Quality Planning

In Support of ISO 13485 and 21 CFR 820 Compliance

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Quality Planning: For ISO 13485 and 21 CFR 820 Compliance

- Topics to be covered:
  - **Definitions will be provided throughout the presentation as applicable**
  - **Types of Quality Plans**
  - **Quality Management System Considerations**
  - **Product Realization Considerations**
  - **Quality Planning References**
  - **Quality Planning Tools**

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- **Types of Quality Plans**
  - Quality Management Plan
    - Strategic Quality Plan
  - Design and Development Plan
    - Verification and Validation Plan
    - Risk Management Plan
  - Product Realization Plan
  - Quality System Audit Plan

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- **Quality Management System Considerations**
  - **Requirements**
    - **What ISO 13485 Requires**
    - **What 21 CFR 820 Requires**

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- **What ISO 13485 Requires:**
  - 5. Management Responsibility
    - 5.4 Planning includes setting quality objectives for
      - the ***quality management system;*** AND
      - for ***medical devices & related services***
      - ***Defining timeframes for achieving objectives***
  - 7. Product Realization
    - 7.1 Planning of product realization includes determination of:
      - product quality objectives & requirements
      - definition of medical device lifetime (record retention)
      - establishing processes & documents
      - resource needs
      - design and development
      - verification & validation
      - monitoring and inspection
      - test activities and product acceptance criteria
      - **RISK MANAGEMENT;** and
      - RECORDS

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- **What ISO 13485 Requires:**
  - 7.3 Design and development
    - Established procedures describing design processes and ALL design activities
      - goals and objectives of the design and development program (i.e. what is to be developed, timeline, etc.)
      - the markets intended
      - identification of organizational responsibilities with respect to assuring quality during the design and development phase, to include interface with any suppliers
      - identification of the major tasks by phases of the design
      - expected outputs (deliverables and records) from each phase

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- **What ISO 13485 Requires:**
  - 7.3 Design and development (cont'd)
    - Established procedures describing design processes and ALL design activities
      - identification of appropriate existing and anticipated measurement & monitoring devices for development of product specifications, verification, validation and production related activities
      - the selection of reviewers & composition of review teams
      - planning transfer to production
      - risk management activities
      - supplier selection

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- **What ISO 13485 Requires:**
  - 7.1 Planning of Product Realization
    - quality objectives and requirements for the product.
    - the need to establish processes, documents, and provide resources specific to the product.
    - required verification, validation, monitoring, inspection and test activities specific to the product, and the criteria for product acceptance.
    - records needed to provide evidence that the realization processes and resulting product meets requirements.
    - output of this planning in a form suitable for the organization's methods of operations.

Note: The organization is required to establish documented requirements for risk management throughout product realization.

- ***Records arising from risk management shall be maintained***
- ***Also: see ISO 14971 for guidance related to risk management...***

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- **What ISO 13485 Requires:**
  - **8.2.2 Internal audit**
    - The organization shall conduct internal audits at planned intervals to determine whether the quality management system
      - a) conforms to the planned arrangements
    - An audit program shall be planned, taking into consideration
      - the status and importance of the processes
      - areas to be audited,
      - results of previous audits.
    - The audit criteria, scope, frequency and methods shall be defined.

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- **What 21 CFR 820 (cGMP for Medical Device Manufacturing) Requires:**
  - **21 CFR Sub Part B Quality System Requirements Section 820.20 Management Responsibility:**
    - **(d)*Quality planning.* Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.**

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- **What 21 CFR 820 (cGMP for Medical Device Manufacturing) Requires:**
  - **21 CFR Subpart C Design Controls 820.30 Design Controls:**
    - **(b)*Design and development planning.* Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.**

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- **Quality Management System Considerations**
  - **QMS Implementation**
    - **Quality Policy and Objectives**
    - **Quality Management System Structure**
      - **Records**
      - **Metrics**

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- **Quality Policy Template**
  - **"The [insert name] company provides safe, reliable, high quality, [insert product and/or service description] to [insert general customer reference, such as "Medical Device Industry" or "Health Care Professionals"] on time and in compliance with all applicable regulatory requirements."**

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- **Tips for Selection of Quality Objectives**
  - Use the S.M.A.R.T. criteria:

S SPECIFIC
M MEASURABLE
A ATTAINABLE
R RELEVANT
T TIME-CONSTRAINED

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- **"Quality Metrics"**
  - A "metric" is a measure.
  - "Quality" is something a "customer" defines.
  - A "Quality Metric", therefore, is a measure of quality as defined by the customer.
    - NOTE 1: A "customer" might be defined as anybody with an expectation of receiving something of value in exchange for something else of value, either external to or internal to an organization.
    - NOTE 2: Not all "Metrics" are "Quality Metrics"

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- **KPI's**
- **KPI = Key Performance Indicator**

  There are MANY definitions:
  - ***Chosen factors*** that directly and indirectly influence the effectiveness of a product or process.
  - A ***significant measure*** used on its own, or in combination with other key performance indicators, to monitor how well a business is achieving its quantifiable objectives.
  - A ***proxy measure of the success*** of part of an organization, or a manager of that part. A type of indicator. The future of the unit or person depends on achieving a satisfactory figure.
  - Also known as Key Success Indicators (KSI). ***Financial or non-financial metrics*** used to reflect the critical success factors of an organization.
- **NOTE 1: All KPI's are also Metrics, but not all Metrics are KPI's.**
- **NOTE 2: Not all KPI Metrics are Quality Metrics.**

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- **Scorecards**
  - A scorecard is part of a broader corporate methodology or management discipline and is a report card of how a given person, business unit or entity performed with respect to certain goals *over a previously defined period of time* (such as quarterly or annually).
  - An Executive Scorecard is analogous to a student's Report Card.
  - There are two popular formats for "Balanced Scorecards" (BSC's):
    - 1.) Customer, Employee, Shareholder, Process
    - 2.) Customer, Learning/Growth, Financial, Internal Business Process/Operation

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- **Scorecard Example (http://www.hospitalsoup.com/public/scorecardshell.pdf)**

Hudson River Psychiatric Center
BALANCED SCORECARD - FIRST QUARTER (JANUARY, FEBRUARY, MARCH) 2000

FINANCIAL PERSPECTIVE Score: /12 %	CUSTOMER PERSPECTIVE Score: /16 %
INTERNAL BUSINESS PERSPECTIVE Score: /32 %	INNOVATION AND LEARNING PERSPECTIVE Score: /20 %

OVERALL SCORE: /80 (%)

FINANCIAL	CUSTOMER PERSPECTIVE	INTERNAL BUSINESS	INNOVATIONS LEARNING
PERSONAL SERVICES Score /4	INCREASE CUSTOMER/STAKEHOLDER SATISFACTION WITH SERVICES Score /16	QUALITY TREATMENT SERVICES Score /16	DEVELOP STRATEGIC SKILLS AND COMPETENCIES Score /8
NON-PERSONAL SERVICES Score /4		PROVIDE SAFE THERAPEUTIC ENVIRONMENT Score /16	IMPROVE TECHNOLOGY INFRASTRUCTURE Score /4
ROSS Score /4			CLINICAL OUTCOMES ASSESSMENT Score /8
Total /12	Total /16	Total /32	Total /20 %

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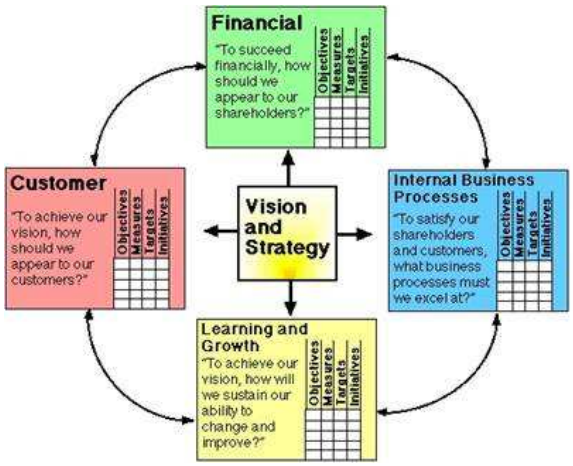
- **Scorecard Example** (http://www.balancedscorecard.org/basics/bsc1.html):



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- **Scorecard Example** (www.capatrak.com):

	Objectives/ Plans (Strategy) (Tie to Quality Policy)	Metrics (KPIs)	Targets/ Goals	Initiatives/ Actions (Tactics)
Customer Relations	(Customer Satisfaction, Regulatory Compliance)			
Finance	(low risk/continual improvement, growth)			
Operations	(continual improvement, best in field, capable processes)			
Organization Sustainability	(competent personnel, employee satisfaction, world class)			

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- **Scorecard Example** (www.capatrak.com):

	Objectives/ Plans (Strategy)	Metrics (KPIs)	Targets/Goals	Initiatives/Actions (Tactics)
Customer Relations	Tie to Quality Policy (Customer Satisfaction, Regulatory Compliance)	Examples:	Examples:	Examples:
		• Retained Customers/Qtr	• 30% of Customers place at least one order within prior 3 months	• Launch purchase with purchase promotion targeted toward existing customers.
		• Repeat Orders per Customer/Qtr	• Of Customers that place orders, at least 60% will have Ordered an item at least once before	• Offer "customer loyalty" incentives (discounts, buy one get one packages, etc.).
		• Customer Satisfaction/Yr	• On a scale of 1 to 10, Average Customer Satisfaction is to improve by at least ½ point in 6 of 7 areas of concern	• First quarter: Perform Customer Satisfaction phone survey to identify areas of concern. • Second and Third quarters:Develop and Implement improvement strategies. • Fourth quarter: Re-survey in third quarter.
		• Complaints/Qtr	• Reduce Complaints by a minimum of 15% over each prior quarter until complaints are eliminated	• Hold weekly Corrective Action Review Board Meetings with Top Management. • Implement Automated Corrective Action Tracking System. • Add Corrective Action Dashboard to Monthly Operations Review Agenda.

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- **Product Realization Considerations**
  - **Work Instructions**
    - **Records**
    - **Metrics**

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- **Quality Planning References**
- **Quality Planning Tools**
  - **Quality Planning Procedure Template**
  - **Strategic Quality Plan Template**

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- **Dashboards**
  - A dashboard is a dynamic set of indicators about the state of a process, piece of equipment, or business metric *at any specific point in time.*
  - A Quality Metrics Dashboard is analogous to the dashboard in a car or the cockpit in a plane but, instead of driving a car, the user is "driving" a process.

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- **Dashboard Example (http://www.primedonline.com/PulseMonitor.htm)**

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- **Dashboard Example (http://dashboardspy.wordpress.com/2006/03/23/)**

Quality Metrics, Scorecards and Dashboards

- Dashboard Examples:
  - http://www.primedonline.com/PulseMonitor.htm
  - http://dashboardspy.wordpress.com/2006/03/23/
- Scorecard Models and Examples:
  - http://www.balancedscorecard.org/basics/bsc1.html
  - http://www.capatrak.com
    (use member access free stuff page)
  - http://www.primedonline.com/PulseMonitor.htm
  - http://www.hospitalsoup.com/public/scorecardshell.pdf

Quality Metrics, Scorecards and Dashboards

- The following free templates will be provided to you via email upon request (send request to dkulisek@capatrak.com) and are or will also be available from the CAPAtrak Download pages at www.capatrak.com. These include:
  - Strategic Quality Plan Template
  - Operating Procedure and/or Work Instruction Template for Inclusion of Quality Metrics
  - Scorecard Template
  - Dashboard Template
- A .pdf version of the handouts for this presentation will also be available for download from the CAPAtrak download page.

Quality Metrics, Scorecards and Dashboards

Thank you!

May I answer your questions?