



Quality Control with Quality Management System

GMP/QSR

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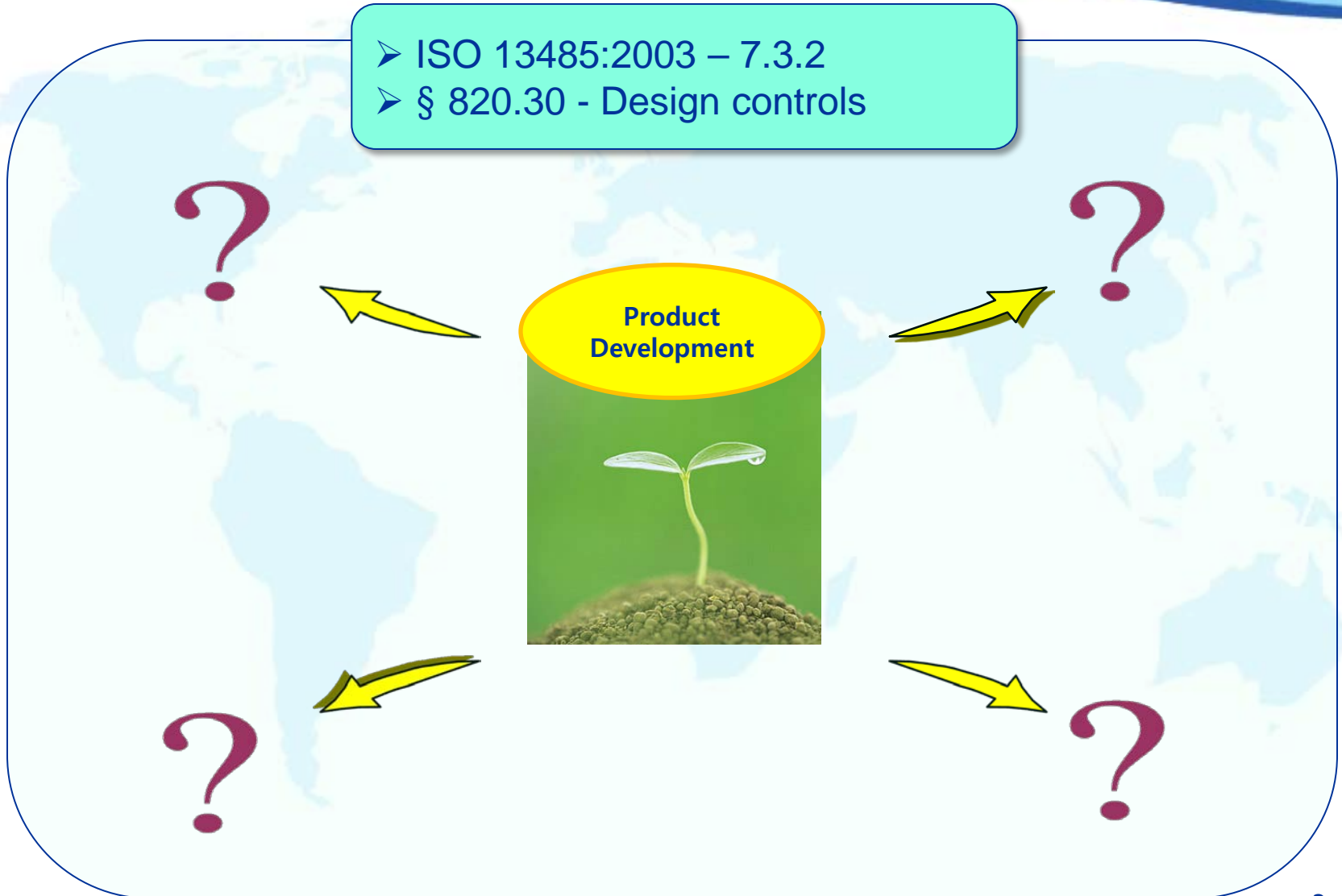
INDEX



- **Meaning of Design and Development Management**
- **What is Quality Management System?**
- **FDA – QSR**

설계관리의 의미

- ISO 13485:2003 – 7.3.2
- § 820.30 - Design controls



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- ISO 13485:2003 – 7.3.2
- § 820.30 - Design controls

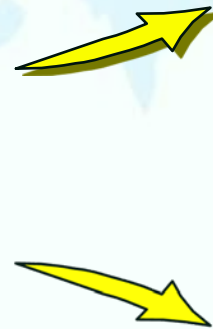
Intended Use

Specification

Product
Development

Regulation

Etc.



- **Development of new product**
- **Consideration of conformity with regulatory requirements from initial step of development**
- **Impossible to enter the market without conformity of regulatory requirements**
- **Possibility to question of maintenance or abolition cause of no market in spite of high cost development after**
- **Need to strategy correspondence against regulatory at initial step of business plan**

- **Quality**
Degree to which a set of inherent characteristics fulfills requirements
- **Quality Management**
Co-ordinated activities to direct and control an organization
- **Quality Control**
Part of quality management focused on fulfilling quality requirements
- **Quality Management System**
Management system to direct and control an organization with regard to quality

Quality management system for Medical devices



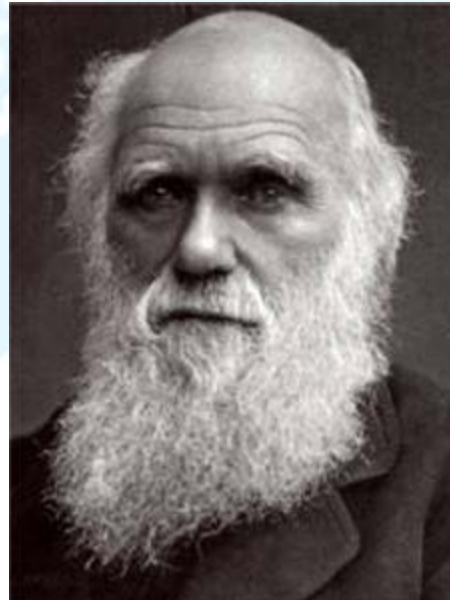
Reason of application of QMS ?

- **To ensure that manufacturer provides stability quality medical devices**
 - **Safe medical devices**
 - **Satisfaction of customer requirements**
 - **Satisfaction of regulatory requirements**
 - **Reasonable quality**

Quality management system for Medical devices



➤ **Darwin Award**



➤ **Fool Proof**

Quality management system for Medical devices



Meaning change of Quality - 1st

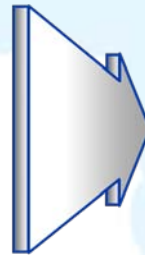
Design &
Development



Production



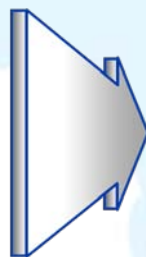
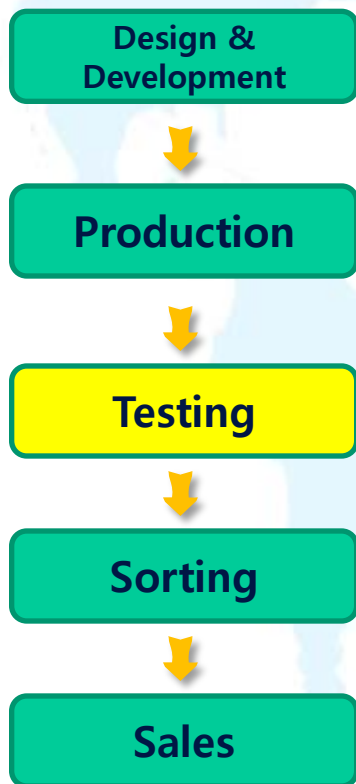
Sales



- Nonconformance Product
- Customer complaints

Quality management system for Medical devices

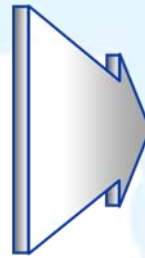
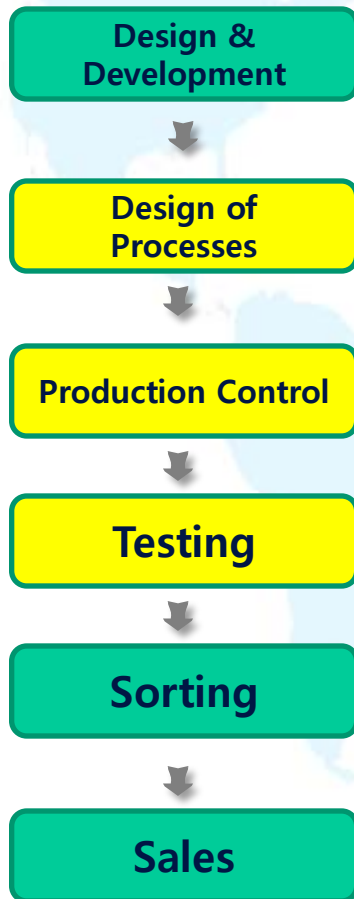
Meaning change of Quality - 2nd



- Reduction of nonconformance
- Design problem
- Customer complains

Quality management system for Medical devices

Meaning change of Quality - 3rd

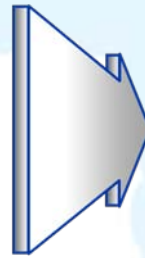
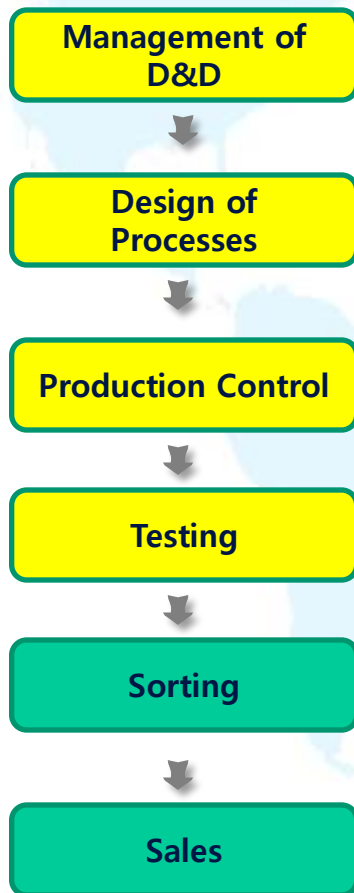


- Improvement of production processes
- Increasing of conformity product
- Design & Development problem
- Customer complaints

Quality management system for Medical devices



Meaning change of Quality - 4th



- Management of Design & Development
- Solving of Design problem
- Reduction of customer complaint

Quality management system for Medical devices



Meaning change of Quality – Quality Management System

➤ Profits of manufacturer side

- Effective implementation of QMS
- Enough providing of resources
- Planned term surveillance evaluation
- Changes and adjustment

Quality management system for Medical devices



Meaning change of Quality – Quality Management System

➤ Profits of Customer side

- Safe consumption
- Periodic management

In this case, CUSTOMER means including end user, purchaser, distributors, etc.

Quality management system for Medical devices



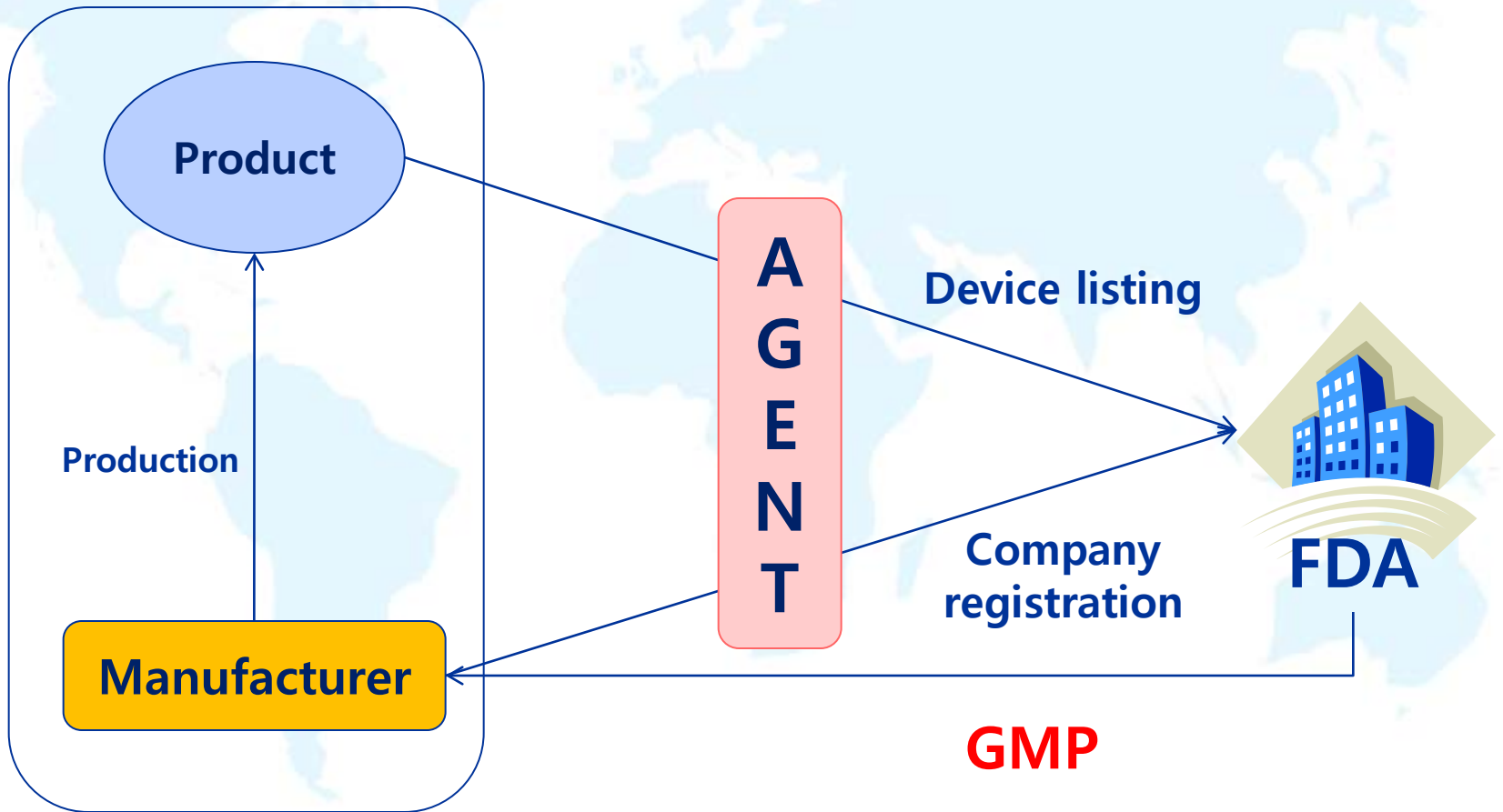
REVIEW

- **What is QMS ?**
- **What is the reason of managing QMS?**
- **Evolution of Quality activities**

- Organization type which could be applied GMP
 - Remanufacturers
 - Custom Device Manufacturers
 - Contract Manufacturers
 - Contract Testing Labs
 - Repackagers and Relabelers
 - Manufacturers of Accessories
 - Initial Distributors

- Organization type of GMP exemption
 - Component manufacturer
 - Case of assembling aimed Component, e.g. raw materials, parts, software, firm ware, label, etc..
 - GMP is applied Finished Device
 - If the component process is in whole manufacturing process, then the manufacturing process is under GMP

FDA – QSR



- QSR: Comprise of 15 Sections
- ISO 13485:2003 comprise of 5 Sections, Main topic is clause 7 (D&D, Purchasing, Production, Service, etc.)



United States: 21 CFR 820		Europe: EN ISO 13485	
A	General Provisions	1	Scope
B	Quality System Requirements	2	Normative References
C	Design Controls	3	Terms and Definitions
D	Document Controls	4	Quality Management System
E	Purchasing Controls	5	Management responsibility
F	Identification and Traceability	6	Resource Management
G	Production and Process Controls	7	Product Realization
H	Acceptance Activities	8	Measurement, Analysis and Improvement
I	Nonconforming Product		
J	Corrective and Preventive Action		
K	Labeling and Packaging Control		
L	Handling, Storage, Distribution and Installation		
M	Records		
N	Servicing		
O	Statistical Techniques		

Subpart A--General Provisions

§ 820.1 - Scope.

§ 820.3 - Definitions.

§ 820.5 - Quality system.

Subpart B--Quality System Requirements

§ 820.20 - Management responsibility.

§ 820.22 - Quality audit.

§ 820.25 - Personnel.

Subpart C--Design Controls

§ 820.30 - Design controls.

Subpart D--Document Controls

§ 820.40 - Document controls.

Subpart E--Purchasing Controls

§ 820.50 - Purchasing controls.

Subpart F--Identification and Traceability

§ 820.60 - Identification.

§ 820.65 - Traceability.

Subpart G--Production and Process Controls

§ 820.70 - Production and process controls.

§ 820.72 - Inspection, measuring, and test equipment.

§ 820.75 - Process validation.

Subpart H--Acceptance Activities

§ 820.80 - Receiving, in-process, and finished device acceptance.

§ 820.86 - Acceptance status.

Subpart I--Nonconforming Product

§ 820.90 - Nonconforming product.

Subpart J--Corrective and Preventive Action

§ 820.100 - Corrective and preventive action.

Subpart K--Labeling and Packaging Control

§ 820.120 - Device labeling.

§ 820.130 - Device packaging.

Subpart L--Handling, Storage, Distribution, and Installation

§ 820.140 - Handling.

§ 820.150 - Storage.

§ 820.160 - Distribution.

§ 820.170 - Installation.

Subpart M--Records

§ 820.180 - General requirements.

§ 820.181 - Device master record.

§ 820.184 - Device history record.

§ 820.186 - Quality system record.

§ 820.198 - Complaint files.

Subpart N--Servicing

§ 820.200 - Servicing.

Subpart O--Statistical Techniques

§ 820.250 - Statistical techniques.

§ 820.3 - Definitions.

(e) **Design history file (DHF)** means a compilation of records which describes the design history of a finished device.

(i) **Device history record (DHR)** means a compilation of records containing the production history of a finished device.

(j) **Device master record (DMR)** means a compilation of records containing the procedures and specifications for a finished device.

§ 820.20 - Management responsibility.

- Quality Policy
- Quality objectives
- Establishment of organization
- Definition of responsibility and authority
- Availability of resources
- Quality representative
- Management review

➤ **820.20 (c) Management review**

- a) Result of internal audit
- b) Feed back from customers
- c) Result of processes and conformance of product
- d) Status of prevention and corrective actions
- e) Follow-up actions of previous management review
- f) Any changes which could be affected of QMS
- g) Suggestion for improvement
- h) New or revised laws and regulations

§ 820.22 - Quality audit.

- Adequacy and effectiveness of QMS
- Impossible to audit for own work directly
- The result is reviewed by qualified person
- Whole audit shall be recorded

§ 820.25 - Personnel.

Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed

ISO 13485:2003 – 6.2

- determine the necessary competence for personnel performing work affecting product quality
- provide training or take other actions to satisfy these needs
- establishment of related document
- record

§ 820.30 - Design controls.

Class III or II products and Class I automated products as software related manufacturer shall establish documented procedure for Design and Development as bellows.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

820.30 (b) Design and development planning.

- Definition of each step of D&D
- Definition of responsibility and authority
- Approval and review by appropriate qualified person.

820.30 (c) Design input.

- Intended purpose of the product
- Instruction for the product
- Requirements of operation, preservation, handling, etc.
- Requirements of operators and patients
- Physical specification (Dimension, volume, etc.)
- Requirements of safety and reliability
- Requirements of biocompatibility

820.30 (c) Design input.

- Clinical follow-up of previous use. (Accident, complaints, etc.)
- Previous D&D information
- Manufacturing processes
- Requirements of sterilization
- Requirements of lifetime or shelf-life
- Requirements of services
- Regulatory requirements
- Etc.

820.30 (d) Design output.

- Information of raw materials, part-list, sub-assembly, etc.
- Drawing
- Developed product (Pilot)
- Software
- Quality assurance system
- Manufacturing processes and inspection methods
- Work environment

820.30 (d) Design output.

- Packing and labeling
- Requirements of identification and traceability
- Installation and services
- Technical documents which submitted to notified body.
- Design dossier

820.30 (e) Design review.

- Conformance with product standards
- Conformance with requirements of environments
- Requirements of functional ?
- Conformance of appropriate raw material used?
- Using of appropriate equipments for production?
- Software ?

820.30 (f) Design verification.

Verification compare to design input

- All result of testing
- Comparison between aimed specification and final drawings
- Date and signature
- Etc.

820.30 (g) Design validation.

Validation compare to design input.

- Simulations
- Description of using
- Environments of expectation
- Using with other equipment or system
- Circumstances of operators and patients (Ability and knowledge)

820.30 (h) Design transfer.

- Application of result of D&D to manufacturing
- Raw materials
- Label
- Critical processes and parameters

820.30 (i) Design change.

- Design change would be occurred as many kinds of reason
- During on development or after finish
- Asked records;
 - Design review, verification and validation
 - Risk management
 - Improvements
 - Etc.

§ 820.40 - Document controls.

Manufacturer shall establish documented procedure

- Approval of documents
- Distribution of documents
- Changes of documents

§ 820.50 Purchasing controls.

Manufacturer shall establish documented procedure to ensure that all purchasing is conformity with required level.

- Evaluation of suppliers
 - Result and criteria of evaluation
 - Result and criteria of management of evaluation follow-up
 - All related records
- Purchasing records
- Verification of purchasing products

§ 820.60 Identification.

- Identification of each step e.g. receipt, production, sales, installation, etc.
- Organization shall establish documented procedure
- Raw materials
- Parts, components and module
- Final products
- Conformity and nonconformity
- Etc.

§ 820.65 Traceability.

- For implantation or life extension equipments
- Purchased LOT
- LOT No. / BATCH No.
- Product No.
- Device History Record (DHR)

§ 820.70 Production and process controls.

- Work instruction, SOP.
- Production parameters (Temperature, humidity, pressure, etc.)
- Changes of manufacturing processes
- Management of work environment
- Worker
- Management of contamination
- Factory
- Equipments
 - Maintenance plan, inspection, calibration, automation processes

§ 820.72 Inspection, measuring, and test equipment.

Monitoring and measuring equipments are ensured that the value is available

- Calibration
- Standard of calibration
- Record of calibration
- Calibration of software stationed
- Protection of broken or unintended balancing

§ 820.75 Process validation.

If it is impossible to inspect and test then it has to be validated about the process

- Follow related procedure
- Records including date and person
- Approval of appropriate workers and equipments
- Using of exact methods and procedure
- Case of software using

§ 820.75 Process validation.

- Process validation
- Definition, review and approval of the equipment
- Installation Qualification (IQ).
- Operational Qualification (OQ).
- Performance Qualification (PQ).

Validation acquired cases

- Automated equipments
 - Automated equipments
 - Automated inspections

- Special processes
 - Sterilization
 - Clean room
 - Purified water

§ 820.80

Receiving, in-process, and finished device acceptance.

Manufacturer establish criteria for inspection, testing and other verifications

- Criteria and methods for incoming inspection
- Criteria and methods for in-process inspection
- Criteria and methods for final inspection
- Maintenance of the records

§ 820.80

Receiving, in-process, and finished device acceptance.

- Release after clearing bellows
 - Completion of whole work and activity of DMR
 - Review of related records and documents
 - Approval of qualified person
 - Date of approval

§ 820.80

Receiving, in-process, and finished device acceptance.

- Criteria for inspection result
 - Activity
 - Date
 - Result
 - Approval
 - Used equipment
 - Above is in DHR

§ 820.90 Nonconforming product.

- Related documented procedure
- Authority of review and handling
- Isolation and handling
- Notice to related customers, suppliers and internal
- Definition of re-work
 - Re-work, repair, disuse, return and concession
 - Retesting after re-work and repair
- Above are in DHR

§ 820.100 Corrective and preventive action.

- Establishment of documented procedure
 - Analysis data – Complaints, defections, records, etc.
 - Recognition of nonconformity and other quality problems
 - Research to cause
 - Action and prevention for recurrence of nonconformity
 - Verification and evaluation
 - Implementations and records of changes
 - Management review
- Documentation and records.

§ 820.120 Device labeling.

- Safety of delivery, preservation and handling
- Label inspection
 - Expired date, handling, LOT No., etc.
 - It is in DHR

§ 820.130 Device packaging.

- Standard of packaging
- Safe design under preservation, delivery and other circumstances
- 1st packaging, 2nd packaging
- Shipping container

§ 820.140 Handling.

- Manufacturer establish procedure for negative situation regarding damage, contamination

§ 820.150 Storage.

- Establishment related documented procedure
- First enter first out, methods of loads
- Searching of appropriate conditions
- Procedure for incoming and shipping

§ 820.160 Distribution.

- Shipping of approval product
- Checking and review of order
- Checking of expired date
- Maintenance of shipping record

§ 820.170 Installation.

- Installation required cases;
 - Appropriate installation methods, inspection, etc.
 - The workers install and record according to fixed procedure by manufacturer

§ 820.181 Device master record.

- Official name of device, drawing, parts, specification, etc.
- Manufacturing processes
 - Equipments, methods, procedures and environment
- Procedure of quality assurance
- Packing and label
- Methods of installation and maintenance

§ 820.184 Device history record.

- Manufacturer maintains LOT, BATCH and each DHR
- Manufacturing date
- Production size (Number of LOT or Batch)
- Inspection result
- Identification of special things and label
- Control number

§ 820.186 Quality system record.

- 820.40 Fixed records by the manufacturer

§ 820.198 Complaint files.

- Records of receipt of complaints, review and handling
- All complaints have to be reviewed
 - All complaints are solved at once
 - Verbal receipts are recorded
 - If applicable, PART 803 (Medical Device Reporting)
- Decision of investigation required

§ 820.198 Complaint files.

- Device name
- Receipt date
- Identification of the device
- Name, address and phone number
- Complaints
- Result and date
- Corrective action
- Responses against complaints

- GMP - Quality System Regulation Final Rule (*Federal Register*)
<http://www.fda.gov/cdrh/humfac/frqsr.html>
- QSIT Inspection Handbook
http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm
- Guideline on General Principles of Process Validation
<http://www.fda.gov/cdrh/ode/425.pdf>
- Design Control Guidance for Medical Device Manufacturers
<http://www.fda.gov/cdrh/comp/designgd.html>
- GMP Guidance Documents - CDRH Office of Compliance
<http://www.fda.gov/cdrh/comp/gmp.html>

A large, light blue world map is centered in the background of the slide. It shows the outlines of the continents in a darker shade of blue against a white background.

Thank you

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