inflated standard deviation to account for changes over time.

**How does this relate to Z-score?**
Z short term = 3 * Cpk
Z long term = 3 * Ppk (or Zst-1.5)

Status:  “Green” if Ppk > 1.3 (Zlt>4.0)
         “Yellow” if 1.3<Ppk<1.0   (4.0<Zlt<3.0)
         “Red” if Ppk<1.0         (Zlt<3.0)
## CtQs in Design Control

<table>
<thead>
<tr>
<th>Z</th>
<th>PPM</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>308,537</td>
</tr>
<tr>
<td>3</td>
<td>66,807</td>
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<tr>
<td>4</td>
<td>6,210</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
</tr>
<tr>
<td>6</td>
<td>3.4</td>
</tr>
</tbody>
</table>

**Process Capability**

**Defects per Million Opportunity**
CTQ What it is, What it is Not

What it is

➤ Brings disciplined approach to a Quality score card that measures quality prior to product launch
➤ Identifies quality issues

What it is not

➤ Does not correct quality issues
➤ A replacement of sound technical judgment
➤ A replacement of sound financial discipline
Key Findings

- Current product drawings require deeper detail specifications for manufacturability.

- Beginning of the learning curve on process capability and control.

- Create a closer relationship with departments or internal customers that provide VOC information.
1. **Tool/Method/Example Summary:** Managing Requirements Through IT Solutions
   - a. Why?
   - b. Automated Requirements Management
   - c. Managing Requirements
   - d. Oversight
   - e. Roles
   - f. ARM Screenshots – Voice Views
   - g. ARM Screenshots – Component Requirement Views
   - h. ARM Screenshots – Design Parameter Level Views
   - i. ARM Screenshots – Process Level Views

2. **Successes**

3. **Opportunities for Enhancement**
Tool/Method/Example Summary

- **Tool/Example Name:** Managing Requirements Through IT Solutions

- **General Description:**
  An example of using an IT tool to capture requirements beginning with the customer/design inputs, translation into design outputs & component/sub-assembly requirements.

- **Typical Uses:**
  - Trace of requirements from highest level product to lowest level process and supplier requirements
  - When ease of retrieval is important

- **Relevant FDA Regulations**
  - 21 C.F.R. § 820.30 (b) --- Design and development planning
  - 21 C.F.R. § 820.30 (c) --- Design input
  - 21 C.F.R. § 820.30 (d) --- Design output
Why?

• Requirements flow down (documented trace) is required by protocol.

Current State:

• System is not linked; a change one place does not automatically change elsewhere.

• Limited traceability from source inputs to final outputs

• Limited re-use across development.
  • New programs often start from scratch
  • No libraries of standardized design

• Time is spent by development team managing requirements in a variety of tools, spreadsheets, customized tools.

• Time spent manually managing metrics
Automated Requirements Management

• Requirements flow down (documented trace) is required by the protocol.
  • ARM tool Benefits

Need / Benefits for ARM

• Reduction of engineering time spent doing NVA “paperwork”
• Time spent manually managing metrics
• Error proofing of requirements management and associated documentation
• Instantaneous query for metrics:
  • Lean Development Practices
  • Goodness assessment
  • Requirements with no source / Requirements with no verification
• Database for learn, capture, propagate of project knowledge and future reuse
• Full traceability from source inputs to final outputs (live link)
Managing Requirements

Design Inputs Requirements

- OUTPUT (e.g. System Requirements) becomes an INPUT to next level flow down

- OUTPUT (e.g. Hardware Specification) becomes an INPUT to next level flow down

Final Design Outputs

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

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

Component Regs

Trace to Design Outputs

Process Planning Matrix

Design Review
Oversight

Need / Benefit of Requirements Management Role

• This project will provide the framework (“what”) is required to be compliant, along with tool (ARM) but systems engineering needs to do the work for each project.

• Requirements management (capture, management and execution) is critical for successful outcomes.

• The project structure is managed by the systems engineering function

• The individual development projects need to collect the data and populate the tool
Roles

**Day to Day Role & Responsibilities ("is")**

- 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 ARM project structure (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 ARM 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
ARM Screenshots – Voice Views

6.0 Voices

Default Voices to Requirements

6.1 PSD

Description here...

<table>
<thead>
<tr>
<th>Voice</th>
<th>Definition</th>
<th>Type</th>
<th>Importance</th>
<th>NUD/ECO</th>
</tr>
</thead>
<tbody>
<tr>
<td>0004: Use existing line</td>
<td>Uses space allocated to existing lithium ion battery line.</td>
<td>Voice of the Customer</td>
<td>50</td>
<td>NUD</td>
</tr>
</tbody>
</table>

Add item here...

6.1 PSD

Description here...

<table>
<thead>
<tr>
<th>Voice</th>
<th>Requirement of Voice</th>
<th>Section in HRM001238</th>
</tr>
</thead>
<tbody>
<tr>
<td>0004: Use existing line</td>
<td>CR0035: Weld process</td>
<td>Manufacturing (component and assembly)</td>
</tr>
</tbody>
</table>
## ARM Screenshots – Component Requirement Views

### Requirement Table

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Unambiguous</th>
<th>Measurable</th>
<th>Limits Defined</th>
<th>Status</th>
<th>Comment (Action Item)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR0010: Cycle Life Capacity</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>NUD: No CFI: EDO: Yes</td>
<td>A1800: perform test</td>
</tr>
<tr>
<td>CR0011: Calendar Life Capacity</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>NUD: Yes CFI: EDO: Yes</td>
<td></td>
</tr>
<tr>
<td>CR0017: New Requirement</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>NUD: Yes CFI: EDO: No</td>
<td></td>
</tr>
</tbody>
</table>

### Where Verified

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Where Verified</th>
<th>Reference Docs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target = ≥ 9.4 mAh</td>
<td>Analysis</td>
<td>7.9 Interfaces (external) - Component Requirements FRM001238, Reviewed?</td>
</tr>
</tbody>
</table>

---

### Company Information

- **Medical Devices**
- **10,001 + employees**
- **Global**
ARM Screenshots – Design Parameter Level Views

2.0 Positive Electrode

<table>
<thead>
<tr>
<th>Subassembly Spec</th>
<th>Component Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES0021: Length</td>
<td>CR0010: Cycle Life Capacity</td>
</tr>
<tr>
<td>DES0020: Width</td>
<td>CR0011: Calendar Life Capacity</td>
</tr>
<tr>
<td>DES0019: Deposition</td>
<td>CR0010: Cycle Life Capacity</td>
</tr>
<tr>
<td>DES0018: Density</td>
<td></td>
</tr>
<tr>
<td>PRO0009: Pressure</td>
<td></td>
</tr>
<tr>
<td>PRO0025: Laser Speed</td>
<td></td>
</tr>
</tbody>
</table>

Choose items to add:

- CR0100: Cycle Life Capacity – Coating Work \text{Instr} \#56872
- CR0011: Calendar Life Capacity – Coating Work \text{Instr} \#56873
- CR0017: Placeholder for new requirement – Custom \text{Instr} 
- CR032: Reliability target established – DSS Lab
- CR033: Dependability target established – AMS Lab
- CR0030: Process Yield at Release – \text{COS tgt}
- CR0034: Cost target – \text{COS tgt}

<table>
<thead>
<tr>
<th>Specification</th>
<th>Process Variable</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES0021: Length</td>
<td>PRO0009: Pressure</td>
<td>Bake</td>
</tr>
<tr>
<td>DES0020: Width</td>
<td>PRO0025: Laser Speed</td>
<td>Cutting Process 234892</td>
</tr>
</tbody>
</table>
ARM Screenshots – Process Level Views

CtQs in Design Control

Company:
- Medical Devices
- 10,001+ employees
- Global
Successes

• Input requirements, specifications, verification method all integrated

• Trace parent/ child relationships from requirements to design specifications and processes

• Export documents that show evidence of trace (to be stored in doc system)

• Immediate update of requirements as new information becomes available

• Pilot library structure for voices and requirements to be re-used in the future

• Established Requirement Goodness Assessment
Opportunities for Enhancement

• Incorporate ARM into all technical reviews

• Populate relevant libraries
  • Design rules
  • Material Requirements
  • Standards library
  • Manufacturing Rules
  • Re-usable requirements

• Instantaneous schedule and cost impact of requirement changes

• Transfer function analytics embedded in the architecture

• Full House of Quality (Houses 1 – 4) functionality

• Pull requirements in from any source (CAD et al)

• Auto populate Test Plans
Table of Contents

1. CTQ Practice Name: Design for Excellence (DFX)

2. How Do You Translate Customer Requirements into CTQs?

3. Tool/Method/Example Summary: DfX Process approach utilizing Quality toolkit
   a. Example DfX Approach Using CTQ’s 1
   b. Example DfX Approach Using Quality Tools 2
   c. DfX Quality Approach 3
   d. DfX Quality Toolkit
CTQ Practice Name: Design for Excellence (DFX)

Delivering excellent Results
- Better Quality=>zero quality incidents
- Reduced Cost Of Non Quality
- Stronger Customer Loyalty
- Faster Product Development

CtQs in Design Control
How Do You Translate Customer Requirements into CTQs?

<table>
<thead>
<tr>
<th>DF “X”</th>
<th>Pillar</th>
<th>Pillar high level objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF CE</td>
<td>DfCE</td>
<td>• Experience Flow, Workflow Analysis,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Value Proposition House</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Integrated Start, Ideal Product Model</td>
</tr>
<tr>
<td>DF R</td>
<td>DfR</td>
<td>• User profile creation, Simulation,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prediction &amp; Robust Design</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lifetime data analysis, ALT/HALT</td>
</tr>
<tr>
<td>DF M</td>
<td>DfM</td>
<td>• Modular Design, Standard Components,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Tolerance analysis, Industrialization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Manufacturing complexity reduction</td>
</tr>
<tr>
<td>DF S</td>
<td>DfS</td>
<td>• Design for Diagnostics, Remote Monitoring &amp; Diagnostics,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Modular Architecture for Installability</td>
</tr>
<tr>
<td>DF C</td>
<td>DFC</td>
<td>• Consumer Care book</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Product Conventions, Tear Down Workshops,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Clean Sheet Analysis, Value Space Insights,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Benchmarking, Demand &amp; Specification Management</td>
</tr>
</tbody>
</table>

- DF CE = Customer Experience
- DF R = Reliability
- DF M = Manufacturability
- DF S = Serviceability
- DF C = Cost
• Trends of globalization, outsourcing and stricter regulatory requirements have increased reliance on technology, software tools, internet, supplier management, and engineering standards (external and internal) in Design and Design Transfer.

• Good practices of yesteryear in physical/chemical testing, detailed physical review of prototypes and released designs are still important to ensure quality.

• Software Quality engineering practices (e.g., CMMi, robust software design, validation and verification) and state of the art software tools (e.g., for configuration, version and defect management) have become critical to ensuring higher quality, fewer defects and fewer recalls.
Tool/Method/Example Summary

- **Tool/Example Name:** DfX Process Approach Utilizing Quality Toolkit

- **General Description:**
  Example DfX steps using Quality tools to analyze root cause for Quality defects associated with CtQ’s

- **Glossary of terms:**
  - DfX, FMEA, Pareto, Fishbone, 5-Why’s

- **Typical Uses:**
  - Tools to determine, analyze and correct quality issues

- **Relevant FDA Regulations:**
  - 21 C.F.R. §§ 820.100 (CAPA), 820.30 (Design Controls), 820.50 (Purchasing Controls)

- **Notes:**
  - These tools/steps tie the CtQ’s to quality defect analyses and implementation of closed-loop corrective actions all the way back into Design
# Example DfX Approach Using CTQ’s 1

<table>
<thead>
<tr>
<th><strong>Description</strong></th>
<th><strong>Prerequisites</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Collect existing Product and/or Process FMEA (or equivalent)</td>
<td>• Identify and prioritize potential failure modes of a product and/or process and critical to quality characteristics and parameters (CTQs)(^1)</td>
</tr>
<tr>
<td>• Collect existing CTQs (or equivalent)</td>
<td>• Failure modes are prioritized by Risk Priority Number, determined by multiplying the risk severity, probability of occurrence, and probability of detection</td>
</tr>
<tr>
<td>• Review existing product and/or process quality issues and status of addressing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Timing</strong></th>
<th><strong>Approach</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1-3 days</td>
<td>• Determine product and/or process Critical to Quality characteristics and parameters</td>
</tr>
<tr>
<td></td>
<td>• Review potential failure modes and calculate RPN number</td>
</tr>
<tr>
<td></td>
<td>• Prioritize the potential failure modes based on highest RPN number</td>
</tr>
<tr>
<td></td>
<td>• Propose corrective actions to eliminate the failure mode</td>
</tr>
<tr>
<td></td>
<td>• In absence of an FMEA, utilize DFMEA excel template</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Key people involved</strong></th>
<th><strong>Outcome</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Entire cross-functional DfX team, working in sub-teams</td>
<td>• Potential prioritized ideas to change the product and/or process to improve quality</td>
</tr>
</tbody>
</table>

\(^1\) Critical to Quality Attributes are characteristics that are important to assure safety, efficacy, performance, and reliability of a product.
### Example DfX Approach Using Quality Tools 2

| Description | Identify the root cause of an existing or potential product quality failure or defect. Two common methods to use:  
|             |  
|             | – **Fishbone Diagram**: analysis to identify the potential factors causing a product quality defect based on the most likely sources of variation  
|             | – **Fault mode analysis**: logic tree that evaluates cause and effect of system defects  
| Pre-requisites | Existing quality issues (paretos of existing defects)  
|               | Potential quality issues (based on output of FMEA workshop)  
| Timing | 1-2 days (to root cause the prioritized failures)  
|         | As needed throughout DfX  
| Process | Start with:  
|         | – Existing quality issues (based on paretos of existing QA defects, supplier workshops)  
|         | – Potential quality issues (based on output of FMEA workshops, teardown for quality)  
|         | Conduct Fishbone or Fault mode analysis to identify root cause and corrective actions  
| Key people involved | Entire cross-functional DfX team, likely working individually or in sub-teams  
|                 | Small groups, as needed throughout DfX  
| Outcome | Root causes identified for prioritized quality issues, both existing and potential issues  
|         | Ideas to correct the root cause of quality defects  

---

**CtQs in Design Control**

**Company:**
- Medical Devices
- 10,001 + employees
- Global
CtQs in Design Control

DfX Quality Approach 3

**Activities**
- **Gather baseline quality data**
  - Collect pareto of existing QA issues (returns, defects, etc.)
  - Identify specs, parts and manufacturing assembly processes critical to quality
  - Review output of CTO/FMEA workshop
  - Baseline the CoQ

- **Conduct Fault tree or Fishbone analysis**
  - Review baseline quality data
  - Conduct with the team either Fault tree or Fishbone (based on team preference/expertise) for the Top X defects
  - Identify root causes/basic causal effect for the defects
  - Record ideas to mitigate defects

- **Prioritize ideas and assign ownership**
  - Prioritize top ideas by:
    - Quality improvement
    - Ease of implementation
  - Assign team ownership for prioritized ideas

- **Develop Ideas**
  - Further explore QA data to verify impact

**Time required**
- **Gather baseline quality data**
  - 1-3 weeks

- **Conduct Fault tree or Fishbone analysis**
  - 3-4 hours

- **Prioritize ideas and assign ownership**
  - ~1 hour (Prioritize)
  - ~1 hour (Ownership)

- **Develop Ideas**
  - 2-6 weeks

**End products**
- **Gather baseline quality data**
  - Top existing and potential quality issues about the product

- **Conduct Fault tree or Fishbone analysis**
  - Ideas to improve product quality

- **Prioritize ideas and assign ownership**
  - Priority ideas assigned to owners

- **Develop Ideas**
  - Priority ideas to present at convention
CtQs in Design Control

DfX Quality Toolkit

**Explanation**

- **FMEA**
  - Identify and prioritize potential failure modes of a product and/or process and critical to quality characteristics and parameters (CTQs)
  - Failure modes are prioritized by Risk Priority Number, determined by multiplying the risk severity, probability of occurrence, and probability of detection

- **Pareto**
  - Analysis of top existing quality issues (‘backward-looking’) that are being tracked via KPIs to identify existing product quality issues that need to be corrected
  - Typical KPIs that are tracked include: customer complaints, recalls, field failure reasons, service call reasons, process yield failures, part inspection failure codes (incoming parts, outgoing products), rework backlog, CAPA closeouts, etc.

- **Cause & Effect diagram**
  - Identify the root cause of an existing or potential product quality failure or defect. Two common methods to use:
    - Fishbone Diagram: analysis to identify the potential factors causing a product quality defect based on the most likely sources of variation
    - Fault mode analysis: logic tree that evaluates cause and effect of system defects

- **2x5xWHY**
  - Identify the underlying, systemic root cause of an existing quality issue
  - Used only to record observations and pass on to non-DfX teams (e.g. IQM, Engineering groups, BIU stakeholders, etc.)
1. Tool/Method/Example Summary: Critical Quality Attributes (CQAs)
   a. Critical Quality Attributes
   b. ICH Q8 Annex Glossary
   c. Key Terms
   d. Identification of Quality Attributes
   e. Quality Attributes
   f. Example Quality Attributes
   g. Critical Quality Attributes
   h. Identification & Classification of CQA’s
   i. Identify CQAs
   j. Example CQA Classification Method
   k. Communicate CQAs
   l. Example Product Drawing (DMR) Excerpt Showing A CQA
Tool/Method/Example Summary

- **Tool/Example Name:** Critical Quality Attributes (CQA’s)

- **General Description:**
  A prioritization tool for product design specifications

- **Glossary of terms:**
  - **Quality Attribute** – A physical, chemical, biological or microbiological property or characteristic that has a defined limit, range, or distribution
  - **Critical Quality Attribute (CQA)** – A physical, chemical, biological or microbiological property or characteristic that shall be within an appropriate limit, range, or distribution in order to ensure the desired product quality
  - **Design Tolerance** – The specified limit, range, or distribution that a Quality Attribute is required to be within according to Design Control documentation

- **Typical Uses:**
  - Help determine manufacturing (production & process control) rigor for verification (inspection) and validation purposes

- **Relevant FDA Regulations:**
Critical Quality Attributes

Draft ICH Consensus Guideline:  

• Clause 2.2:

“…A critical quality attribute (CQA) is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality…”

Note: For this company, “Critical Quality Attribute” (CQA) is synonymous with “Design CtQ.”
ICH Q8 Annex Glossary

Critical Quality Attribute (CQA):
A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

CPP is a process control specification

Critical Process Parameter:
A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

CQA is a product design specification

Edge of Failure:
The boundary to a variable or parameter, beyond which the relevant quality attributes or specification cannot be met.

Proven Acceptable Range:
A characterised range of a process parameter for which operation within this range, while keeping other parameters constant, will result in producing a material meeting relevant quality criteria.

Pertains to the limit/range/distribution
Key Terms

**Quality Attribute** – A physical, chemical, biological or microbiological property or characteristic that has a defined limit, range, or distribution.

**Critical Quality Attribute (CQA)** – A physical, chemical, biological or microbiological property or characteristic that shall be within an appropriate limit, range, or distribution in order to ensure the desired product quality.

**Design Tolerance** – The specified limit, range, or distribution that a Quality Attribute is required to be within according to Design Control documentation.

Design specs/tolerances may be depicted as:

\[ x_0 + x_P - x_N \]

in which,

- \( x_0 \) = nominal value (target value)
- \( x_P \) = positive tolerance
- \( x_N \) = negative tolerance.

Quality Attributes are either “Critical” or “non-Critical”

Identical to the definition in ICH Q8 Annex but with “should” replaced by “shall”.
Identification of Quality Attributes

1. **Design Control process (per QSR)**: Ensures that Design Inputs (including DI acceptance criteria) are developed that comprehensively meet the requirements of the Intended Use and User Needs.

2. **Risk Management process (per ISO 14971)**: Reviews Design Inputs to ensure that sufficient Design Inputs have been identified to address identified Hazards.

3. **Design Control process (per QSR)**: Ensures that Design Outputs (including quality attributes) are developed that comprehensively meet the requirements of the Design Inputs.
Quality Attributes

- Quality Attributes are **product design specifications** and are documented in the DHF as:
  1. **Design input acceptance criteria** (in the Design I/O document) *and/or*
  2. **Design output specifications/tolerances** (in the DMR)

**DMR (Product Design)**
1. Product drawing specs
2. Labeling text & artwork
3. Material specs
4. Software items (code)
5. Product test specs

### Design Outputs

- **Design Spec/tolerance 1-1-1-1**
- **Design Spec/tolerance 1-1-1-2**
- **Design Spec/tolerance 1-1-1-3**
- **Design Spec/tolerance 1-1-2-1**
- **Design Spec/tolerance 1-1-2-2**
- **Design Spec/tolerance 1-1-2-3**

### DIO Document

<table>
<thead>
<tr>
<th>Intended Use/ User Need</th>
<th>DI #</th>
<th>Design Input</th>
<th>DI Acceptance criteria</th>
<th>DI Acceptance criteria Justification</th>
<th>DO #</th>
<th>Design Outputs (PN/Feature)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-1</td>
<td>xxxx</td>
<td>Design Input Acceptance criteria 1-1</td>
<td>xxxx xxxx</td>
<td>1-1-1</td>
<td>Design PN/Feature 1-1-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1-1-2</td>
<td>Design PN/Feature 1-1-2</td>
</tr>
</tbody>
</table>

("Refinement of Design Input" (Product performance criteria))
Example Quality Attributes

**Design Input Acceptance Criteria**
- Implant fixation force
- Implant actuation sound
- Drill heat (temperature)
- Drill metal debris rate

**Design Output Specs/Tolerances**
1. Implant thickness, Device color
2. Product identification text on device
3. Implant material
4. Software platform/revision
5. Drill torque, Voltage output, Sterility Assurance Level, Device weight, Video resolution

**DIO Document**
- 1. Product drawing specs
- 2. Labeling text & artwork
- 3. Material specs
- 4. Software items (code)
- 5. Product test specs

Manufacturing has visibility of all product design specs in the DMR
Critical Quality Attributes

- **CQA’s are critical product design specifications**
  - CQA’s are product design specifications where being in-spec is considered “critical” for product quality

- Note: Expectation is that manufactured product will meet all product design specifications (quality attributes) in the DMR, whether designated as “critical” or not
  - In accordance with QSR Subpart G, *Production and Process Controls*
  - The designation of a product design specification as “critical” merely conveys that the consequences of being out of spec are severe, so additional focus is prudent during manufacturing, verification, etc.

Verify (Inspect) or Validate
- **Critical Quality Attributes**
- Verify (Inspect) or Validate with more rigor
- **Quality Attributes**
CQA information is intended to facilitate discussion and collaboration between design engineers, manufacturing engineers, and quality engineers, for example, as follows:

- **Manufacturing personnel typically use CQA information to help determine process risk levels and/or appropriate process control levels for testing (inspection levels such as AQL/RQL) and process validation (process capability levels such as PpK/CpK).**

- **Furthermore, if a non-critical quality attribute requires a costly manufacturing process, the manufacturing engineer can discuss this with the design engineer and quality engineer to determine if expanding the design tolerance might allow the substitution of a less costly manufacturing process without compromising product quality.**

CtQs in Design Control

Identification & Classification of CQA’s

1. Locate quality attributes (measurable product design specifications) in the DHF.
2. For a given quality attribute: Would a significant departure from design tolerance result in unacceptable product quality? If yes, the quality attribute is a CQA.
3. Is further classification of the CQA necessary? (for CQA stakeholders)
   - If yes, classify the CQA using an established classification method.
   - If no, ensure that CQAs are clearly communicated (designated) in the DHF for the benefit of CQA stakeholders.

Company: J
- Medical Devices
- 10,001 + employees
- Global
Identify CQAs

For a given quality attribute, if a significant departure from design tolerance is predicted to result in unacceptable product quality (i.e., major customer dissatisfaction and/or unacceptable risk), that quality attribute is identified as a CQA.

*Note: For most quality attributes, a large, unlimited departure from design tolerance inevitably results in unacceptable product quality, but this does not imply that most quality attributes are CQA’s. The main purpose of CQA identification is to highlight those quality attributes for which a substantial, but limited departure from design tolerance has unacceptable consequences.*
Identify CQAs

For CQA identification purposes, the concept of a “significant departure” from design tolerance is interpreted as follows:

1. For continuous quality attributes with linear design tolerance, a significant departure from design tolerance should be defined as departure up to a factor of 2 from design tolerance (i.e., up to a 100% departure from design tolerance).

Identify CQAs

2. For discrete quality attributes, any departure from design tolerance may be considered a significant departure, but project team personnel should subjectively decide what constitutes a significant departure.

Example 1: For an implant, the color specification “green” might be considered a CQA if manufacturing that implant as any color other than green (e.g., “blue” or “red”) is predicted to result in unacceptable product quality.

Example 2: For product containing software, the software revision level might be considered a CQA if manufacturing the product with an incorrect software revision is predicted to result in unacceptable product quality.
Identify CQA’s

For CQA identification purposes, the consequence of a significant departure from design tolerance (i.e., the failure effect) is determined using any of the following methods or combination of methods:

1. Judgment of engineering, quality assurance, clinical affairs, and/or marketing personnel on the project team
2. Inspection of Risk Management File info
3. Inspection and analysis of field data, test data, theoretical models, NC/CAPA information, standards, regulations, and/or literature for similar products
Example CQA Classification Method

Severity based CQA Classification

Class N/A/B/C based on:
- The highest severity of potential harm that is predicted as a consequence of a departure from the design tolerance.

<table>
<thead>
<tr>
<th>SEVERITY of Predicted HARM</th>
<th>S0</th>
<th>S1</th>
<th>S2</th>
<th>S3</th>
<th>S4</th>
<th>S5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No injury</td>
<td>Limited</td>
<td>Temporary or Reversible</td>
<td>Intervention Required</td>
<td>Permanent Impairment</td>
<td>Death</td>
</tr>
<tr>
<td>CLASSIFICATION of CRITICAL QUALITY ATTRIBUTES</td>
<td>Class N</td>
<td>Class A</td>
<td>Class B</td>
<td>Class C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note 1: Other severity scales can be used, such as FMECA severity scales.

Note 2: The CQA classification must not be confused with the A/B/C software safety classification in IEC 62304. These two classifications have different meanings/purposes.
Communicate CQAs

Critical Quality Attributes (CQA’s) are designated (communicated) as such in one or more of the following locations in the DHF:

1. The Design I/O document
2. Product drawings
   *Examples: critical dimensions, critical materials, critical product test specs*
3. CQA list (if any)
4. Production and process control plans
   *Examples: Inspection plans, attribute charts, process validation plans*

Symbols (if any) used to designate CQA’s must be clearly defined such that the meaning (implication) of the symbol is clear to CQA stakeholders.
Example product drawing (DMR) excerpt showing a CQA

# INSPECTION ITEM | INSPECTION CRITERIA | INSPECTION INSTRUMENT | REF | SUPPLIER | RANK | INSPEC LOC | DIAGRAM / COMMENTS
--- | --- | --- | --- | --- | --- | --- | ---
8 | Dimension | 2.340 +/- .005 in | video comparator, caliper | pg. 2 (C4) | Approved supplier sample plan | A | 
9 | Dimension | 0.002 +/- .003 in | micrometer | pg. 2 (C3) | Approved supplier sample plan | A | Measure dimension at the each of the points on the cassette body as shown below:
### Table of Contents

1. Critical Parameter Management
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Critical Parameter Management

Philosophies, examples, and methods
What is Critical Parameter Management?

• Most Basic Definition – Systemic and disciplined management and continuous improvement of our customer’s and company’s critical needs and wants *(parameters)* through all product life cycle stages.

• This is deployed Lean Six Sigma
What is Critical Parameter Management?

• The management processes for *Safeguarding* customer, business, and market critical things throughout our business processes.

• Focusing on – *Safety, Performance, & Compliance*

• This includes:
  - capturing the critical parameters
  - disciplined risk characterization & mitigation
  - robust design
  - robust production process design & deployment
  - diligent control & monitoring systems
Critical Parameter Management (CPM) Terms

• Critical – highly significant, must-have, essential
• CPM – Critical Parameter Management – the process of managing Critical Parameters
• Critical Parameter – a device or process parameter (*design feature*) that must be present, must be robust, must be optimized, must be controlled.
• CtQ – Critical to Quality characteristic - a specification, a process setting, an essential characteristic
**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
CtQs in Design Control

Critical Parameter Management Process Model

Voice of the Customer
- Needs, Wants, Safety & Performance
- Risks, Experiences, Market Desires

Voice of the Business

DFSS = Critical Parameter Management
- Specification Transfer

CTQ Product and Process Control Systems
- Specifications, Settings
- & Controls Transfer

Post-Market Monitoring (Complaints Processes)

Production Processes & Control Systems
- Field Feedback into Process Improvement & Control
- Field Feedback into Product & Process Development

Design Transfer
CPM Ownership
From DA to QE

Company:
- Medical Devices
- 10,001 + employees
- Global
Critical Parameters are identified in Design and translated throughout the QMS and ultimately is used to focus control & monitoring and prioritized feedback loops.
CPM Process Model – Identification Targets - QE

Each Quality Engineer has been retrospectively identifying their Critical Parameters for their assigned products.

The identified Critical Parameters are then:
1. Assessed for capability
2. Mitigations defined
3. Improvement plans created
4. Controls & Monitors implemented

Starting with complaints and working to the left, critical safety, performance and compliance parameters identified.
CtQs in Design Control

CPM Process Model – Identification Targets - DA

In a **Prospective** manner – the development team, led by DA, identifies their Critical Parameters and rigorously tests them.

Starting with Customer Input and working to the right, critical safety, performance and compliance parameters identified

The identified Critical Parameters are then:

1. Assessed for capability
2. Risk assessed & Mitigations defined
3. Specifications created
4. Designs made robust
5. Tested and **optimized**
6. Deployed to commercialization

Transfer Function

\[ CP_{output} = f(x_{input}) \]
CtQs in Design Control

CPM – CPM document – Control & Monitoring

After all Critical Parameters and their associated downstream inputs are defined, in detail, and captured in one place.

This process provides transferability to future employees.
# CPM – AngioSeal VIP Real-Life Example

Control & Monitoring requirements are established and documented and are under change control.
Once the control plan is established, we then evaluate and monitor Capability as can be seen on the table at left. This provides ongoing assessment and action item planning.
CtQ Benefits

- Significant External Risk Reduction
- Development cost savings – focus on critical reduces sampling requirements on non-critical.
- Speed to market significantly improved
- Production cost savings – Failure costs dramatically reduced
- Significant complaints reductions for defects
- Significant time savings throughout
- Knowledge! Throughout the product life cycle
- Supreme auditability – facts available
Critical Parameter Management – Beginning Steps

- Retrospectively identify commercialized product Critical Parameters
- Define Critical Parameter Management Process within PDP and Quality System
- Train all CPM stakeholders on CPM process – DFSS and CPM (Lean Six Sigma)
- Prospectively start the CPM process on all future New Products and Processes
- Maintain and continuously improve Critical Parameter Management process
CtQs in Design Control

CPM - Process Control & Monitoring
CTQ’s (How Determined)

- Review of field complaints for high severity items impacting the patient.
- Consulted with Product Surveillance for assistance with interpreting complaints.
- Cross-functional review of what constitutes high severity complaints.
Identification of Critical Controlling Parameters

EXAMPLE

- Anchor
- Suture Assembly
- Collagen
- Hemo Sheath
- Introducer

Key
- Cp1
- Cp2
CtQs in Design Control

Critical Parameter Analysis - Example Product

This is an example of how to arrive at a CTQ and its controls

- Severe tissue damage to patient
  - Good insertion of the device into the patient
    - Improperly mating parts (OTC)
    - Incongruently placed components (low occurrence)
  - Damaged tips on sheath
- Severe bleeding or surgery to patient
  - Sheath & PVC stopcock should not leak or separate at hub
  - Leaks or separation at cap or hub base

Key Processes
- Welding step and weld neck design (ITC)
- Material handling practices (ITC)
- Handling (OTC)
- Proper hub molding (OTC)
- Consistent welding of cap to hub (ITC)
- Bonding of stopcock (PVC to sideport)
- Seal quality including wet quality

Current Improvement Areas and Notes
- Improve welding neck design
- Improve handling wash procedure
- Improve weld containers and packaging
- Improve handling practices
- Control of glue dispensers
- Monitor weld step (gap, pressure, time)
- Review dimensions of PVC tubing O.D. and sideport I.D.
- Process being outsourced

Potential Failure Modes (CTQs)
- Improper welding neck design
- Improper handling wash procedure
- Improper weld containers and packaging
- Improper handling practices
- Improper weld containers and packaging
- Improper glue dispensers
- Improper monitor weld step (gap, pressure, time)
- Improper control of glue dispensers
- Improper review dimensions of PVC tubing O.D. and sideport I.D.
- Process being outsourced

Company:
- Medical Devices
- 10,001 + employees
- Global
Example Product CTQ Parameters

- **Embolism**
  - Anchor break (6 Critical Control Point)
  - Suture break (3 CCP)
  - Guidewire distal tip break (1 CCP)
  - Dilator tip break (1 CCP)
  - Hemo sheath tip (1 CCP)

- **Bio-Incompatibility**
  - Collagen Composition (1 CCP)
  - Anchor Composition (1 CCP)

- **Infection / Sterility**
  - Header Bag (1 CCP)
Example Product Deployment of CPM

• Critical Product and Process Parameters
  - Capability and state of control

• Gap analysis
  - Where we are now
  - Improvement plans to achieve desired “State of Control”

• CPM will involve a reoccurring review of the critical parameter and controls with adjustments made as necessary.
Critical To Quality Parameter Monitoring

- Weekly meetings to communicate
  - issues
  - status
  - successes

- We will look at the following each week (QE’s daily):
  - Pareto of defects (Threading, Knot Tie, Crushing, Heat Shrink, Loading, ADAM, Final Inspect, Pouching)
  - Suture Break Force Run Charts (Threading)
  - Suture Retention Run Charts (Heat Shrink)
  - Bypass Sheath Force Run Charts (ADAM)
  - Peel test results (Pouching, Lot Release)
  - Deployment Tests (Lot Release)
  - Moisture Test (Lot Release)
  - Trend data (Lot Release)
Peel Strength of Package Sealer
CtQs in Design Controls Company Presentations

Individual presentation from member companies on how they use CtQs in design controls.

Company: A
- Medical Devices
- 1001-5000 employees
- North America

Company: B
- Medical Devices
- 10,001 + employees
- Global

Company: C
- Medical Devices
- 10,001 + employees
- Global

Company: D
- Medical Devices
- 10,001 + employees
- Global

Company: E
- Medical Devices
- 1001-5000 employees
- Global

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

Company: G
- Medical Devices
- 5001-10,000 employees
- Global

Company: H
- Medical Devices
- 10,001 + employees
- Global

Company: I
- Medical Devices
- 10,001 + employees
- Global

Company: J
- Medical Devices
- 10,001 + employees
- Global

Company: K
- Medical Devices
- 10,001 + employees
- Global