OVERVIEW of ISO 13485:2003 Medical Devices — Quality Management Systems

Requirements for Regulatory Purposes

Jack E. Moore, Jr. (Credits to Gunter Frey)
Director Regulatory Affairs & Compliance
BD Asia Pacific Region
November 4, 2008

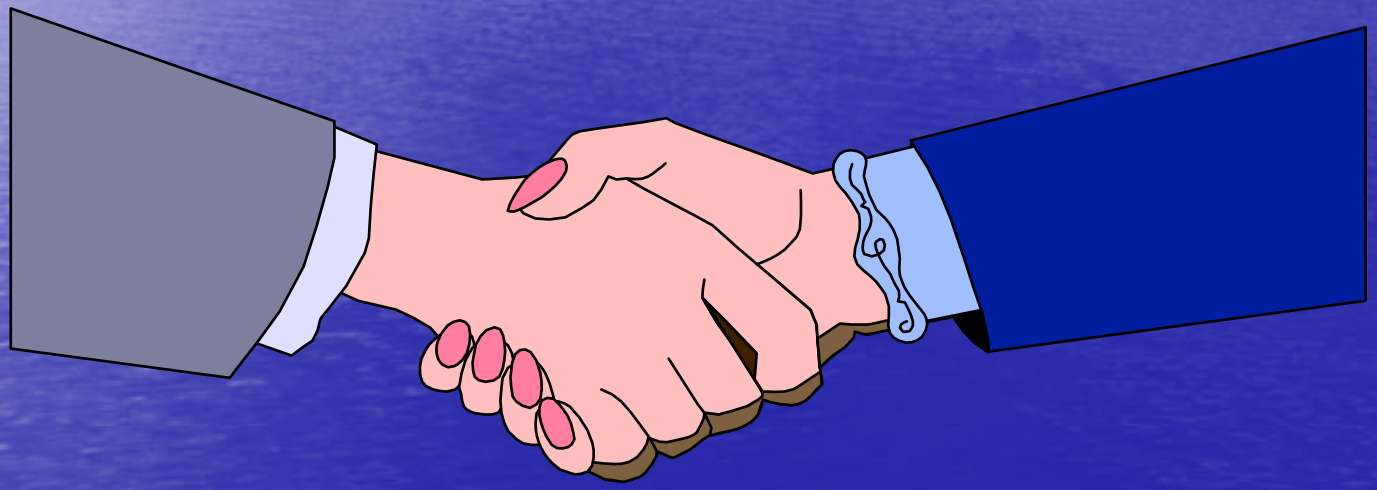
Objectives of this Overview: Answer the Following Questions

- What is the Definition of a Quality Management System?
- What are the Benefits that a Quality Management System offers?
- Why is a Quality Management System Required? (Importance of having one)
- What is the "Big Picture" of the Quality Management System "Process"? (How does ISO 13485 fit into Big Picture?)
- What should you understand about and be looking for in the elements of a Quality Management System?
- What are the next steps should **you** take?

Key Words: This is what Jack Plans to present**!!!**

Introductions

- Name
- Position / Department
- Your Expectations from this training!



Key Words: Let's set expectations so no one goes away disappointed**!!!**

Quality Management System Definition

- The system including written policy and organizational structure, responsibility, and actions that establish the quality policy and objectives that are required to meet the regulations, standards and goals set by the company.
- Note: …as a means of ensuring that product conforms to specified requirements…

ISO 13485:2003 Quality Management System: General Requirements

- *The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard.*

Benefits of using ISO 13485 quality management system for medical devices – Page 1 of 2

- A Standardized approach to structure Quality Systems, to enable consistent execution of processes with repeatable and predictable outcomes – "product meeting specification"

  A PREVENTION MODEL for developing and manufacturing medical devices!!!

- Prevention of product nonconformances is more effective and less expensive than Detection and Correction
- Improved performance quality, less wastage, better use of resources, lower product failures
- Ability to obtain CE Mark and market products in Europe.
- Many other countries are acknowledging CE Marked products in their local regulatory systems

Key Words: Predictable, repeatable, reliable & prevention

Benefits of using ISO 13485 quality management system for medical devices – Page 2 of 2

- CE Marked products are more and more acceptable (in demand) internationally to customers!
- Allows Medical Industry Regulators to use a standardized evaluation of quality system of medical device companies (tried and proven system of competent authorities and notified bodies)
- Viewed by customers as a commitment to the quality of a company's medical devices
- Achieve higher customer satisfaction by providing higher level of quality assurance for customers
- Increase competitive advantage, PLUS Minimize and manage risk

Key Words: standardized, customer satisfaction, minimize risk

Why is a Quality System Required? (Importance of having one)

- Safer products for the people of India!
- Opens international markets for India manufactured medical devices
- Improve the perception of medical devices manufactured in India
- Achieve higher customer satisfaction by providing higher level of quality assurance for customers
- Minimize and manage risk
- Plus many of the same benefits from the previous two slides!!!

Key Words: Trust, credibility, compliant, less fires to fight

Why Have a Quality System?

- Customer
  - Safety
  - Satisfaction
- Best and safest product
- Compliance with Regulation and Standards
- Good business sense

What is the Big Picture of the ISO Quality System "Process"?

- Instituted by Regulatory Authorities
  - Europe by the "Competent Authorities" in each country
- Law and Regulation
  - Europe – Medical Device Directive – (MDD)
- Guidance
  - Supplemented by MEDDEV (EU Commission - MEDical DEVices: guidance document)
- Definitions
- Supporting Standards
  - ISO 13485:2003 Quality System Standard + many more
- Systemic Oversight (audits)
  - Europe by "Notified Bodies"
- ISO Standards review and updating as learning occurs in the medical device industry
  (example – ISO 14971 Risk Management versus EN1441 Risk Analysis)

What should you understand about and be looking for in the elements of a Quality Management System?

Important Definition / Distinction

Legal Manufacturer

and

Manufacturing facility

ISO 13485 quality management system for medical device legal manufacturers and manufacturing facilities of medical devices

Page 1 of 2

Legal Manufacturer ???

(Legal) 'manufacturer' means the natural or legal person with responsibility for the design *(design control)*,

manufacture, packaging and labeling of a device before it is placed on the market under his own name,

regardless of whether these operations are carried out by that person himself or on his behalf by a third party

(may be subcontracted to a manufacturing facility).

ISO 13485 quality management system medical device legal manufacturers and manufacturing facilities of medical devices

Page 2 of 2

Manufacturing Facility ???

The manufacturing facility is the actual physical location where the product is manufactured.

The manufacturing facility will manufacture the product for the legal manufacturer.

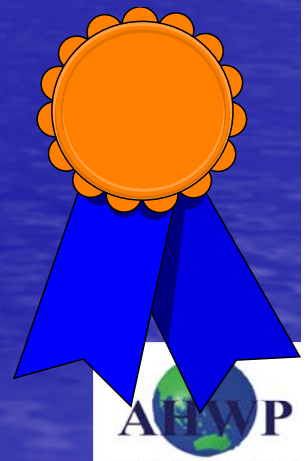
The manufacturing facility and legal manufacturer MAY be at the same address **OR** they may be on different continents.

In the case where they are separate addresses the legal manufacturer may appoint or contract with the manufacturing facility to manufacture the product for them.

What is Quality?

Quality*

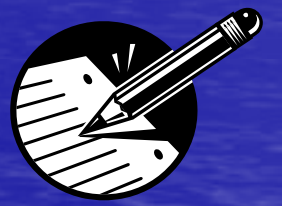
A product or service is deemed a “Quality” product or service when it meets all of its customer agreed upon requirements for form, fit and function. This assessment is made by the product or service customer.



* Definitions vary from Quality Guru to Quality Guru, but this definition will meet the need for this training

The Original - ISO 13485 Quality System Elements

1. Management Responsibility
2. Quality System
3. Contract Review
4. Design Control Process Control
5. Document and Data Control
6. Purchasing
7. Control of Customer Supplied Product
8. Product Identification and Traceability Documentation
9. Process Control(s)
10. Inspection and Testing
11. Control of Inspection, Measuring and Test Equipment
12. Inspection and Test Status
13. Control of Nonconforming Product
14. Corrective and Preventive Action (CAPA)
15. Handling, Storage, Packaging, Preservation and Delivery
16. Control of Quality Records
17. Internal Quality Audits
18. Training
19. Servicing
20. Statistical Techniques



Note: ISO 13485:2003 "LOOKS" A LOT Different!

The New - ISO 13485:2003 Quality Management System Organization

4.1 General requirements
4.2 Documentation requirements
5.0 Management responsibility
5.1 Management commitment
5.2 Customer focus
5.3 Quality policy
5.4 Planning
5.5 Responsibility, authority and communication
5.6 Management review
6.0 Resource management
6.1 Provision of resources
6.2 Human resources
6.3 Infrastructure
6.4 Work environment

7.0 Product realization
7.1 Planning of product realization
7.2 Customer-related processes
7.3 Design and development
7.4 Purchasing
7.5 Production and service provision
7.6 Control of monitoring and measuring devices
8.0 Measurement, analysis and improvement
8.1 General
8.2 Monitoring and measurement
8.3 Control of nonconforming product
8.4 Analysis of data
8.5 Improvement

Note: ISO 13485:2003 is called the "Process Approach"!

What is the Process Approach? (also known as “Process Model”)

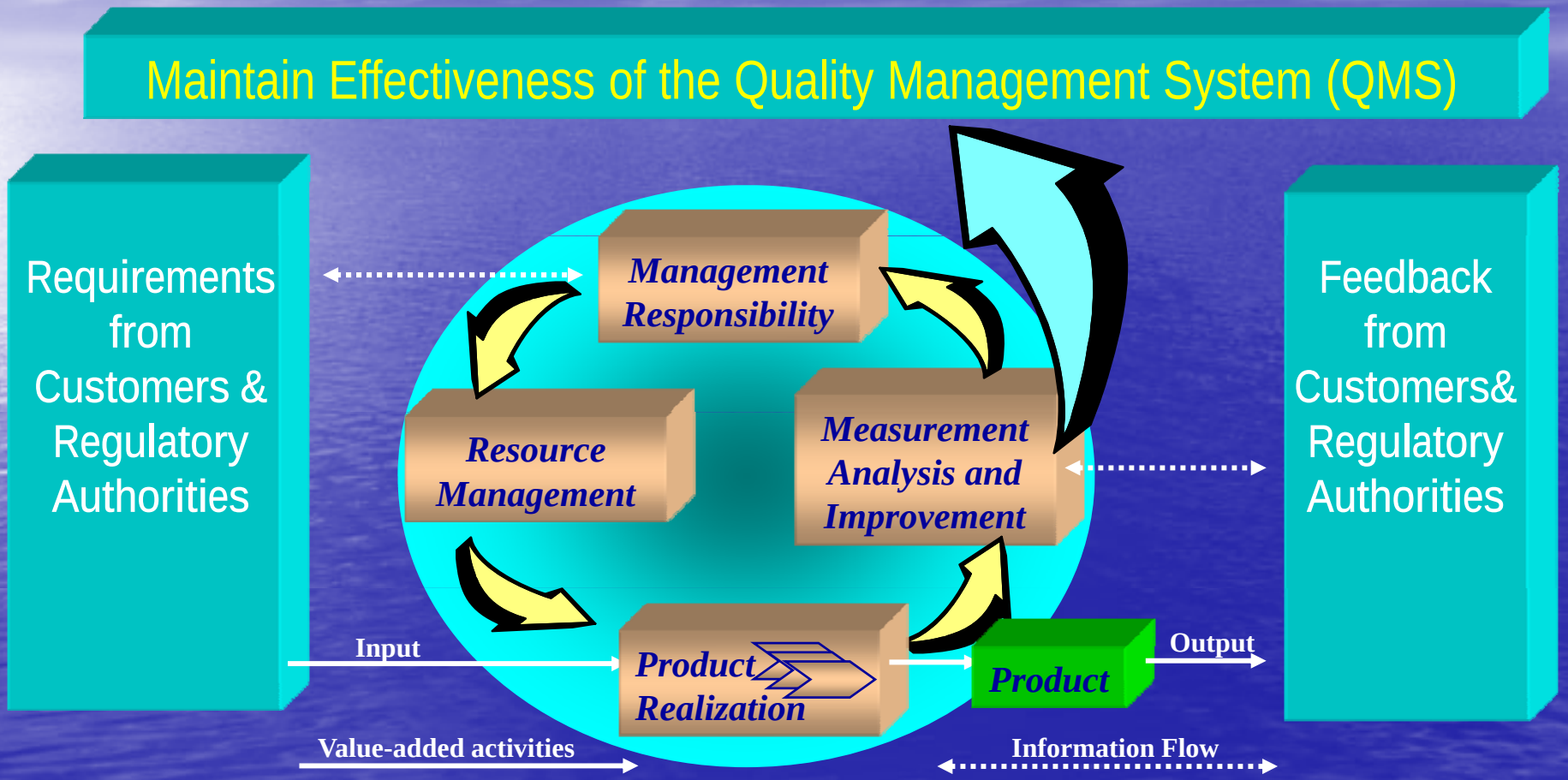
The application of a system of processes within an organization,

together with the identification and interactions of these processes,

and their management, can be referred to as the “process approach”.

ISO 13485:2003 Process Model (Process-oriented struc

ISO 13485:2003 is intended to promote a process approach when developing, implementing, operating and improving a Quality Management System.



4. Quality Management System = QMS

4.1 - General requirements

Implementation and maintenance of an effective QMS to provide medical devices meeting customer and regulatory requirements.

Activities include:

- internal audits, management review, corrective and preventive actions, independent external assessments, etc.

Enables:

- Response to external factors (regulatory requirements, customer feedback) and internal factors (personnel, facilities, processes, etc.)

4. Quality Management System

4.2 - Documentation requirements

- what is to be done and by whom,
- when, where, and how it is to be done,
- what materials, equipment and documents are to be used,
- how an activity is to be monitored and measured, and
- records and files (such as Design History File, Technical File, Complaint File, device records, etc.)
- all the above documents MUST be controlled and retention periods defined!

Examples: Quality Manual, procedures, work instructions, flow charts, forms, templates, specifications, etc.

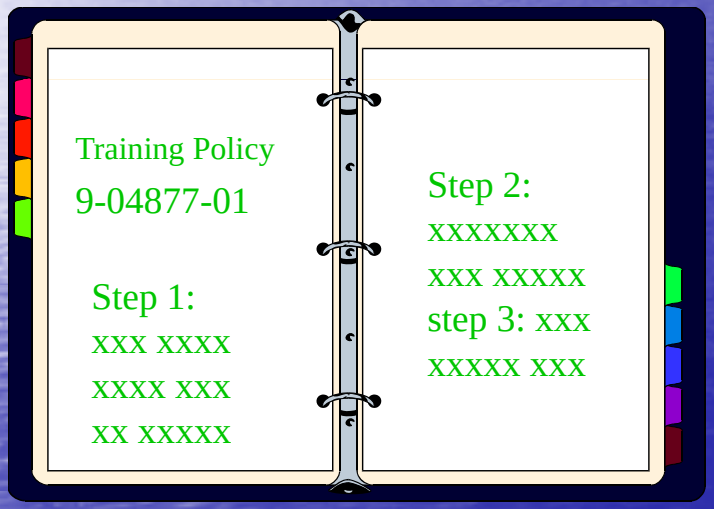
Quality Records

Examples of Quality Records:

- Quality Audits
- Training Records
- Document Change/Control Procedures & Records
- Purchasing Procedures & Records
- Equipment Maintenance Activities
- Calibration Procedures & Records
- Process Validations
- Non-conforming Product Records
- Labeling Control Procedures
- Handling, Storage, Distribution Procedures
- Complaint Files

Procedures

Document the procedure/process to be followed and create a quality record to capture the results obtained when the process is in operation/use.

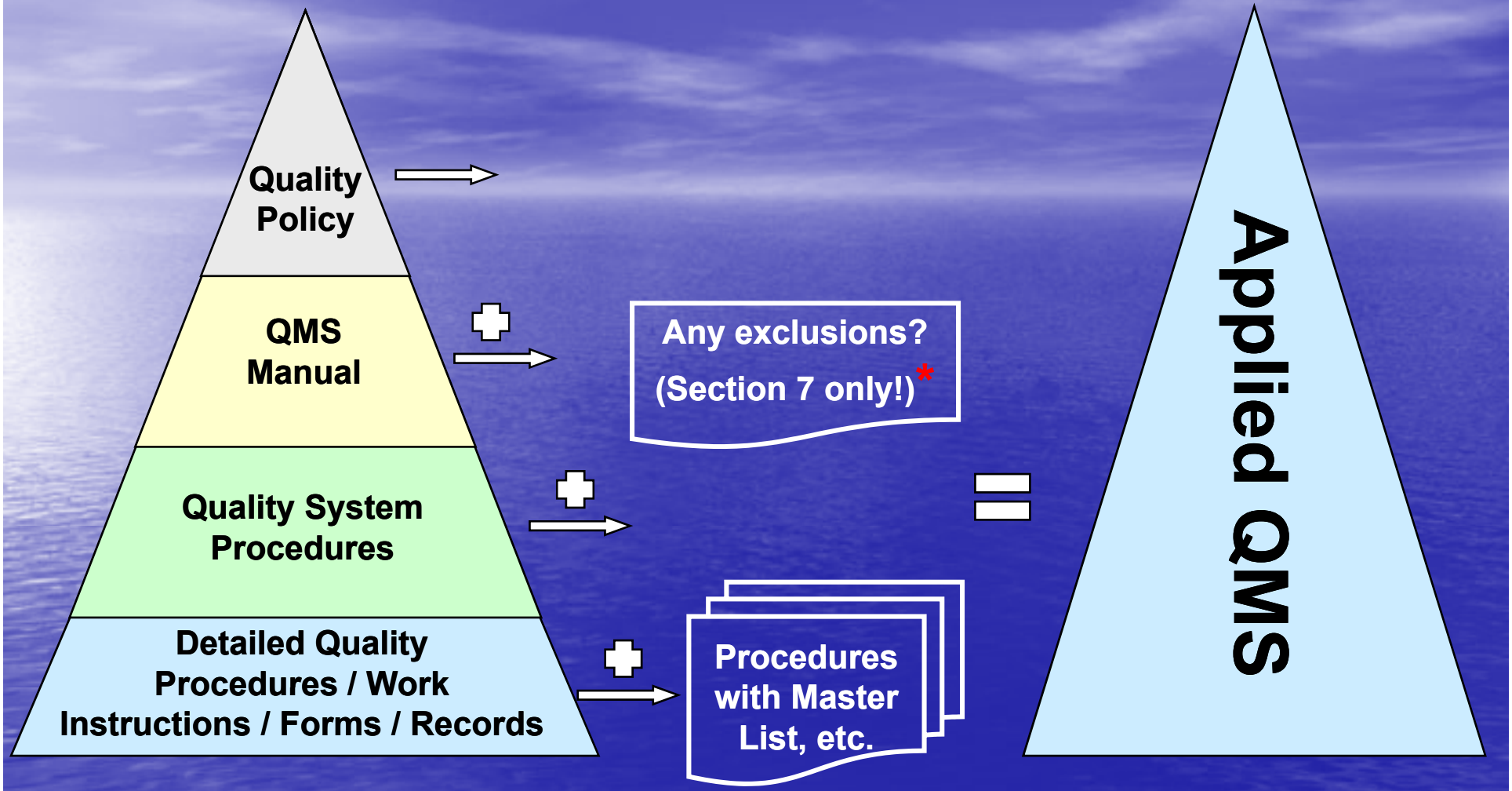


Say what you do, and Do what you say....

Then provide objective evidence... that the work was actually performed!

Key Words: Quality Records = Objective Evidence**!!!**

Quality Management System Definition/Illustrati



*see next slides

ISO 13485 SCOPE Definition
Product Realization - Exclusions

FICCI
Federation of Indian Chambers of Commerce and Industry

Exclusions of design and development (7.3) from the QMS is allowed only if allowed by regulation.
See NOTE 2 of 7.1: The organization ***MAY*** also apply the requirements given in 7.3 to the development of product realization processes.

Organizations whose quality management systems exclude design and development control (7.3 of ISO 13485), are still ***required to comply with the product verification and validation requirements as specified in 7.1 of ISO 13485 dealing with product realization***. In such organizations, the ***controls included in 7.3 should be considered for all changes made to the product***. Such changes will require objective evidence (e.g., product verifications and validations, inspection and test specifications, revised procedures, etc.) of the results of the activities described in 7.3 of ISO 13485.

Product Realization - Non-applicability

"Non-inclusion" of product realization requirements is allowed if those functions are not required by the nature of the medical device being provided by the organization.

For example, an organization providing single-use, sterile medical devices may not need to include within its quality management system elements related to installation and servicing.

5. Management Responsibility

5.1 Management commitment

Is demonstrated by actions ensuring processes operate as an effective network of interrelated processes

Accomplished by:

- ensuring sequence & interaction of processes effectively achieve planned results,
- clear definition & control of process inputs, activities & outputs,
- monitoring inputs and outputs to verify processes are linked and operate effectively,

5. Management Responsibility

5.1 Management commitment (cont.)

Accomplished by:

- identifying hazards and managing risks,
- data analysis to facilitate improvement of processes,
- identifying process owners with responsibility & authority, and
- managing each process to achieve the process objectives.

5. Management Responsibility

5.2 Customer focus

- ensure customer requirements are understood
- availability of necessary resources to meet requirements

(See also clauses 7.2.1 and 8.2.1 of ISO 13485)

5. Management Responsibility

5.3 Quality policy

Establishes commitment to:

- quality
- continuing effectiveness of the quality management system
- meeting customer and regulatory requirements,

Defines:

- clear quality objectives for the business
- the relationship of these objectives to customers' requirements.

Should be reviewed periodically for continued applicability

Case Study: Quality Policy

- The policy of Superior Devices, Inc., is to strive to sell products that satisfy our customers, comply with applicable standards and regulations, and reward employees who contribute substantially to our financial success with a share of our profits.
- Is this a good quality policy? Why or why not?

5. Management Responsibility

5.4 Planning

Includes:

- setting quality objectives & associated targets for the ***quality management system*** AND for ***medical devices & related services*** (see 7.1 a)
- defining timeframes for achieving targets

An organization's QMS is influenced by ***varying needs***, ***particular objectives***, the ***products provided***, the ***processes*** employed, the ***size & structure*** of the organization, etc.

5.4 Planning

Important

ISO13485 does **NOT** imply uniformity in the structure of quality management systems or uniformity of documentation!

5. Management Responsibility

5.5 Responsibility, authority and communication

Examples demonstrating Responsibility & Authority:

- documented position descriptions, including responsibilities and authorities
- organization charts
- can be included in documented procedures or flowcharts.
- Independence must be demonstrated for certain activities (e.g. internal audits, one design review participant; management representative)

Above documents must be controlled (see 4.2.3).

5. Management Responsibility

5.5 Responsibility, authority and communication

One management representative - designated by top management!

Functions can be entirely related to quality management system activities or in conjunction with other functions and responsibilities within the organization.

If responsibility for other functions, ensure no conflict of interest between the responsibilities!

5. Management Responsibility

5.5 Responsibility, authority and communication

Within an effective quality management system communications must be:

- encouraged
- clear and understandable
- bi-directional
- at all levels of the organization
- open and active

Examples: Internal audits, external assessments, management reviews, bulletin boards, all employee meetings, suggestion boxes, etc.

5. Management Responsibility

5.6 Management Review

Periodic assessment of the QMS for continued suitability, adequacy and effectiveness. **Inputs include:**

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system,
g) recommendations for improvement, and
h) new or revised regulatory requirements.

5. Management Responsibility

5.6 Management Review

Outputs include:

a) agenda
b) attendance record
c) presentation materials
d) improvements needed to maintain the effectiveness of the quality management system and its processes
b) improvement of product related to customer requirements
c) resource needs
d) statement of conclusion the effectiveness of the quality management system

Case Study: Management Reviews Part 1

- Perfect Devices, Inc., (PD) established their quality system 5 years ago, and things have been running smoothly. They have been producing the same devices for the past 5 years. The FDA inspection 6 months ago was NAI. PD performs management reviews annually.
- Is an annual management review sufficient?

Case Study: Management Reviews Part 2

- Superior Medical, Inc., (SM) established their quality system 5 years ago. This year's production was double that of 5 years ago. Six months ago SM installed an ethylene oxide sterilization chamber and started distributing sterile devices. Several sterilization lots have failed. SM performs management reviews annually.
- Is an annual management review sufficient?

6. Resource Management

6.1 Provision of resources

Resources can be:

- people
- infrastructure
- work environment
- information
- suppliers and partners
- natural resources
- financial resources

Adequate resources are prerequisite to an effective QMS

6. Resource Management

6.2 Human Resources

Personnel performing work affecting product quality and device safety and effectiveness must be competent ….

- Qualifications include:
  - Education
  - Experience
  - Skills
  - EFFECTIVE Training (initial and refresher)
  - Formal certification (e.g. welding, soldering)

- Organization must be able to demonstrate this!

6. Resource Management

6.3 Infrastructure

Includes:

- Buildings
- Work space
- Utilities (water, electricity, waste management, etc.)
- Process equipment (software and hardware)
- Equipment maintenance activities & frequency
- Supporting services (cleaning, etc.)

If not considered and appropriately defined, the above examples can potentially affect conformance with product requirements!

Key Words: Inappropriate storage of Medical Devices can be detrimental to maintaining their quality and functional performance!!!

Case Study: Facilities

- Oops! An existing piece of equipment was moved to make room for some new equipment. When scheduled maintenance was due on the first piece of equipment, the maintenance man was unable to perform these tasks, as the equipment was too close to the wall. He got creative and suggested installing doors in the wall to allow access to that side of the equipment. This is an outside wall!
- Is this an acceptable solution? Why or why not?

Case Study: Storage & Handling

- Oops! A manufacturing batch/lot of medical devices was stored in the warehouse for future shipment to customers. A large rain storm caused a roof leak and some of the boxes of product were wet from the leaking water. The boxes eventually dried after the storm had passed and were shipped to customers several weeks later.
- Is this an acceptable solution? Why or why not?

6. Resource Management

6.4 Work Environment

The most significant factors within the work environment that can affect product quality are:

- process equipment,
- established work environment (controlled environments, clean rooms, etc.)
- personnel – internal and ***external***! (health, cleanliness, protective equipment/gear, i.e. static dissipating wrist bands, hoods & gowning, etc.)

"Established" means defined, documented, implemented and maintained!

Case Study: Clean Rooms

- An electrical outlet in the clean room is not working, and an electrician has been called to replace it. SOPs (procedures) require employees who work in the clean room to wear a hair cover, face mask, shoe covers, lab coat and gloves.
- Should the electrician follow the same gowning procedures? Why or why not?

Determining Cleanroom Requirements

Sterility Requirements

- Machine Controls
  - Sterility Assurance Levels (SAL)
  - Sterility Validation
- People
  - Bioburden
  - Pyrogen

Key Words: Medical Device Requirements ≠ Drug Requirements

Key Words: ISO 13485:2003 does NOT prescribe Cleanroom Requirements nor any other similar processing requirements!!!

7. Product Realization

7.1 Planning of product realization

"Product realization" describes the processes starting with

- planning
- determination of customer requirements
- customer communication
- design and development (7.3),
- purchasing (7.4),
- production and servicing (7.5),
- control of monitoring and measuring devices (7.6)
- delivery of the medical device
- record keeping requirements

7. Product Realization

7.1 Planning of product realization

This includes:

- product quality objectives & requirements
- definition of medical device lifetime (record retention!)
- establishing processes & documents
- resource needs
- design and development (7.3),
- verification & validation
- monitoring and inspection
- test activities and product acceptance criteria
- RISK MANAGEMENT
- RECORDS

7. Product Realization

7.2 Customer-related processes

Focus is on product and services to be supplied. This includes requirements related to the product:

- design input/output for new product development,
- customer delivery expectations vs. delivery schedules
- customer feedback & communications relative to orders placed or product delivered
- regulatory or legal requirements
- design related factors included in customer orders
- unspecified customer expectations.

7. Product Realization

7.2 Customer-related processes

Review of product requirements prior to committing to supply:

- product requirements defined & documented
- resolution of contract/order discrepancies
- ensure ability to meet defined requirements

Review of post-marketing product performance

- additional product information (e.g. service, additional applications, maintenance, upgrades)
- customer complaints
- advisory notices

 Again, records are key! 

7. Product Realization

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

7. Product Realization

7.3 Design and development
Established procedures describing design processes and ALL design activities (cont.)

- 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

FICCI
Federation of Indian Chambers of Commerce and Industry

7. Product Realization

7.3 Design and development

Design inputs include:

- intended use of the device,
- Indications and contra-indications for use of the device,
- performance claims and performance requirements (including normal use, storage, handling and maintenance),
- user and patient requirements,
- physical characteristics,
- human factors/usability requirements,
- safety and reliability requirements,
- toxicity and biocompatibility requirements,

7. Product Realization

7.3 Design and development

Design inputs (cont.):

- electromagnetic compatibility requirements,
- limits/tolerances,
- measurement and monitoring instruments,
- risk management or risk reduction methods
- reportable adverse events, complaints, failures for previous products,
- other historical data,
- documentation for previous designs,
- compatibility requirements with respect to accessories and auxiliary devices,

7. Product Realization

7.3 Design and development

Design inputs (cont.):

- compatibility requirements with respect to the environment of intended use,
- packaging and labeling (including considerations to deter foreseeable misuse),
- customer/user training requirements,
- regulatory and statutory requirements of intended markets,
- relevant voluntary standards (including industry standards, national, regional or international standards, “harmonized” and other consensus standards),

7. Product Realization

7.3 Design and development

Design inputs (cont.):

- manufacturing processes,
- sterility requirements,
- economic and cost aspects,
- lifetime of the medical device requirements, and
- need for servicing.

Case Study: Hospital vs. Home Use

- For several years Advanced Devices has been selling a patient monitor for use in the hospitals. Recently one of their salespeople suggested marketing the patient monitor for home use since patients are spending less and less time in the hospital.

- Will home use change the design input? Why or why not?

Case Study: Hospital vs. Hom Use

Considerations:

- User less skilled, no medical training
- Users impaired? Poor vision, poor manual dexterity?
- User environment different; electromagnetic interference from TV, cell phones, etc.
- Multiple users, etc.

7. Product Realization

7.3 Design and development

Design outputs may include:

- specifications for raw materials, component parts and sub-assemblies,
- drawings and parts list,
- customer training materials,
- process and materials specifications,
- finished medical devices,
- product and process software,
- quality assurance procedures (including acceptance criteria),
- manufacturing and inspection procedures,

7. Product Realization

7.3 Design and development

Design outputs (cont):

- work environment requirements needed for the device,
- packaging and labeling specifications,
- identification and traceability requirements (including procedures, if necessary),
- installation and servicing procedures and materials,
- documentation for submission to the regulatory authorities where the medical devices will be marketed, if appropriate, and
- a record/file to demonstrate that each design was developed and verified in accordance with the design and development planning

7. Product Realization

7.3 Design and development

Design reviews may address the following questions:

- Do designs satisfy specified requirements for the product?
- Is the input adequate to perform the design and development tasks?
- Are product design and processing capabilities compatible?
- Have safety considerations been addressed?
- What is the potential impact of the product on the environment?
- Do designs meet functional and operational requirements, for example, performance and dependability objectives?

7. Product Realization

7.3 Design and development

Design reviews (cont.):

- Have appropriate materials been selected?
- Have appropriate facilities been selected?
- Is there adequate compatibility of materials, components and/or service elements?
- Is the design satisfactory for all anticipated environmental and load conditions?
- Are components or service elements standardized and do they provide for reliability, availability and maintainability?
- Is there a provision in tolerances, and/or configuration, for interchangeability and replacement?

7. Product Realization

7.3 Design and development

Design reviews (cont.):

- Are plans for implementing the design technically feasible (e.g. purchasing, production, installation, inspection and testing)?
- If computer software has been used in design computations, modeling or analyses, has the software been validated, authorized, verified and placed under configuration control?
- Have the inputs to such software, and the outputs, been appropriately verified and documented?
- Are the assumptions made during the design processes valid?

Case Study: Design Review

- Can a formal design review be conducted without holding a meeting?
- Would circulating design review issues and approving outcomes by e-mail or on paper be an acceptable alternative to holding a meeting?

Case Study: Design Review

- Nowhere in the standard or the guidance is it stated that a design review must be conducted by holding a meeting!
- If all design review requirements of the standard are met, the design review could take place by e-mail or review of paper summary.
- Design reviews conducted by e-mail or paper probably are best used for relatively simple reviews.

Case Study: Design Review

- Please keep in mind that additional requirements may exist for electronic records, as well as electronic signatures.
- If design reviews are conducted via e-mail or paper copy circulation, results of the review will still need to be documented. Documentation typically includes identifying attendees, which is best done by signatures next to printed name. Print a signature page from the e-mail, sign and scan it and retain in the Design History File.

Case Study: Design Review

- Persons making authorized entries on records or verifying such entries should do so in clear legible writing, and should confirm the entry by adding their initials, signature or equivalent, and the date (14969 guidance).

7. Product Realization

7.3 Design and development

Design verification is necessary to ensure that the design outputs conform to specified requirements (design inputs).

- tests (bench tests, lab tests, chemical analysis, etc.)
- alternative calculations,
- comparison with proven design,
- inspections, and
- document reviews (e.g. specifications, drawings, plans, reports).

7. Product Realization

7.3 - Design and development

Design validation goes beyond the technical issues of verifying output met input. It is intended to ensure that the medical device meets user requirements and the intended use.

- actual or simulated conditions
- consider capability and knowledge of user
- operating instructions
- compatibility with other systems
- the environment in which it will be used
- any restriction on the use of the product
- performed on production or production equivalent unit(s)

If production equivalent – need to document why it is equivalent!

7. Product Realization

7.3 Design and development
Control of design and development changes

- Product design may require change or modification for many reasons.
- Change can happen during or after the design phase
- Changes may result from:
  - design review
  - design verification or validation
  - omissions or errors during the design phase which have been identified afterwards

7. Product Realization

7.3 Design and development

- Changes may result from:
  - difficulties in manufacturing, installation and/or servicing
  - risk management activities,
  - requests from the customer or supplier,
  - changes required for corrective or preventive action
  - changes needed to address safety, regulatory, or other requirements
  - improvements to function or performance

7. Product Realization

7.3 Design and development

- When changes are necessary, evaluate effects on:
  - product requirements and specifications
  - intended use
  - current risk assessment
  - different components of the product or system
  - manufacture, installation or use
  - Verification and validation
  - the regulatory status of the product

7. Product Realization

7.4 Purchasing

Supplier selection and control consists of:

- establishing criteria (product, parts, quality system, process controls, metrology, etc.)
- evaluating against those predetermined criteria
- selecting
- ongoing monitoring

The extent depends on the nature and risk associated with the product or service, and includes outsourced processes.

Purchasing should only occur from list of approved suppliers!

Case Study: Purchasing Controls

- Perfect Devices, Inc. is evaluating potential suppliers of a plastic resin for injection molded parts. Perfect contacted several potential suppliers to schedule audits to evaluate them, but two large firms have declined to be audited.
- What should Perfect Devices, Inc. do?
  1. Buy only from firms allowing audits?
  2. Find another way to evaluate large firms?
  3. Other alternatives?

7. Product Realization

7.4 Purchasing

Purchasing information describes the product to be purchased in sufficient detail, such as:

- technical information and specifications,
- test and acceptance requirements,
- quality requirements for products, services, and outsourced processes,
- environmental requirements (in manufacturing, storage, transportation, etc.)
- regulatory requirements,
- certification requirements

Case Study: Incoming Acceptance - 1

- Perfect Devices, Inc. recently selected three new suppliers based on the following information:
  1. Aim To Please, Inc.: Supplier audit documented an excellent quality system.
  2. A-1 Plastics: Refused audit, highly recommended by other device manufacturers.
  3. OK Parts, Inc.: Sole source of component! Supplier audit: No quality system!

- Which approach to acceptance of incoming components would you recommend for each supplier?

Case Study: Incoming Acceptance - 2

Aim to Please, Inc. - A-1 Plastics - OK Parts, Inc.

FIRST: It depends on the part being sourced!

Then you may use - From ANSI.ASQ Z1.4:

1. "Tightened Inspection followed by normal inspection when 5 consecutive lots are acceptable
2. "Normal Inspection" followed by reduced inspection and 10 consecutive lots are accepted and additional criteria in 8.3.3.b are met.

7. Product Realization

7.4 Purchasing

Purchasing information (cont.):

May also include:

- requirements for product approval and subsequent changes
- procedures, processes & equipment
- qualification of personnel
- QMS requirements
- method of communication
- responsibilities (special instructions, traceability & test records, record retention & retrievability, etc.)
- conditions for review & changes to purchasing agreement

SUPPLIER RECORDS and the **ORGANIZATION'S RECORDS**

7. Product Realization

7.4 Purchasing

Verification of purchased product to ensure specified requirements are met:

- receiving Inspection (shipments are complete, properly identified, undamaged)
- product incoming inspection (100%, sampling, skip lot, etc.)
- certification of suppliers
- certificates of conformance or acceptance test reports from supplier

Must be procedurally defined within the organization's QMS, ***including actions when requirements are not met***!

Applies to *ALL product received from outside the organization's QMS*!

7. Product Realization

7.5 Production and service provision

Control of production and service requires ***controlled conditions*** and includes many aspects:

- infrastructure (see 6.3)
- documentation and records (procedures, specifications, work instructions, test results, etc.)
- defined by *impact on quality* & *regulatory requirements* as well as *output from risk management activities*
- suitable equipment (process, measurement, monitoring)
- activities for release, delivery, and post delivery, including traceability

Records are key!

Case Study: Installation Instructions

- Zap Em, Inc. manufactures linear accelerators for radiation therapy for cancer. Zap Em installs the equipment for a significant fee. Hospitals have requested installation instructions for self-installation. Zap Em says they would be glad to provide instructions and equipment if the hospital employees attend Zap Em's 2 day installer training for $9,500.
- Is Zap Em entitled to withholding instructions from 3rd party installers unless they attend a training course?

7. Product Realization

7.5 Production and service provision

Validation of processes for production & service is required where the resulting output cannot be verified!

- defined criteria for review and approval of processes
- approval of equipment and ***personnel qualification*** 
- use of specific methods and procedures
- criteria for revalidation 
- software used in automated processes **MUST** be validated 

7. Product Realization

7.5 Production and service provision

Validation of processes for production & service (cont.)

Process validation activities can be described in phases:

- definition, review and approval of equipment specifications
- installation qualification (IQ)
- operational qualification (OQ)
- performance qualification (PQ)

Validation is a complex activity – SG 3 has developed specific guidance on this topic (GHTF/SG3/N99-10:2004).
A separate presentation “Process Validation Guidance” addresses this in greater detail.

7. Product Realization

7.5 Production and service provision

Identification is required throughout the product realization process. It includes:

- raw materials
- components
- finished medical devices

This facilitates fault diagnosis in the event of quality problems and is a pre-requisites for traceability!

Provisions for identifying & segregating returned medical devices from conforming product must also be established!

7. Product Realization

7.5 Production and service provision

Traceability means the ability to trace the history or location of a product or activity by recorded identification:

- forward to customers (also known as “device tracking”)
- backward to raw materials, components, processes used in manufacturing, calibration, etc.

Example: trace a nonconformity back to it’s source and determine location of the remainder of the affected batch/series.

Particular requirements are defined for implantable devices!

7. Product Realization

7.5 Production and service provision

Customer property within the context of the standard is defined as property or assets owned by the customer and under control of the organization.

Examples of such property are

- raw materials or components supplied for inclusion in product (including packaging materials),
- product supplied for repair, maintenance or upgrading,
- product supplied for further processing (e.g., packaging, sterilization or testing),
- customer intellectual property

These must be properly identified, safeguarded, maintained, etc.

7. Product Realization

7.6 Control of monitoring and measuring devices

The standard explicitly refers to monitoring and measuring devices, **including software**. To ensure valid results, instruments shall be

- calibrated or verified at specified intervals (traceable to standard!)
- uniquely identified (traceability to products!)
- protected from damage/deterioration or inadvertent adjustment during storage and use

Software used in the monitoring or measurement process must be validated!

Exempt from calibration may be: instruments used for indication only (not quantitative!), volumetric measurement glassware, etc.

8. Measurement, analysis and improvement

8.1 General

Monitoring and measurement processes are required to:

- ensure product conformance
- ensure conformance of the QMS
- maintain effectiveness of the QMS

These processes include measurement and analysis of products AND processes.

8. Measurement, analysis and improvement

8.2 Monitoring and Measurement

Feedback as key performance indicators of the QMS include:

- customer related information, post-market surveillance, etc.)
- internal & external audit results
- monitoring and measurement of processes (not limited to production processes but also QMS processes!)
- monitoring and measurement of product (may extend to point of installation!)

8. Measurement, analysis and improvement

8.3 Control of nonconforming product
This includes nonconforming product occurring in the organization's own facilities as well as to nonconforming product **received** or **delivered** by the organization.

- determine product(s) affected
- identify the nonconforming product (at supplier, in house, in transit, at customer)
- document the existence and root cause of the nonconformity
- evaluate the nature of the nonconformity

8. Measurement, analysis and improvement

8.3 Control of nonconforming product (cont.)

- determine and record disposition to be made,
- control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision
- notify others as appropriate (regulatory authorities, customer, supplier, alternate manufacturing facilities, etc.)
- define and implement **corrective** and **preventive** actions
- assess the effectiveness of corrective and preventive actions

8. Measurement, analysis and improvement

8.4 Analysis of data

This includes determination, collection, and analysis of appropriate data to demonstrate the

- suitability and effectiveness of the QMS and
- to evaluate if improvement of the QMS effectiveness can be made.

This encompasses supplier performance, product conformance, trends of processes & products, feedback, etc.

The results of these activities should feed into management reviews as well considered for risk management activities. They also serve to identify opportunities for preventive actions.

Case Study: Data Analysis

- Which items below would be appropriate data sources to analyze to identify non-conforming product and quality problems?

1. Incoming Acceptance Records
2. Complaints
3. Service Records
4. Sales Figures
5. Internal Audits
6. Records of Installation
7. Customer Lists
8. Reports of external audits
9. Personnel Records
10. Lawsuits
11. Finished device Acceptance Records
12. In process Acceptance Records

Case Study: Data Analysis

- Which items below would be appropriate data sources to analyze to identify non-conforming product and quality problems?

1. **Incoming Acceptance Records**
2. **Complaints**
3. **Service Records**
4. Sales Figures
5. **Internal Audits**
6. **Records of Installation**
7. Customer Lists
8. **Reports of external audits**
9. Personnel Records
10. **Lawsuits**
11. **Finished device Acceptance Records**
12. **In process Acceptance Records**

8. Measurement, analysis and improvement

8.5 Improvement

This again covers a broad scope:

- continued suitability and effectiveness of the QMS
- documented complaint investigations and resulting actions
- product advisory notices (field corrective actions, etc.) communicated to customers and (where applicable) to regulatory authorities

8. Measurement, analysis and improvement

8.5 Improvement

Corrective action is intended to eliminate nonconformities with the intent to prevent recurrence. Nonconformities may be identified

- in the QMS
- on the product
- in manufacturing processes
- in metrology
- with training
- environmental conditions
- control of equipment
- with suppliers, etc.

8. Measurement, analysis and improvement

8.5 Improvement

Effective **corrective action** includes the following:

- clear and accurate identification of the nonconformity
- affected process(es) or procedure(s)
- identification of affected device(s) and recipient(s)
- identification of the root cause of the nonconformity,
- action required to prevent recurrence
- required approvals prior to taking action
- records that corrective action was taken as identified
- Effectiveness checks (likely to prevent recurrence, no new risks introduced by the corrective action, etc.)

8. Measurement, analysis and improvement

8.5 Improvement

Preventive action is initiated to address ***potential*** nonconformities. Sources to consider include information & data from:

- receiving and incoming inspection
- products requiring rework, reject or yield data
- customer feedback and warranty claims,
- process measurements,
- identification of results that are out-of-trend but not out-of-specification,
- suppliers performance
- service reports, and,
- concessions/deviations.

FICCI
Federation of Indian Chambers of Commerce and Industry

While the information covered during this session is based on ISO13485:2003 and ISO/TR14969, it essentially describes GOOD BUSINESS PRACTICES.

Key Words: Properly managed operation!!!

BD
Helping all people live healthy lives

AHWP
ASIAN HARMONIZATION WORKING PARTY

If successfully implemented, the organization's quality system will meet the requirements of the European Medical Device Directive (MDD 93/42/EEC).

BD

Helping all people live healthy lives

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Becton Dickinson
198 Yishun Avenue 7
768926
Singapore

Holds Certificate No: **FM 78945**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The design, development, manufacture and distribution of disposable blood pressure transducers and monitoring devices, kits and associated pressure monitoring and fluid administration accessories, supportive insertion and post operation management components, coronary and peripheral catheters, cannulae, central venous catheters and introducers.

The provision of sterilization services to EN550.

For and on behalf of BSI:

President, BSI Management Systems America, Inc.

Originally Registered: **07/27/2003** Effective Date: **05/13/2008** Expiry Date: **06/21/2011**

CMDCAS Recognized Registrar

Page: 1 of 1

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.

BSI Management Systems

Discussion Question

What are the next steps should you take after completing this workshop?

- ✓ Get a copy of ISO 13485:2003
- ✓ Get a copy of ISO/TR 14696
- ✓ Get a copy of ISO 14971:2007
- ✓ Get more training in these standards & implementation!!!
- ✓ ISO Internal Auditor Training TOO!!!
- ✓ Work with Medical Device Industry "Partners" to learn!!!

Key Words: Learn all you can and Regulate with Knowledge!!!

Discussion Question

What should you NOT do after completing this workshop?

- ✓ **Think you know ISO 13485:2003**
- ✓ **Try to regulate by specific quality system requirements**
- ✓ **Tell your boss you are ready!!!** ☺

Key Words: Prepare yourself with training, knowledge and practice, to make good OBJECTIVE observations of a QMS and make good judgments and do not start before your are REALLY ready!!!

FICCI
Federation of Indian Chambers of Commerce and Industry

OPEN
Question & Answer (hopefully!!!) Session

BD
Helping all people live healthy lives

AHWP
ASIAN HARMONIZATION WORKING PARTY

FICCI
Federation of Indian Chambers of Commerce and Industry

For further guidance, please refer to ISO/TR 14969

Thank you for your time and attention.

BD
Helping all people live healthy lives

AHWP
ASIAN HARMONIZATION WORKING PARTY

APPENDIX

Examples of Key Records

- Management Review (5.6.1)
- Education, training, skills and experience (6.2.2.e)
- Product realization processes (7.1.d)
- Product requirements review and action (7.2.2)
- Product requirements inputs (7.3.2)
- Design reviews and actions (7.3.4)
- Design verification and actions (7.3.5)
- Design validation and actions (7.3.6)
- Design changes (7.3.7)
- Design change reviews (7.3.7)

Examples of Key Records (cont.)

- Supplier evaluation and actions (7.4.1)
- Process validation (7.5.2)
- Traceability (7.5.3)
- Customer notification regarding damage to customer property (7.5.4)
- Production or service delivery, as determined to be necessary for special processes (7.5.2)
- Review of previous measuring results when measuring equipment is found not to conform to requirements (7.6)
- Calibration or verification (7.6)

Examples of Key Records (cont.)

- Internal audits (8.2.2)
- Product release authorization (8.2.4)
- Nonconformities and actions taken (8.3)
- Corrective actions taken (8.5.2 e)
- Preventive actions taken (8.5.3 d)