ISO13485:2003
- An Overview -
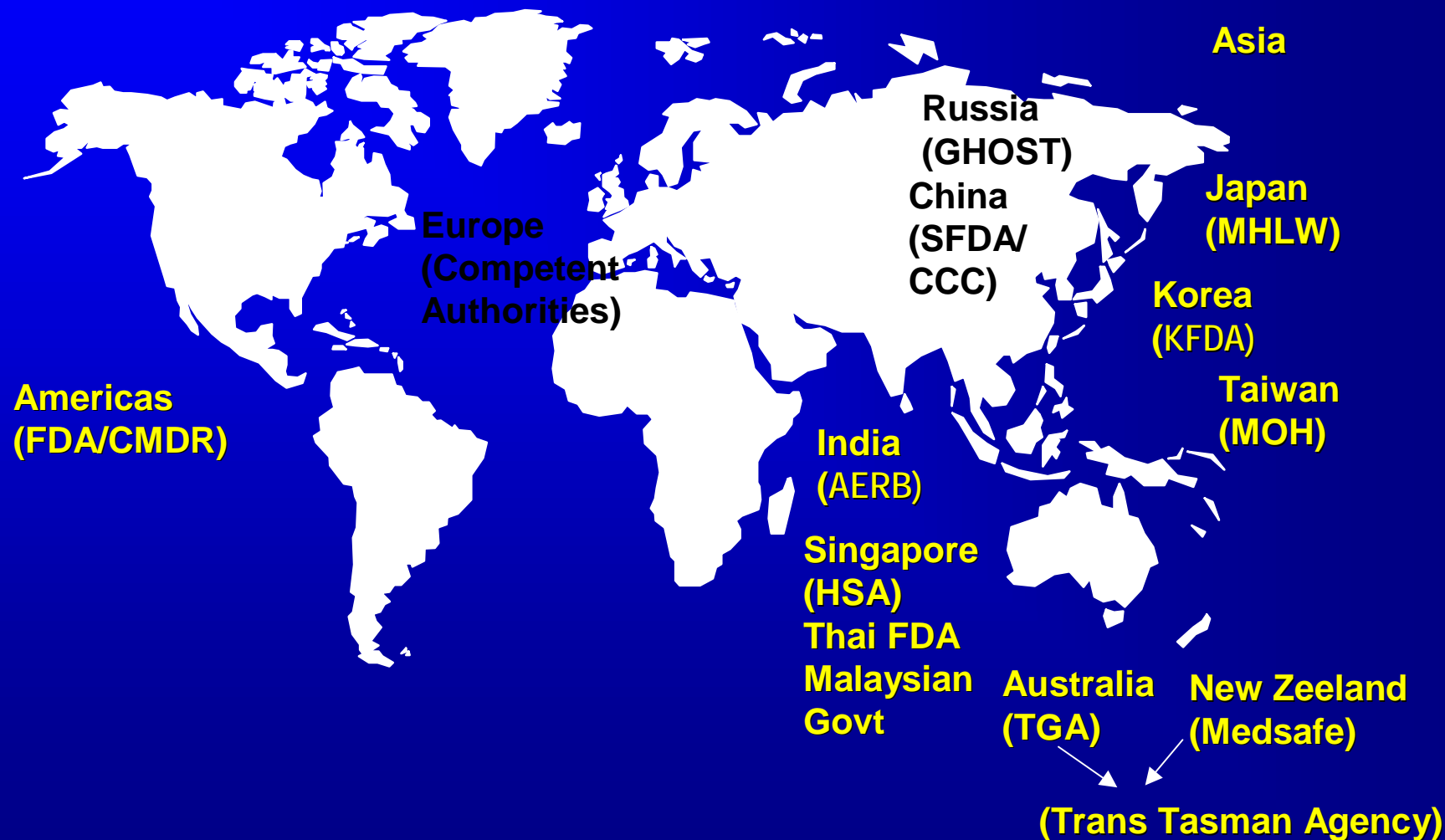
Gunter Frey

Member, SG3

NEMA

Asia-Pacific
Economic Cooperation

Regulatory Authorities – A Global View

Timeline for Major Standards & Regulations

Asia-Pacific Economic Cooperation

GHTF

ISO9001:1994 — Retired

ISO9001:2000

ISO13485:1996

To be retired 07/2006

ISO13485:2003

EN46001:1996

Retired 03/2004

21CFR Part 820:
1978 GMP (Preamble still in effect today!)
1997 QSR (Replaced GMP except preamble!)

EN/ISO13485:2000

To be retired 07/2006

1978 Federal Food, Drug, and Cosmetic Act (and amendments)

EN/ISO13485:2003

1990 Safe Medical Devices Act (amends Food, Drug, and Cosmetic Act)

1999 Japan GMPi

1999 KFDA GMPi

2000 SDA Requirements for Quality Assurance

1998 CMDR

1993 MDD

1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005

Blue boxes depict regulations

Global Medical Devices Quality System Requirements

ISO13485:2003

USA:
21CFR820
QSR

Europe:
EN/ISO13485

China:
SDA Requirements for Quality Assurance

ISO9001:2000

Korea:
KFDA GMPi

Japan:
GMP
GMPi
PAL

Canada:
CMDR
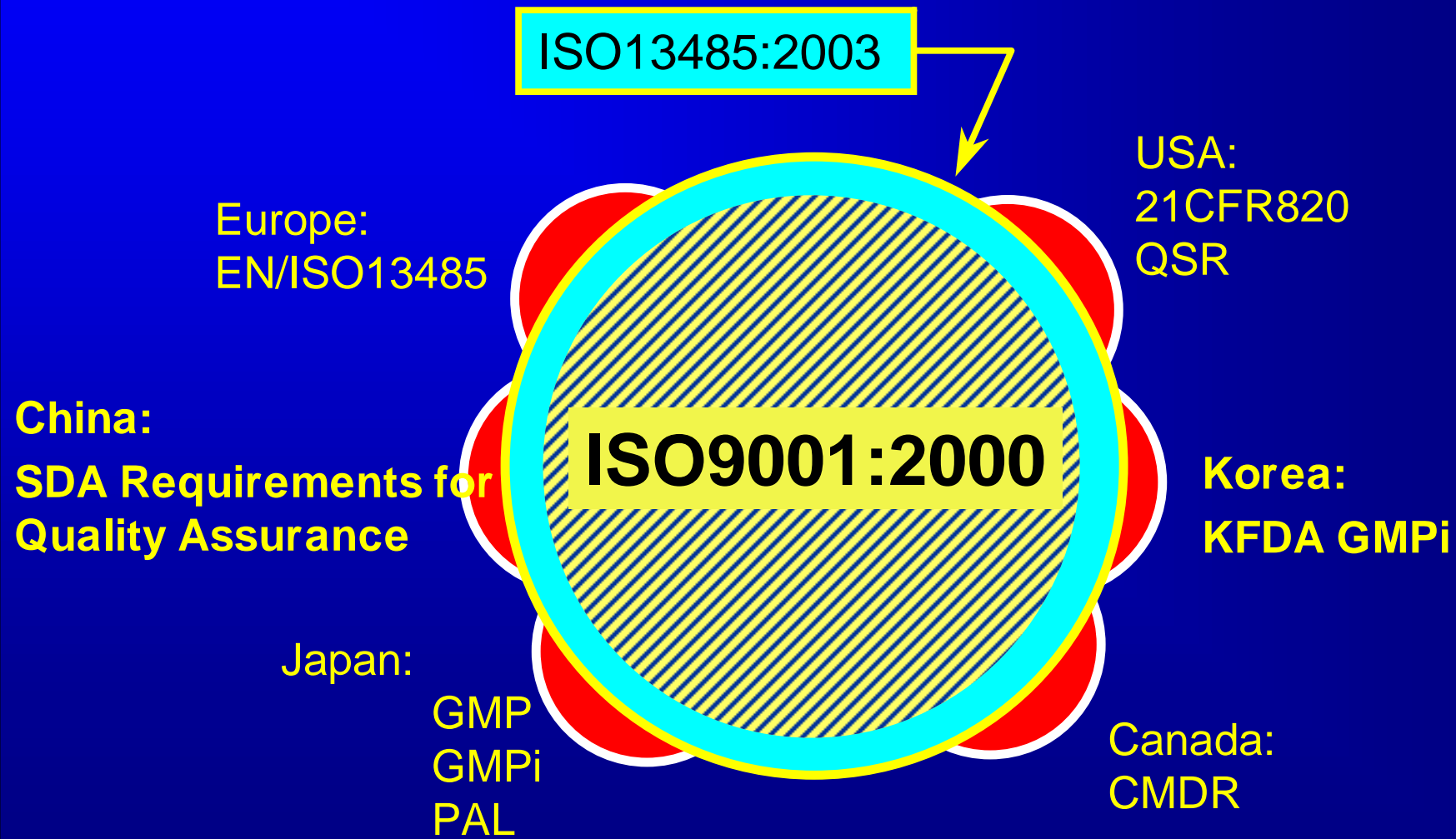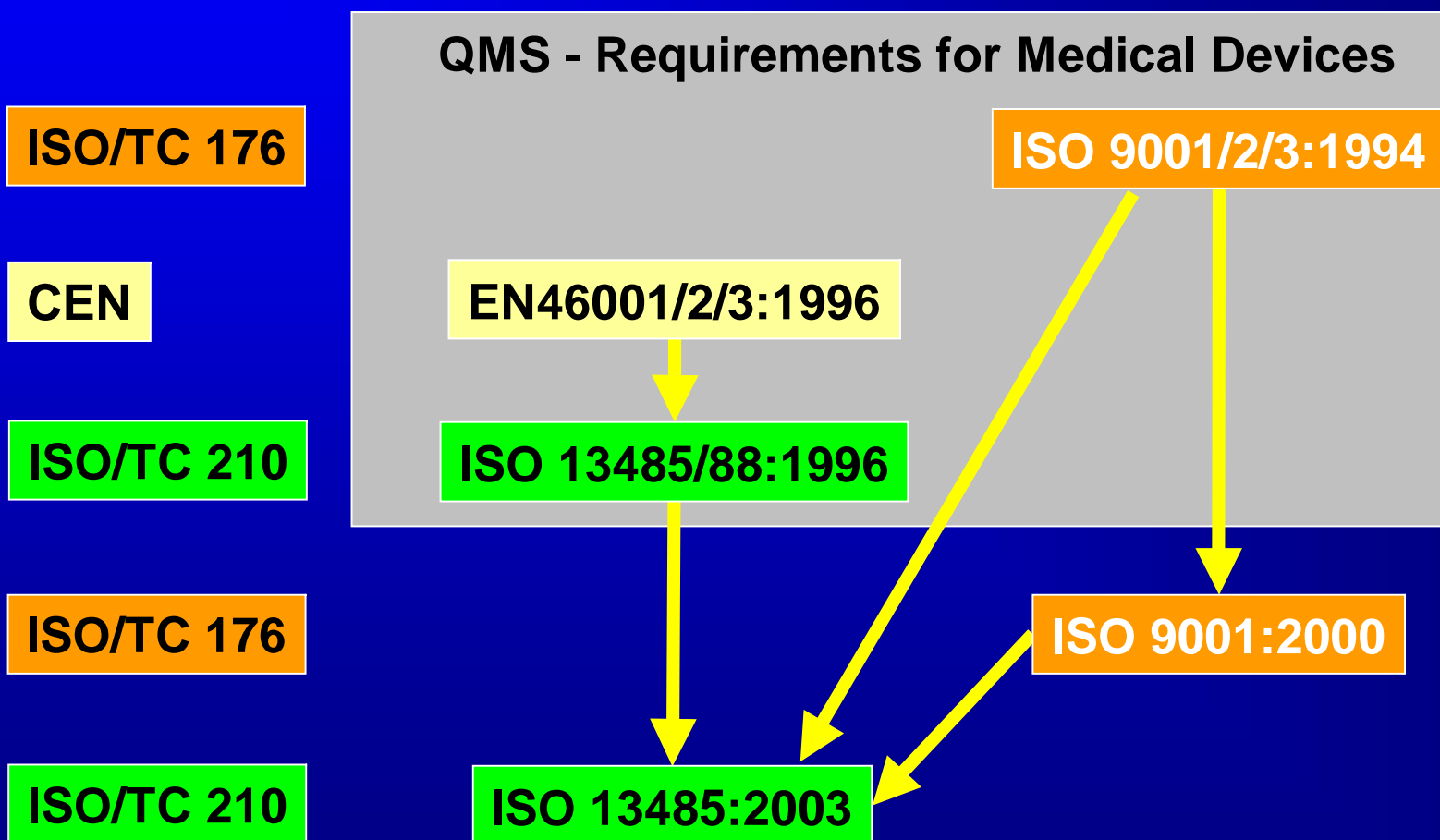
This presentation is based on

➢ **ISO13485:2003,** *Medical devices - Quality management systems - Requirements for regulatory purposes*

➢ **ISO/TR 14969,** *Medical devices - Quality management systems - Guidance on the application of ISO13485:2003*

This presentation focuses on the key sections of ISO13485:2003:

Section 4.0 - Quality Management System Requirements

Section 5.0 - Management Responsibility
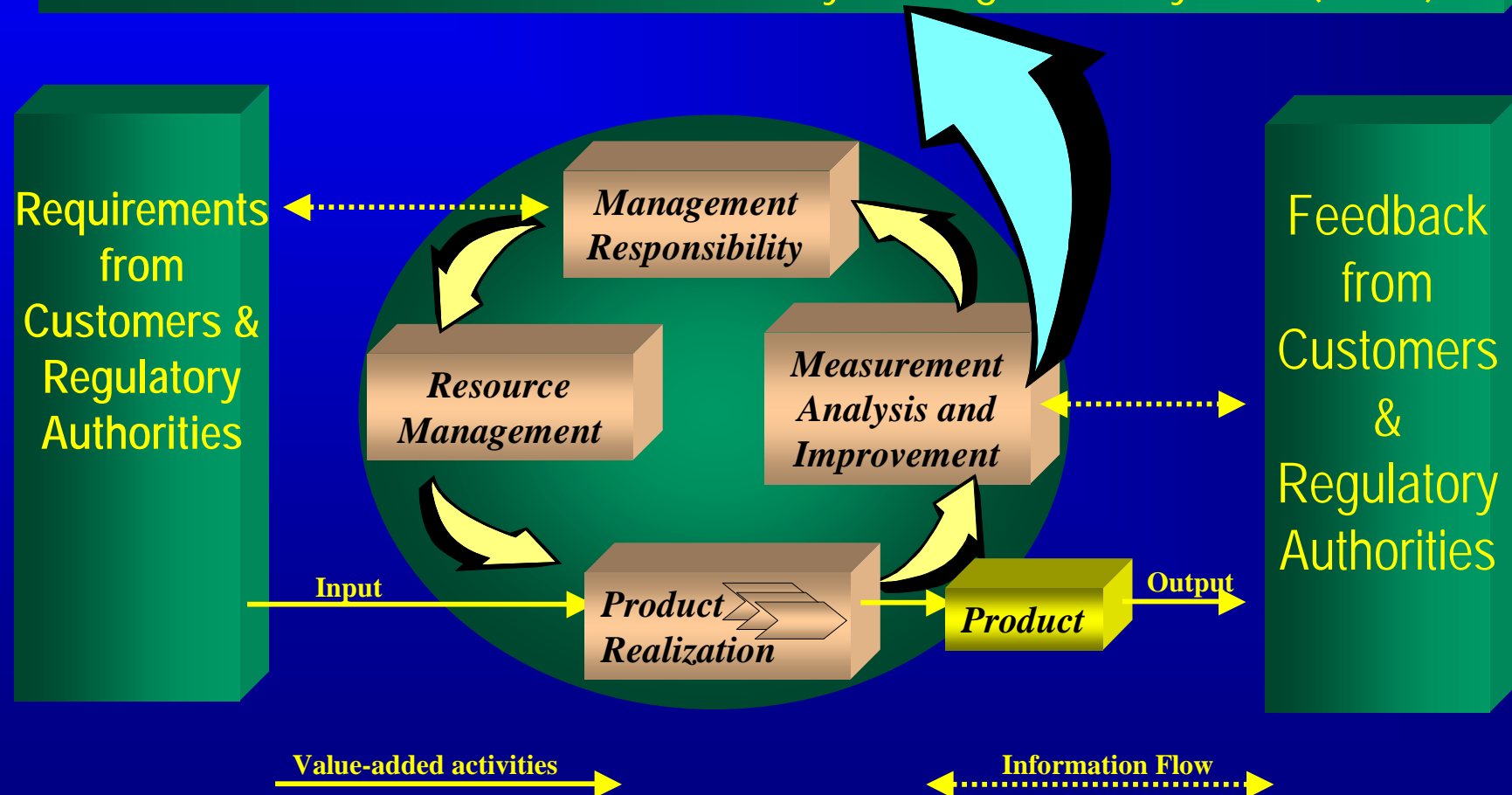
Section 6.0 - Resource Management

Section 7.0 - Product Realization

Section 8.0 - Measurement, Analysis, and Improvement

ISO 13485:2003 promotes a process approach when developing, implementing, and improving a QMS

Maintain Effectiveness of the Quality Management System (QMS)

Requirements from Customers & Regulatory Authorities

Management Responsibility

Resource Management

Measurement Analysis and Improvement

Input

Product Realization

Product

Output

Feedback from Customers & Regulatory Authorities

Value-added activities

Information Flow

4. Quality Management System

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:

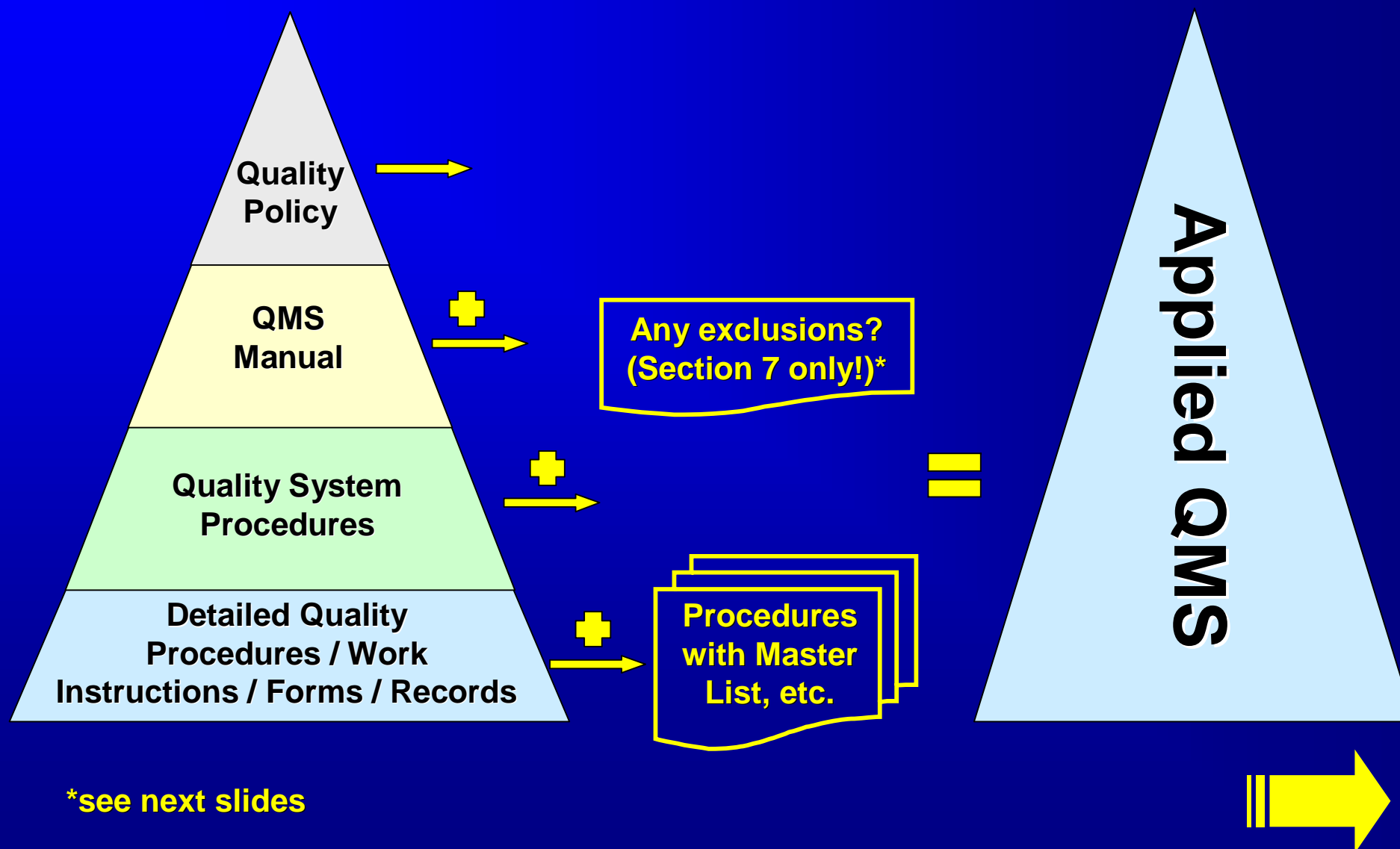➢ Response to external factors (regulatory requirements, customer feedback) and internal factors (personnel, facilities, processes, etc.)

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 System Definition

Quality Policy

QMS Manual

+

Any exclusions? (Section 7 only!)*

Quality System Procedures

+

Detailed Quality Procedures / Work Instructions / Forms / Records

+

Procedures with Master List, etc.

=

Applied QMS

***see next slides**

Product Realization - Exclusions

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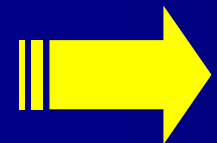
"Non-inclusion" of product realization requirements is allowed if those functions are not required by the nature of the medical device being provided by the organization.

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.
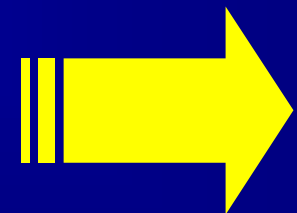
5. Management Responsibility

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**

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.
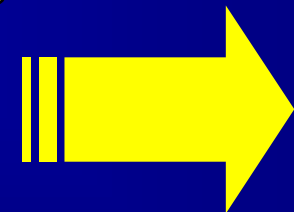
5. Management Responsibility

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

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
- <u>EFFECTIVE</u> 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!

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!

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

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.

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.):

➢ Is there a provision in tolerances, and/or configuration, for interchangeability and replacement?

➢ 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?

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!

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

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*!

7.5 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!

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

7.5 Production and service provision

Preservation of product applies throughout the product realization processes and includes storage, handling, transportation and delivery (may include installation).

> ➢ gloves, static-dissipative measure, gowning,
> ➢ temperature, humidity, dust (particle count),
> ➢ packaging
> ➢ method of transportation (air, sea, ground, environmentally controlled, etc.)

To avoid damage, deterioration or contamination during handling, storage, distribution.

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.

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.

While the information covered during this session is based on ISO13485:2003 and ISO/TR14969,

it essentially describes

GOOD BUSINESS PRACTICES.

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

For further guidance, please refer to
ISO/TR 14969

**Thank you on behalf of Study Group 3
and the GHTF for your time and attention.**

Questions?

APPENDIX

- ➢ 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)

➢ 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)

- ➢ 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)