Case for Quality – Library of Successful Quality Practices for Medical Devices

Introduction to the library:

The medical device sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases and in the improvement of the quality of life for people with various ailments and disabilities, and thus, the manufacture of quality products is essential.

Along with FDA, we believe that product quality goes beyond compliance to the current Quality System Regulation (21 C.F.R. Part 820). AdvaMed companies came together and aligned on a common definition of Quality.

qual·i·ty
/ˈkwälətē/

noun

1. the result of ensuring that features and characteristics of a product that define its ability to consistently satisfy customer needs are realized, and the products:
    i. are safe, effective, and provide usability;
    ii. achieve desired uniformity, reliability, and performance;
    iii. and satisfy customer and user requirements and expectations regarding design, production, delivery, and service.

Hosted by:

AdvaMed
Advanced Medical Technology Association

AdvaMed has agreed to host a library of successful quality practices employed by representative member companies that reflect current practices that foster the development and manufacture of high quality medical devices.

- This Library is a compilation by AdvaMed member companies of successful Quality practices employed in their companies for practical use.
- The Library provides a selection of practices (and explanations of their value) from which users can view current industry practices.
- It is intended for quality professionals to use as a resource, not as a prescriptive guidance/textbook/checklist.
- It also can serve as a road map or toolkit for companies to enable them to improve their quality systems and product quality using proven methods already employed in the industry.
- Larger companies also can benefit by seeing a wide range of practice to enhance their current practices.

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Case for Quality Library -Site navigation and instructions

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 BACK to the last page you were on.

Clicking on the GREEN arrow icon will take you to the NEXT sequencial 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.

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Case for Quality – Library of Successful Quality Practices for Medical Devices

Introduction to the library:

The Library of Successful Quality Practices is not technology-specific, and is not intended to be exhaustive/all-inclusive. These practices do not correct quality issues or act as a replacement of sound technical judgment or sound financial discipline.

The second section of the library is on **Supplier Quality / Purchasing Controls**.

We define "Critical to Quality (CtQ)" as: a product, service, or process characteristic that is quantifiable and measurable and has been determined to be essential to the device's quality, per the medical device quality definition."

Eventually, all major aspects of the Quality System Regulation (21 C.F.R. Part 820) will be represented in the Library of Successful Quality Practices.

Disclaimer

The information contained in this site is for educational and informational use. It is intended to be a resource of ideas for Successful Quality practices and is not intended to be a comprehensive compilation or prescriptive checklist of those best practices. Companies are free to use the industry methods detailed in the documents provided on this site to improve their quality systems and product quality. These studies and educational materials have been compiled from AdvaMed member companies; they are not created or endorsed by AdvaMed. AdvaMed makes no guarantees as to their accuracy, completeness, or timeliness.

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Case for Quality -Library of Successful Quality Practices for Medical Devices

Identifying and properly characterizing CtQs ultimately should result in higher quality products and services, as well as optimizing cost and speed to market. Some of the benefits to be realized can include:

Disciplined Approach

CtQs bring a disciplined approach to a Quality score card that measures quality prior to product launch and identifies critical quality elements.

Improved Quality

Capturing CTQs early in the product development lifecycle provides a traceable body of knowledge from initial Voice of the Customer [VOC] through the final delivery of a product to a customer. Knowing what is critical allows product development teams, and ultimately manufacturing units to ensure the right focus is on those items that are most critical from characterization, to 'right' levels of sampling and testing, this focus should result in a reduction in complaints. In addition, it preserves the view back to the customer and allows the ability to trace back to why a given parameter is important. As improvements to future generations of products are considered, this information is a valuable input to the change management process, with CTQs in place, important customer requirements will not be eliminated inadvertently because there is the knowledge flow from VOC to operational parameters.

Cost of Quality

Focusing on CTQs also can result in cost savings in development as product development teams can allocate activity to the most important aspects of the product. This focus can then translate down into production cost savings as product development delivers a product and process that is more fully characterized, reduces sampling requirements for non-critical aspects of the process, and can result in dramatically reduced failure costs.

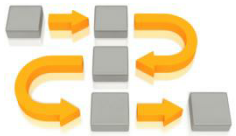
Speed to Market

is significantly improved. Applying focus where it is needed should reduce speed to market and avoid rework from lack of understanding of CtQs.

Significant complaints reductions for defects.

Significant time savings throughout

Knowledge throughout the product life cycle



Supreme auditability - facts available.

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Case for Quality - Benefits of Using Library of Successful CtQ Practices

Compliance can be leveraged into business value when combined with:

Quality performance is directly impacted by specific practices in product and process design including quality controls and product simplicity. There is an efficient frontier reflecting a tradeoff between quality performance and cost; however few if any Medical Devices companies have reached this point in quality maturity and still have significant opportunity to improve both.

Identifying and properly characterizing CtQs attributes can result in higher quality products and services, as well as optimizing cost and speed to market. Some benefits can include:

Improved Quality

Capturing CTQs early in the product development lifecycle provides a traceable body of knowledge from initial Voice of the Customer [VOC] through the final delivery of a product or service to a customer. Knowing what is critical allows everyone in the value chain to apply focus on what is most important.

Cost of Quality

By improving product and process quality you reduce the cost of poor quality. This can be a significant cost to your business and includes reworked products, complaints, recalls, warranties or other, non-routine events.

Improved Compliance

CTQs help deliver products and services that are fully characterized . This improves organizational knowledge around product risks.

Speed to Market

CTQs apply focus where it is needed and can reduce speed to market and avoid unnecessary testing and rework.

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Case for Quality – Supplier Quality/Purchasing Controls CtQ Successful Practices Library

Introduction to Supplier Quality / Purchasing Controls CtQ Successful Practices:

- The Supplier Quality / Purchasing Controls CtQ Successful Practices portion is the second entry in AdvaMed's Library of Successful CtQ Practices.

There are 10 presentations included that illustrate the successful practices currently used by AdvaMed companies, along with appendices that provide more detail on specific aspects of design control (obtaining voice of the customer requirements and translating these requirements into CtQs.

The Supplier Quality / Purchasing Controls CtQ Portion of AdvaMed's Library of Successful Practices is organized as follows:

CtQs in Supplier Quality / Purchasing Contols Company Presentations:

Individual presentation from member companies on how they use CtQs in supplier quality / purchasing controls.

Risk Management:
Risk Management Overview

Transfer To Other Volumes:
Connect to other volumes in the AdvaMed's Library of Successful Practices

Definition Highway:
Supplier Quality / Purchasing Controls Glossary

Lessons Learned:
Supplier Quality / Purchasing Controls Lessons Learned

Appendix A:
MedAccred Information for AdvaMed

Appendix B:
Production Part Approval Process For Internal & External Suppliers

Appendix C:
Internal Suppliers

Section is under construction

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Case for Quality – Design Control CtQ Successful Practices Library

Introduction to Design Control CtQ Successful Practices:

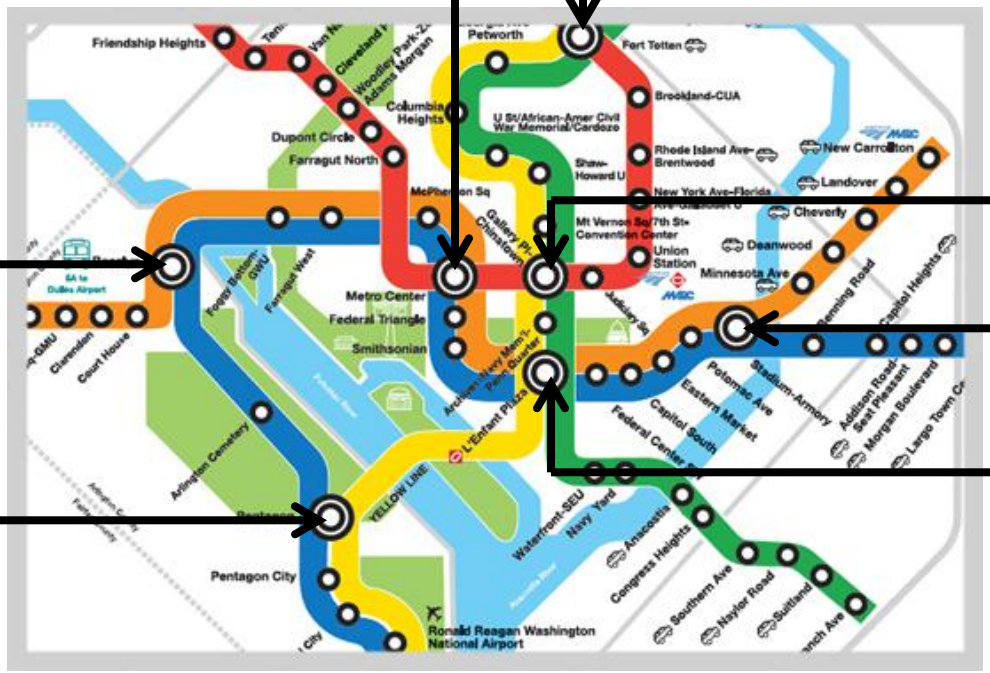
- The Design Control CtQ Successful Practices portion is the first entry in AdvaMed's Library of Successful CtQ Practices.
- Design Control CtQs are intended to identify the practices, processes, and cultures required to effectively manage the design and development of new or exisiting medical devices.
- It explains how the CtQs fit into a product's lifecycle and how they align with 21 C.F.R. Part 820, Essential Design Requiremments, and FDA's QSIT Inspectional Guidance.
- There are 11 presentations included that illustrate the successful practices currently used by AdvaMed companies, along with appendices that provide more detail on specific aspects of design control (obtaining voice of the customer requirements and translating these requirements into CtQs.

The Design CtQ Portion of AdvaMed's Library of Successful Practices is organized as follows:

Macro View Product Life Cycle
Macro View of where CtQs fit into the Product Lifecycle.

CtQ Essential Design Requirements
Graphic overview of how CtQs align with Essential Design Requirements, as set forth in 21 C.F.R. Part 820

CtQs in Design Controls Company Presentations
Individual presentation from member companies on how they use CtQs in design controls.



CFR820 CtQ Library Roadmap
Roadmap of how Design CtQs align with FDA's Quality System Regulation (21 C.F.R. Part 820).

CtQ QSIT
Graphic overview of how CtQs align with QSIT Inspection Guidance.

Appendices A:
Processes/tools for determining the Voice of the Customer

Appendices B:
Processes/tools for translating the Voice of the Customer into CtQs

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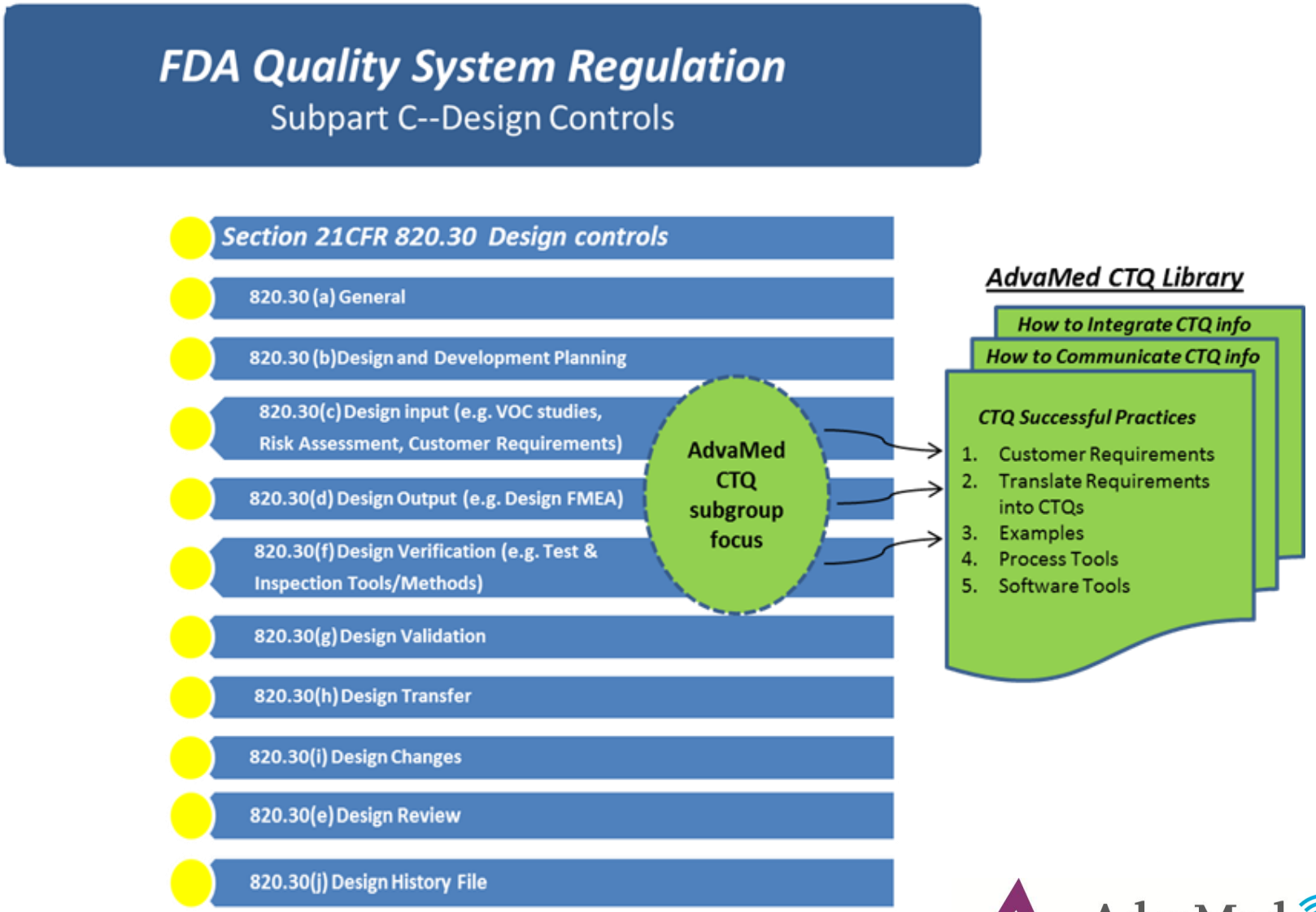
Case for Quality – Design Control CtQ Successful Practices Library

Macro View Product Life Cycle:



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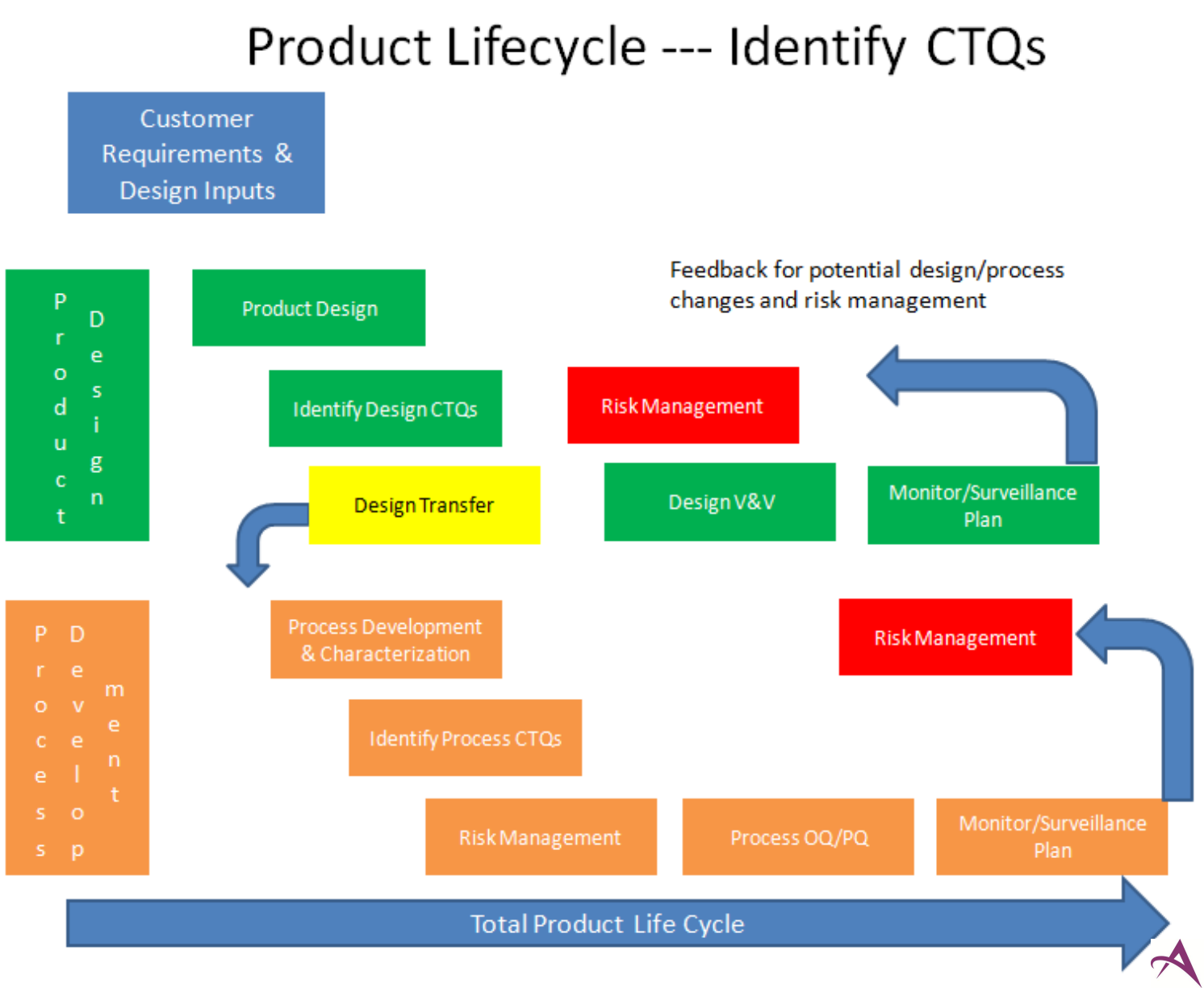
Macro View Product Life Cycle:



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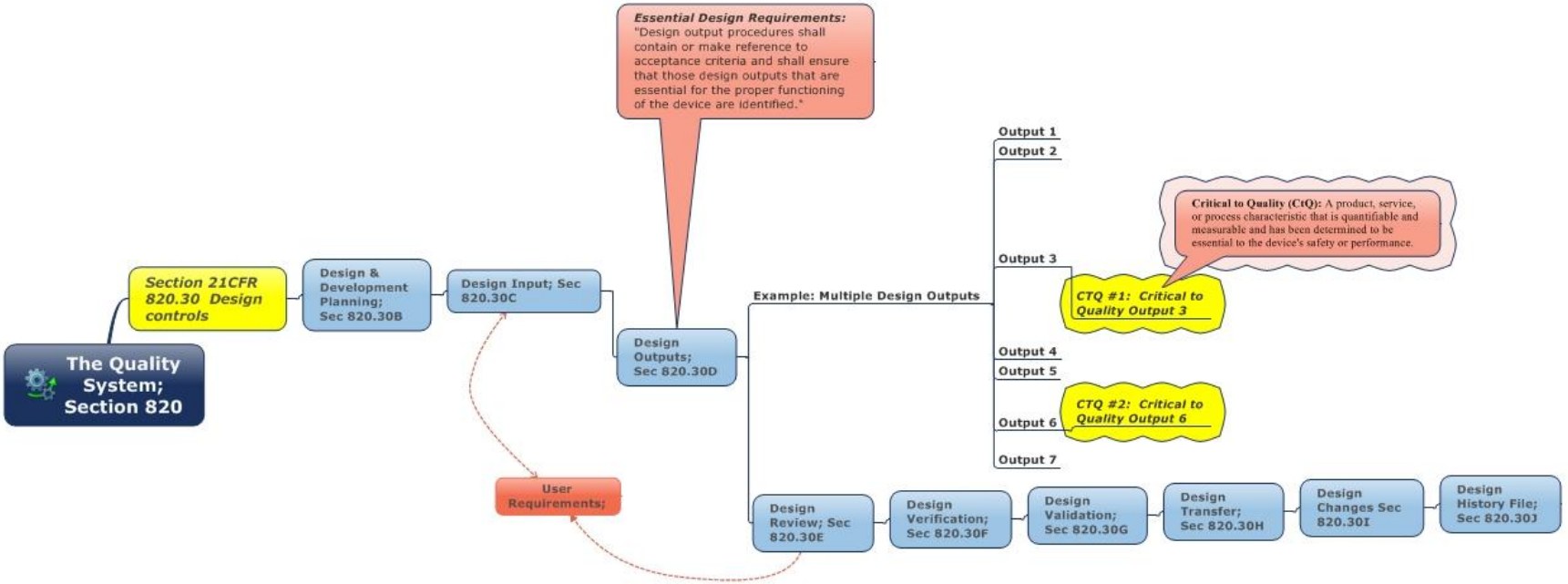
CtQ Essential Design Requirements:



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Case for Quality – Design Control CtQ Successful Practices Library

Glossary of Terms/Acronyms :

Corrective and Preventive Action (CAPA)
Cascade Method/Requirements Cascade
Critical Functional Response (CFR)
Cp
Capability Index (CpK)
Critical Customer Requirements (CCR)
Critical Parameter Management (CPM)
Critical Process Parameter (CPP)
Critical Quality Attribute (CQA)
Critical to Customer (CtC)
Critical to Function (CtF)
Critical to Process (CtP)
Critical Parameter Management (CPM)
Critical Process Parameter (CPP)
Critical Quality Attribute (CQA)
Critical to Customer (CtC)
Critical to Function (CtF)
Critical to Process (CtP)
Critical to Quality (CtQ)
Design for Customer Experience (DFCE)
Design for Manufacturability (DFM)
Design Failure Modes and Effects Analysis (DFMEA)
Design Failure Modes, Effects & Criticality Analysis (DFMECA)
Design for Quality (DFQ)
Design for Reliability (DFR)
Design for Serviceability (DFS)
Design for Six Sigma (DFSS)
Design of Experiment (DOE):
- Robust Design [Taguchi Method]
- Transfer Function

Design Tolerance
Edge of Failure
Fault Tree Analysis (FTA)
Failure Modes and Effects Analysis (FMEA)
Failure Mode, Effects, and Criticality Analysis (FMECA)
House of Quality (HOQ)
- Quality Function Deployment (QFD)

Ishikawa
KJ Analysis/Affinity Diagram
Key Process Input Variable (KPIV)
Key Performance Output Variable (KPOV)
Language Processing
Monte Carlo Simulation
Measurement System Analysis (MSA)
Process Failure Mode Effects Analysis (PFMEA)
Product Life Cycle Practice (PLCP)
Process Performance Rate (Pp)
Process Performance Index (PpK)
Proven Acceptable Range
Pugh Matrix
Quality
Quality Attribute
Quality Function Deployment
Requirements Document
Standard Operating Procedure (SOP)
Subteam Interactions Management
Technology Development Matrix (TDM)
Transfer Function
V Model
Value Curve/Value Stream Map
Voice of the Business (VOB)
Voice of the Customer (VOC)
Voice of the Process (VOP)

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Corrective and Preventive Action (CAPA): are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. A systematic investigation of the root causes of identified problems or identified risks are performed in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action). (See 21 C.F.R. § 820.100)

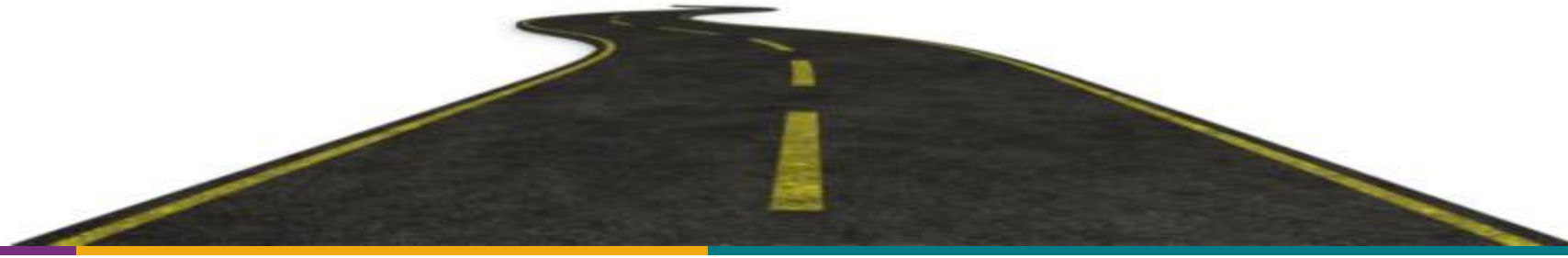
Cascade Method/Requirements Cascade: is the process of taking all design inputs and creating design outputs. There are 3 elements of a cascade: Parent requirement [y]; Child requirement [x]; and Transfer function [f()].

Critical Functional Response (CFR): is a measurable and controllable output of device subsystems or subassemblies.

Cp: is a measure of capability defined as the ratio of the specification width to short-term process performance width

Capability Index (CpK): is a statistical measure of process capability, which is the ability of a process to produce output within specification limits. It is an adjusted short-term capability index.

Critical Customer Requirements (CCR): are customer expectations regarding an aspect of a product or service (e.g., quality, speed, etc.). Such an expectation is a CCR when the customer may be expected to refuse to purchase, or to purchase from a competitor, if the expectation is not met.



Critical Parameter Management (CPM): is an important part of a rigorous, systems engineering-driven product development process. CPM is an engineering methodology for managing, analyzing, and reporting system performance throughout each stage gate or phase of the process. It is an engineering practice specifically intended to maintain the robustness of the system through detailed design and manufacturing

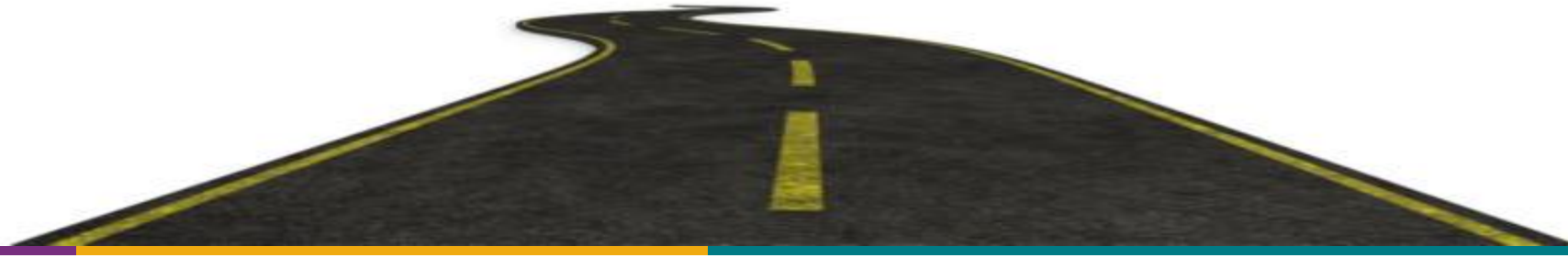
Critical Process Parameter (CPP): is a process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

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.

Critical to Customer (CtC): is a quantifiable standard of performance for a product that is essential for that product to meet the requirements of the customer.

Critical to Function (CtF): is a means of communicating dimensions critical to success of the design, tolerance, and other non-geometrical information.

Critical to Process (CtP): are the key process input variables that influence other critical approaches.



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Critical to Quality (CtQ): is a product, service, or process characteristic that is quantifiable and measurable and has been determined to be essential to the device's quality, per the medical device quality definition.

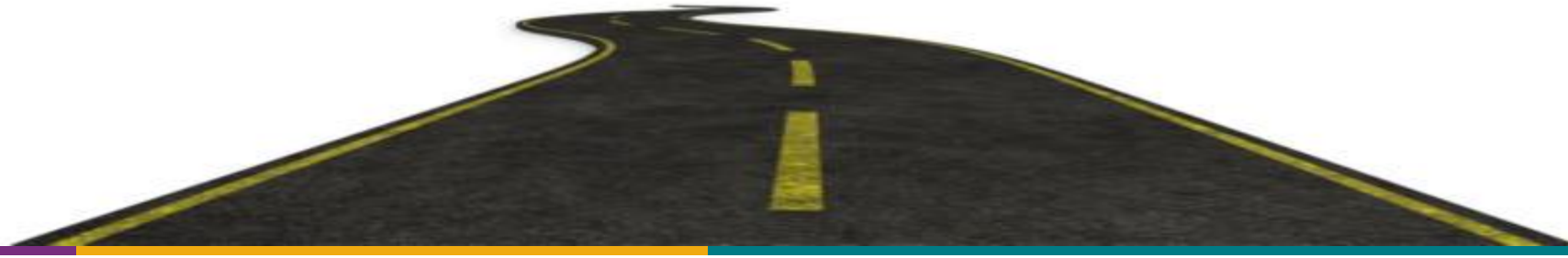
Design for Customer Experience (DFCE): is design that meets customer's needs and wants.

Design for Manufacturability (DFM): is designing products so that they are easy to manufacture.

Design Failure Modes and Effects Analysis (DFMEA): is a quantitative method to review as many components, assemblies, and subsystems in the device as possible to identify failure modes, and their causes and effects. DFMEA is used to uncover design risk, which includes possible failure, degradation of performance, and potential hazards. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet.

Design Failure Modes, Effects & Criticality Analysis (DFMECA): is a criticality analysis that compares the probability of failure modes against the severity of their consequences. The result highlights failure modes with relatively high probability and severity of consequences, allowing remedial effort to be directed where it will produce the greatest value.

Design for Quality (DFQ): the role of quality in the total production cycle, including customer inputs, competitive benchmarking, performance specifications, product and process design, manufacturing variability, and product reliability.



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Design for Reliability (DFR): designing a product to ensure that it is able to perform to a required level of reliability

Design for Serviceability (DFS): designing a product to ensure that it is able to be serviced in simple and reliable ways.

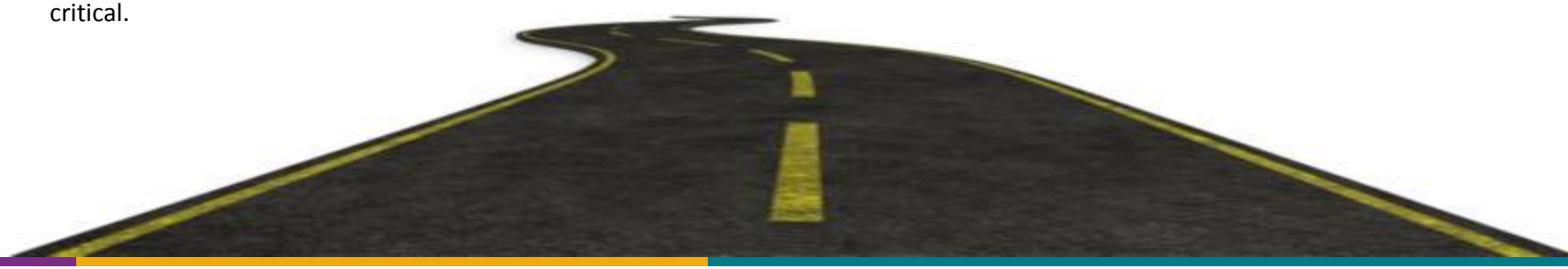
Design for Six Sigma (DFSS): is an approach or tool to design for and capture optimum parameters for producing a given product at high quality levels.

Design of Experiment (DOE): is a statistical tool used to evaluate the impact of multiple factors or 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.

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

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

Fault Tree Analysis (FTA): is a deductive, top-down logic diagram analytical approach where the undesired event/failure/safety hazard is first identified, and then the paths/contributing factors to this event are identified to determine which process failures are most critical.



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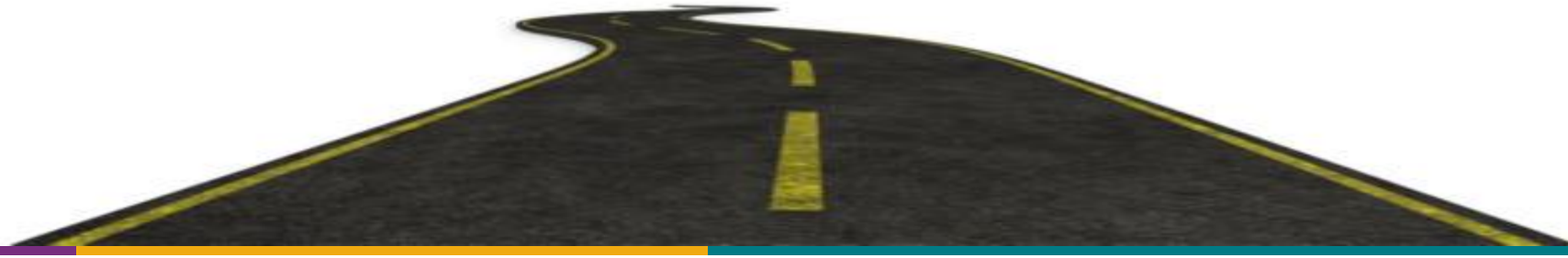
Failure Modes and Effects Analysis (FMEA): is a bottom-up assessment used to identify each potential failure mode for all components of the system and trace these effects up through the system's hierarchy to identify negative effects at the subassembly, assembly, and system levels.

Failure Mode, Effects, and Criticality Analysis (FMECA): is a process to ensure potential failure modes are classified according to their severity or risk.

House of Quality (HOQ): also called **Quality Function Deployment (QFD)** is a tool to systematically translate customer requirements into quantitative parameters that can be used to produce a given product.

Ishikawa: (also known as a fishbone, herringbone, and cause-and-effect diagram) is diagram (created by Kaoru Ishikawa) that illustrates the causes of a specific event. For design controls, Ishikawa diagrams are used to graphically represent where quality defect issues might arise, identify potential factors contributing to these issues, and help to determine specific resources required at specific times.

KJ Analysis/Affinity Diagram: is a tool to organize ideas/issues by sorting them into groups based on their natural themes or relationships.



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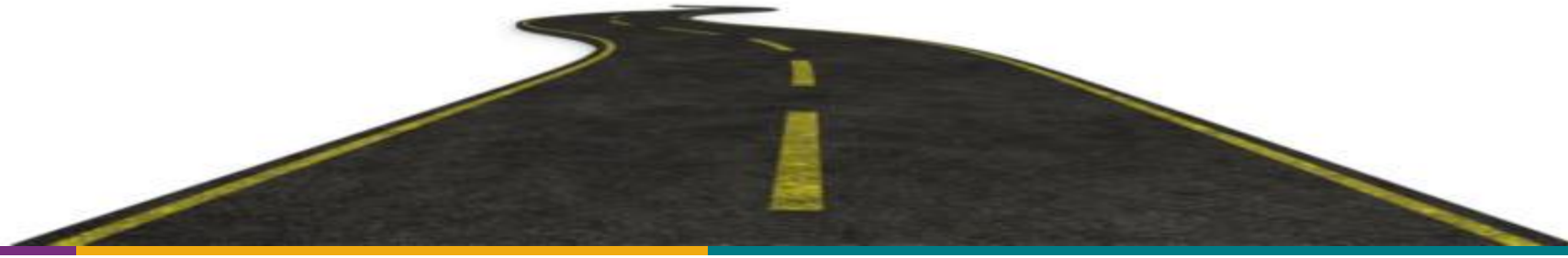
Key Process Input Variable (KPIV): is an input factor that has been determined to be a source of variability in and important for the output of the process. Once the key process input variables for a process are determined, statistical experiments can be designed that can reveal optimal values for each factor to achieve desired output quality. KPIV can be considered input that significantly impacts the variation found in KPOV (Key Performance Output Variables)

Key Performance Output Variable (KPOV): sometimes referred to as "Key Characteristics," are traits or features of a part, piece of material, assembly, subsystem, or system that, when variation exists, has a significant influence on fit, performance, reliability, manufacturability, or assembly. KPOVs are characteristics that impact efficiency, performance and/or customer satisfaction.
Language Processing: is a process to use customer input to refine and fully develop CtQs.

Monte Carlo Simulation: is a computerized mathematical technique that employs repeated random sampling to obtain numerical results; typically simulations are run multiple times to obtain the distribution of an unknown probabilistic entity. These simulations allow for the accounting of risk in quantitative analysis and decision making.

Measurement System Analysis (MSA): is a method to identify the components of variation in the measurement. It is used to qualify a measurement system for use by quantifying its accuracy, precision, and stability.



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Process Failure Mode Effects Analysis (PFMEA): is a structured analytical tool used to identify and evaluate the potential failures of a process. PFMEA helps to ascertain the impact of the failure, and identify and prioritize the action items with the goal of mitigating risk.

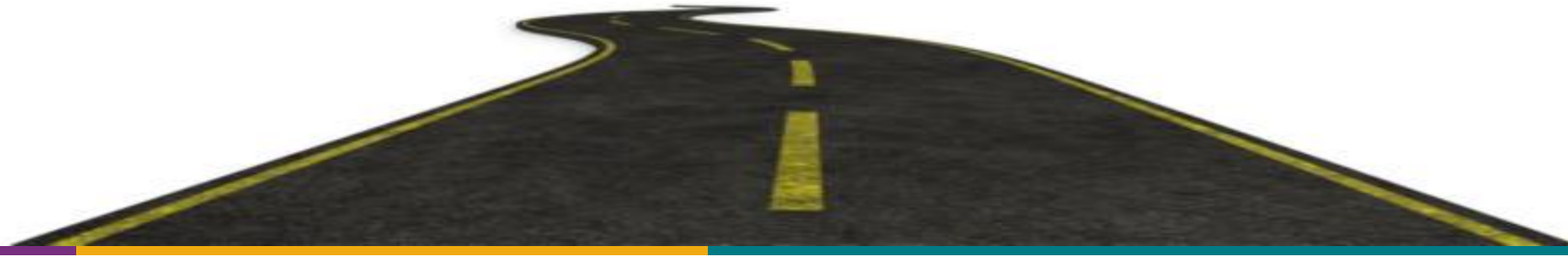
Product Life Cycle Practice (PLCP):

Process Performance Rate (Pp): is used to summarize a system's performance in meeting upper and lower specification limits. It shows how the system is actually running when compared to the specifications.

Process Performance Index (PpK): is a measure of process performance and tells how well a system is meeting specifications and accounts for the overall variation of all measurements taken.

Proven Acceptable Range: is a characterized 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.

Pugh Matrix: is a quantitative technique used to rank the multi-dimensional options of an option set, e.g., is concept “A” better than concepts “B” or “C?”



Quality: is the result of ensuring that features and characteristics of a product that define its ability to consistently satisfy customer needs are realized, and the products: are safe, effective, and provide usability; achieve desired uniformity, reliability, and performance; and satisfy customer and user requirements and expectations regarding design, production, delivery, and service.

Quality Attribute: is a physical, chemical, biological, or microbiological property or characteristic that has a defined limit, range, or distribution.

Quality Function Deployment: See "House of Quality"

Requirements Document: is 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.

Standard Operating Procedure (SOP): is a set of written instructions/ established methods that describe a process to be followed by an organization in specified situations.

Subteam Interactions Management: is a graphical tool to allow a team to identify potential interactions and manage them.

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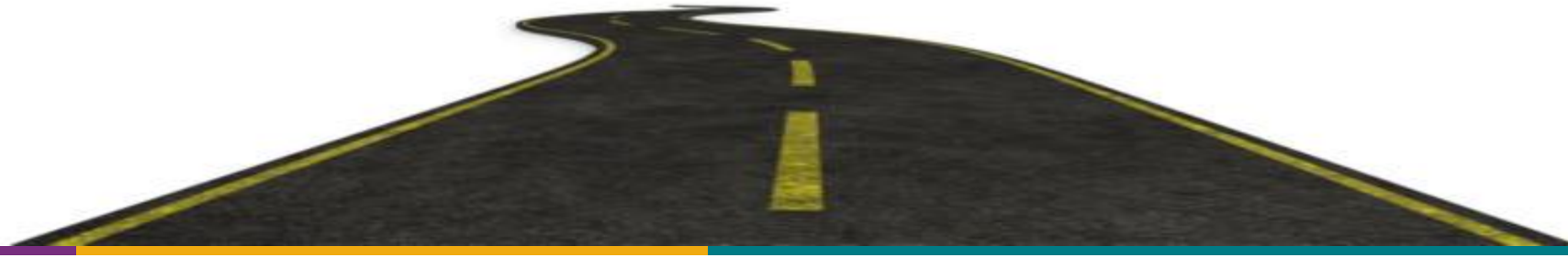

Technology Development Matrix (TDM): is used to identify which projects to undertake based on customer needs. The technology development projects are evaluated, prioritized, and scheduled in accordance with available resources using this matrix.

Transfer Function: is a mathematical formula describing the ratio of the output of a system to the input of a system

V Model: is a graphical representation of a device's development lifecycle. The "V" depicts the sequence of steps in a project life cycle development. It describes the activities to be performed and the results that have to be produced during product development. The left side of the "V" represents the decomposition of requirements, and creation of system specifications. The right side of the V represents integration of parts and their validation.

Value Curve/Value Stream Map: is a diagram used to compare products on a range of factors by rating them on a scale from low to high.

Voice of the Business (VOB): reflects the needs of a business and its stakeholders, including profitability, revenue, growth and market share.

Voice of the Customer (VOC): reflects the needs, wants, and requirements of the customer.

Voice of the Process (VOP): is an assessment of the process performance and capability to achieve both business and customer needs, whether it is under control, and what significance to attach to individual measurements.

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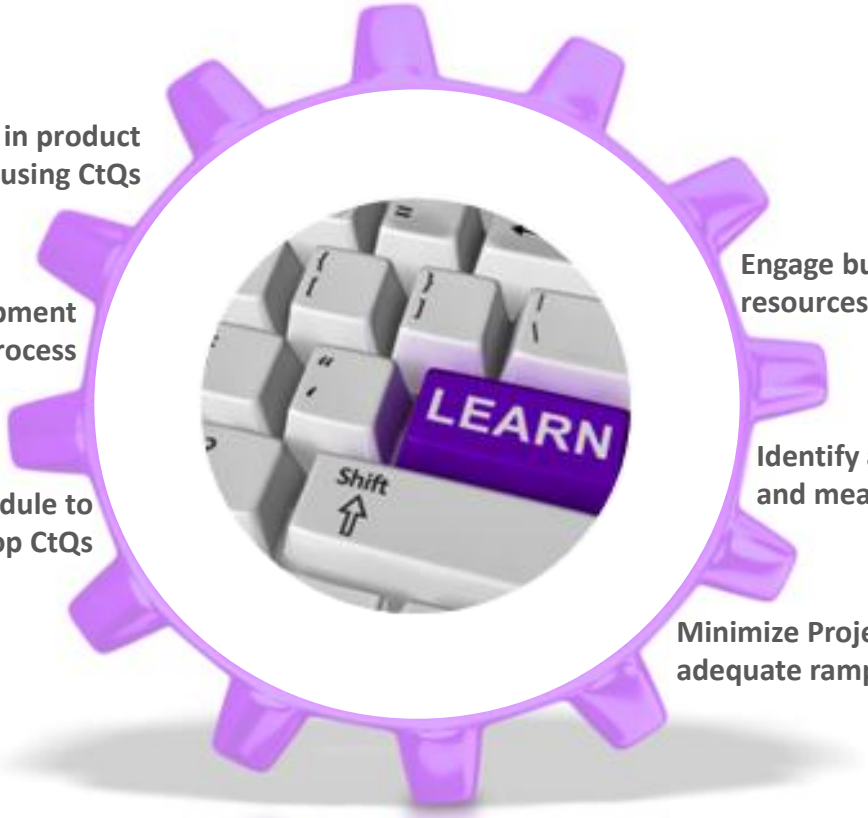
Case for Quality – Design Control CtQ Successful Practices Library

Lessons Learned:

Manage changes in product features/scope using CtQs

Build CtQs into the development process vs. post design process

Allow time in the schedule to fully develop CtQs



Engage business and quality / regulatory resources early and often in the design process.

Identify a clear process for CtQ identification and measurement in production process.

Minimize Project Leader changes or have adequate ramp up for new Project Leaders

A common pitfall is to identify everything as critical, which defeats the purpose of identifying CtQs. The main point of CtQ identification is to prioritize those product design specifications that warrant the most attention (time and resources).

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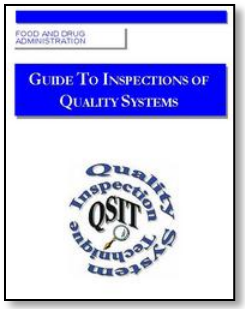
Case for Quality – Resources



FDA QSIT Inspectional Guidance Documents:

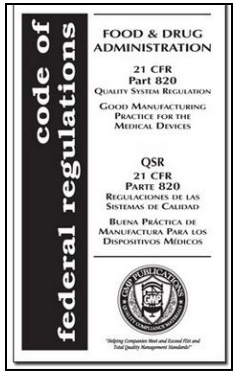
The link to FDA's GUIDE TO INSPECTIONS OF QUALITY SYSTEMS" on FDA's website is:

http://www.fda.gov/downloads/iceci/inspections/ucm142981.pdf

Understanding Barriers to Medical Device Quality:

The link to the document on FDA's website is:

http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf



Regulations:

The link to: 21 C.F.R. Part 820 is:

http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol8/pdf/CFR-2013-title21-vol8-part820.pdf

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