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Preparing for **ISO 13485:2016**

Further Reducing Risk to Public Health Worldwide

Providing for Healthcare Everywhere
From Medical Devices Made Anywhere

Presented by: Grant Ramaley
ISO 13485 Working Group
International Accreditation Forum

Certified once, Accepted Everywhere

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Preparing for **ISO 13485:2016**

A Brief Overview

29,617 certificates*

Deemed credible under ISO/IEC IAF accreditation

*Latest ISO Survey https://www.iso.org/the-iso-survey.html

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Preparing for **ISO 13485:2016**

Further Reducing Risk to Public Health Worldwide

More Regulatory Focus - More Risk Management

(EU) 2017 745

QMS Requirements for the European Medical Device Regulation

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ISO 13485 Working Group
International Accreditation Forum

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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Where United States and ISO came together…

…the agency believed that it would be beneficial to the public and the medical device industry for the cGMP regulation to be consistent with the requirements for quality systems contained in International Organization for Standards (ISO) 9001:1994 and at the time the ISO committee draft (CD) revision of ISO/CD 13485 Quality Systems – *FDA preamble*

The FDA QSR was crafted to align with ISO 13485 in 1997.

1997

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Where US FDA Aligned with ISO 13485:1996

4.1 Management responsibility	820.20 - Management responsibility
4.2 Quality system	820.5 - Quality system
4.4 Design control	820.30 - Design controls
4.5 Document Control	820.40 - Document controls
4.6 Purchasing	820.50 - Purchasing controls
4.8 Material Identification, traceability	820.60 - Identification 820.65 - Traceability
4.9 Production and process control	820.70 - Production controls
4.10 Inspection and testing	820.80 - Recv, in-proc, finished device acceptance
4.11 Inspection Measuring and Test Equipment	820.72 - Inspection, measuring, and test equipment
4.12 Inspection and test status	820.86 - Acceptance status
4.13 Control of Nonconforming Product	820.90 - Nonconforming product
4.14 Corrective and Preventive Action	820.100 - Corrective and preventive action
4.15 Handling, storage, and delivery	K--Labeling and Packaging Control L -- Handling, Storage, Distribution,
4.16 Control of Quality Records	17 820.22 - Quality audit
4.17 Internal quality audits	18 820.25 - Personnel
4.18 Training	
4.19 Servicing	§ 820.200 - Servicing
4.20 Statistical Technique	§ 820.250 - Statistical techniques

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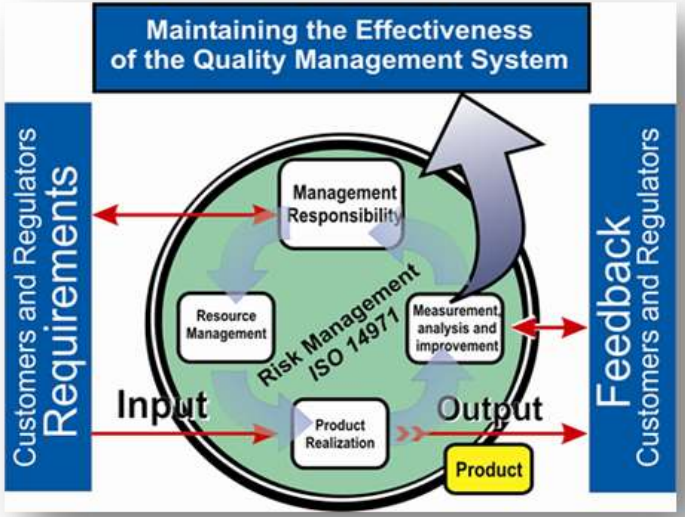
Where it fell apart

"The Process Approach"

2000-2003

ISO introduced "the Process Approach", which combined 20 processes into 8 larger Processes.

ISO reduced requirements for Documented procedures. US FDA wanted more from the new standard.



ISO's Process Approach

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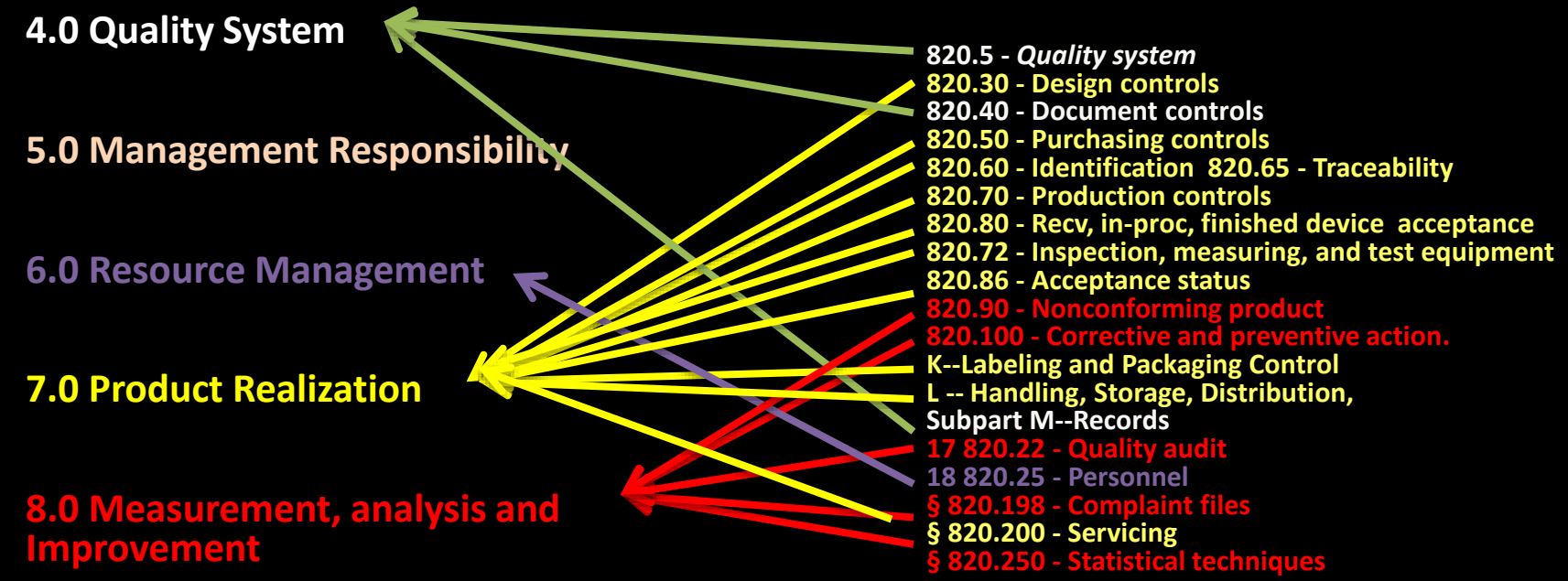
ISO 13485:2003 Adopted More of US FDA Part 820



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FAST FORWARD

ISO 13485:2016

More regulations are aligned with ISO 13485:2003/2016

Korean KGMP & Japanese GMP - MO 169

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FAST FORWARD

ISO 13485:2016

More Regulations using ISO 13485

Australia TGA's Quality System

Canadian SOR 98-282 "CMDCAS"

European "Harmonized Standard"

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These European Medical Device Regulations
go into effect beginning May 26, 2020

EU 2017 745 (Medical Devices Regulation)
EU 2017 746 (In-Vitro Diagnostic Regulation)

Annex IX and Article 10(8)

(Same for both regulations)

Must comply by 27th May 2024

(Same for both regulations)

Quality Management System

EN ISO 13485

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FAST FORWARD

ISO 13485:2016

More Regulatory Compliance

More focus on Managing Risks

More of what we should have been doing?

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So what's the difference?

ISO 13485:2016

Biggest Changes

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What changed?

Quality System Section 4.

4.1.1 – …*"The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements".*

Identify roles employees may have in in the quality system

- Sales Associates
- Service Technicians
- Employees who have roles in complaint reporting procedures

Document "Roles" in the QMS

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Document the Roles of the

'Authorized Representative'

Article 11

Specifies a list of obligations of the AR, which the Manufacturer is to actively support.

Document "AR Roles"

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What changed?

*4.1.2 The organization shall apply a **risk based** approach to the control of the appropriate processes needed for the quality management system;*

It is more essential than ever to understand the sources of hazards with each device and reduce risk appropriately.

			Less Risk --- RISK --- More Risk				
			Noticeable by user	Patient or user inconvenience or temporary discomfort	Causes injury that does not require additional professional medical intervention	Injury requiring additional professional medical attention	Potentially life threatening or causing permanent impairment
	**Likelihood of harm		1	2	3	4	5
5	More than 1/100	Frequent	5	10	15	20	25
4	1/100 to 1/1000	Probable	4	8	12	16	20
3	1/1,000 to 1/10,000	Occasional	3	6	9	12	15
2	1/10,000 to 1/100,000	Remote	2	4	6	8	10
1	1/100,000 to 1/1 million	Improbable	1	2	3	4	5
	Broadly Acceptable			Reasonably Acceptable			Intolerable

* The liklihood of harm should be derived from complaint and adverse event data that relate to each particular hazardous situation.

More Risk Management

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Annex 1 Section 3

3. Manufacturers shall establish, implement, document and maintain a risk management system.

Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating.

Risk Management for the Lifecycle!

What changed?

Quality System Section 4

4.1.5 When the organization chooses to outsource any process, …The controls shall be proportionate to the risk involved and …The controls shall include written quality agreements.

Quality Agreements shall be framed in the context of the risk of the supplied part, service and/or medical device.

Risk Based Quality Agreements

Risk Based Supplier Control

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What changed?

Quality System Section 4.

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system.

Any software required by the quality system must be validated.

Must have a procedure for Software Validation

What changed?

Quality System Section 4.

4.2.3 "Medical device file" (MDF) The Medical Device File (MDF) includes a description of the product, work instructions for manufacturing, testing, servicing etc.

It may reference more than one "file"

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"European Technical Files may include the MDF"

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What changed?

Quality System Section 4.

4.2.5…The organization shall document procedures to define the controls needed for the identification, storage, security and integrity… and implement methods for protecting confidential health information

Do you store confidential health information of patients?

Secure patient information!

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What changed?

Management Responsibility 5.0

5.6.2 Review input

The input to management review shall include:

…. complaint handling;

… reporting to regulatory authorities;

When less is best!

Complaints and MDRs.

Management Must Review Complaints and "MDRs"

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Special Focus - Vigilance Articles

(EU) 2017 745

Article 87 - Reporting of serious incidents and Field Safety Corrective Action (FSCA)

Article 88 - Trend reporting

Article 89 - Analysis of serious incidents and FSCA

Article 90 - Analysis of vigilance data

Monitor, Analyze and Report

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What changed?

Management Responsibility 5.0

5.6.3 Review output

The output from management review shall include…changes needed to respond to applicable new or revised regulatory requirements;

Final Dates to adopt these new requirements	1 March 2019	ISO 13485:2016
	27 May 2024	Regulation (EU) 2017/745
	27 May 2024	Regulation (EU) 2017/746

Must Plan for Regulatory Changes

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Concerning Voluntary use of 'Harmonised Standards'

Those procedures and techniques shall specifically cover:

— identification of applicable general safety and performance requirements [of Annex 1] and solutions to fulfill those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account

Annex IX 2.2 ('c') paragraph 2

"Common Specifications" (CS) – A specification intended to be developed to address a more general requirement of the medical device regulation.

Will you use Harmonized Standards?

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Concerning Voluntary use of 'Harmonised Standards'

"…Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner."

Second sentence of Article 10 (9)

You must evaluate changes to standards
In a timely manner if you are using them.

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What changed?

Resource Management 6.0

6.2 Human resources

The organization shall…

a) determine the necessary competence…

b) achieve or maintain the necessary competence;

COMPETENCE "the ability to apply knowledge and skills to achieve intended results" ISO 17021:2015

Focus on "Competence"

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What changed?

Resource Management 6.0

6.2 Human resources

…The methodology used to check effectiveness is proportionate to the risk ….

"What is difficult in training will become easy in a battle" –
Alexander Suvorov -

More Risk? More "Competence" Expected

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Concerning Competency of At Least one RA Representative

permanently and continuously at their disposal

Article (14) Person responsible for regulatory compliance

either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year

Companies with 50 or fewer employees and gross 10 million Euro or less annually – may retain an external RA Rep. Per – Article 14, by way of reference to Article 2 of 2003/361/EC

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices..."

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What changed?

6.4 Work environment and contamination control

6.4.1 Clean room standards – More clearly implied

6.4.2 Contamination control for sterile devices – More control of biological and particulate contamination.

6.4 Satisfies

Annex IX 2.2 (d)

(EU) 2017 745

More Environmental Controls

What changed?

7.1 Planning of product realization –

Plan on what is to be documented, to support the infrastructure and control of work environment.

Plan to include: handling, storage, distribution and traceability activities specific to the product.

A Little More Planning is Required

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What changed?

7.2 Customer-related processes–

7.2.1 Determination of requirements related to product

Adds user training to ensure specified performance and safe use of the medical device.

7.2.2 Review of requirements related to product

Applicable regulatory requirements

Review user training, if it is necessary

Patient or User Training?

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What changed?

7.2 Customer-related processes–

7.2.3 Communication

"The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements."

HSA Health Sciences Authority

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CFDA

Australian Government
Department of Health
Therapeutic Goods Administration

Know what to communicate and when

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Procedures for handling communication may be in different procedures, depending on purpose.

The quality management system shall address at least the following aspects:

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders; **Article 10 (9) (j)**

More communication nodes for the EU

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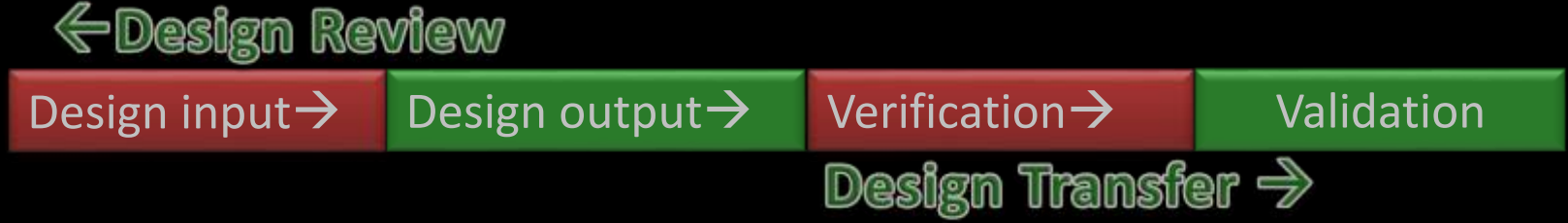
What changed?

7.3.2 Design and Development Planning

The design and development plan must document the methods to ensure traceability of design and development outputs to inputs;

Design Documentation should link all of these activities



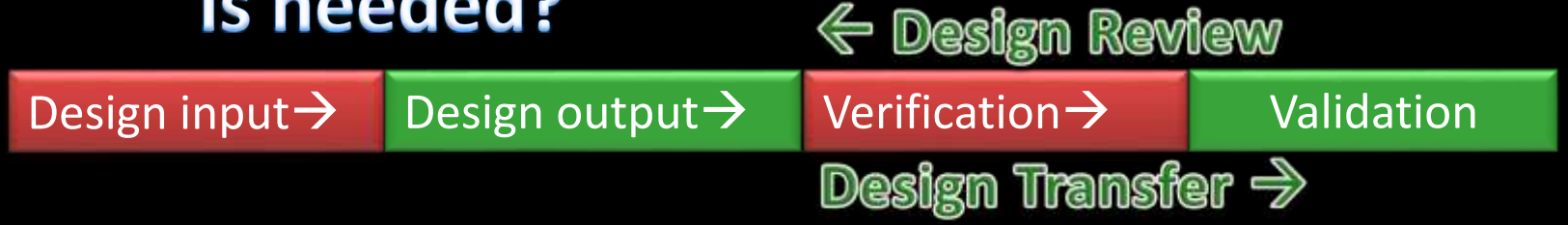
Plan to ensure traceability

What changed?

7.3.2 Design and Development Planning

f) the resources needed, including necessary competence of personnel.

What expertise is needed?



Consider 'competency' requirements

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What changed?

7.3.3 Design and Development Inputs

Inputs relating to product requirements shall include **usability**

Include 'Usability' in your Risk Management Process

Design input ← **ISO 14971**

Scale 'usability' effort consider IEC 62366

Reduce risk of 'Use errors'

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What changed?

7.3.5 Design and Development Review

…include the identification of the design under review, the participants involved and the date of the review...

Design Review Records

Design input→	Design output→	Verification→	Validation

← Design Review

Must Now Record Who, What and When

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What changed?

7.3.6 Design and Development Verification

…shall document methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size....

Design input→	Design output→	Verification	Validation

*"Is there a need for a **larger** sample size?"*

Justify the validity of your Verification

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What changed?

7.3.7 Design and Development Validation

…shall document methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size....

"Do we have enough people for our user group?"

Justify the validity of your Validation

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What changed?

7.3.7 Design and Development Validation

…Design validation shall be performed with… "Representative product" (e.g.) *initial production units, lots, or batches, or their equivalents*..... ISO 13485:2016 & FDA Part 820.30 (g)

Is our prototype like the real thing?

Validation needs Realistic Models

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What changed?

7.3.7 Design and Development Validation

If …the medical device is connected to, or has an interface with other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Does it work when connected?

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What changed?

7.3.8 Design and Development Transfer

Each manufacturer shall document procedures for transfer of design and development outputs to ma ufacturing.

Biggest Changes?

Can you Build what you Designed?

Biggest Changes?

Preparing for
ISO 13485:2016

Medical Device File

Design Transfer

Making sure we can make what we intended during design

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What changed?

7.3.9 Design and Development Changes

Procedures for “Design change” shall determine the effect on existing;

- ✓ *1) Function*
- ✓ *2) Performance*
- ✓ *3) Safety*
- ✓ *4) Applicable regulatory requirements*
- ✓ *5) Intended use*

Check your “Design Changes”

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What changed?

7.3.9 Design and Development Changes

Procedures for "Design change" shall determine the effect on existing

- ✓ *6) product in production*
- ✓ *7)*product in the field*
- ✓ *8) risk management input/output*
- ✓ *9) product realization process.*

**Same as ISO 13485:2003*

Check your "Design Changes"

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What changed?

7.3.10 Design and Development File

…shall include records generated to demonstrate conformity to the requirements for design and development …and development changes.

Biggest Changes

And the Design Change Records

Design input Records	Design output Records	Verification Records	Validation Records

Design and Development *History File

Reference 21 CFR Part 820 j) Design history file.

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What changed?

Biggest Changes

7.4 Purchasing

7.4.1 Purchasing Process

"The organization shall establish criteria for the evaluation and selection of suppliers".

" Proportionate to risk"

"Planned and monitored"

"Record monitoring of suppliers"

"Written agreements"

...And more!

Many little Changes

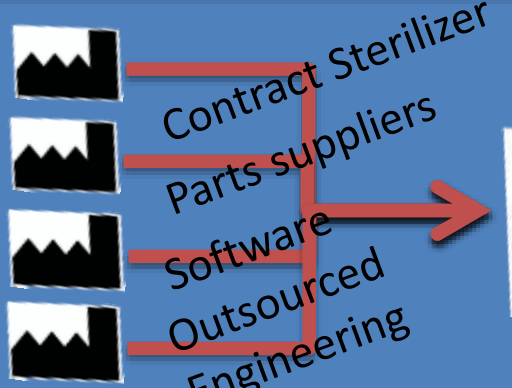
= Big Change

Manage risk of suppliers' product

Biggest Changes?

Preparing for
ISO 13485:2016

1 MORE FOCUS ON SUPPLY CHAIN



ISO 13485 or ISO 9001 Suppliers?

ISO 13485
MD Manufacturer
MD Distributor

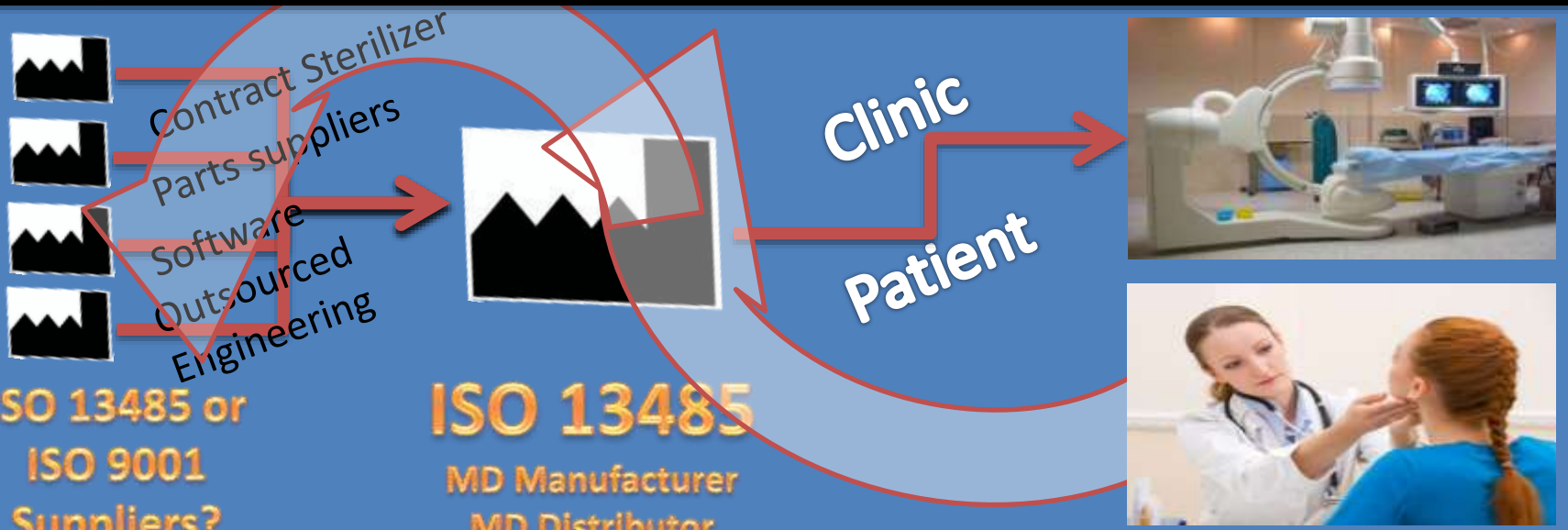
Clinic

Patient

Biggest Changes?

Preparing for
ISO 13485:2016

1 MORE FOCUS ON SUPPLY CHAIN



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What changed?

7.5.1 Control of product and service provision

"Planned, carried out, monitored and controlled to ensure that product conforms to specification…"

- ✓ -- Monitor the process
- ✓ -- Qualify infrastructure

Any software used in the production must be validated (see 4.1.6)

Qualify and Monitor Production Processes

What changed?

7.5.2 Cleanliness of product

Must now document cleanliness of product or contamination control

…if… product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;

IS IT INVASIVE? REUSABLE?

Is Cleanliness Significant in Use?

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What changed?

7.5.4 Service activities

The organization shall analyze records of servicing activities carried out by the organization or its supplier:

1)…are they to be handled as a "Complaint"?

2)…for in put to improve…

SERVICING

Complaint Handling & Monitoring During Servicing?

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"Complaint" means any

ISO 13485 Definition Includes "Usability" which concerns "Use-errors"

written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, ***[usability],*** *safety, [effectiveness], or performance of a medical device after it is released..*

'incident' *means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including* ***use-error*** *due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;*

Article 2 definition (64)

(EU) 2017 745

More Focus on "Use Error"

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What changed?

7 Product realization

Process Validation

7 .5 Production…

7.5.6 Validation of processes for production and service provision.

The organization shall document procedures for validation of processes, Including…

g) approval of changes to the processes.

More Accountability – *"Who approved it"?*

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What changed?

7 Product realization

Process Validation

7 .5 Production…

7.5.6 Validation of processes for production and service provision.

…software validation and revalidation shall be <u>proportionate to the risk.</u>

More Risk = More Process Validation of Software

What changed?

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

…document procedures for the validation of processes for sterilization and sterile barrier systems.

Keeping sterile products sterile?

What changed?

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

ISO 17607-1 …Requirements for materials, sterile barrier systems and packaging systems

ISO 17607-2 …Validation requirements for forming, sealing and assembly processes

More validation of sterile product packaging

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What changed?

7.5.8 Identification

If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.

(EU) 2017 745 Articles 27 & 28

Is "UDI" a Regulatory Requirement?

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What changed?

7.5.9 Traceability

…shall define the extent of traceability in accordance with applicable regulatory requirements

How much traceability is required by the Medical Device Regulation?

Traceability to doctors? Patients??

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Article 18

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

…AND MUCH MORE

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What changed?

7.5.11 Preservation of product

The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by.

Concerns over alteration through distribution

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What changed?

7.5.11 Preservation of product

a) designing and constructing packaging and shipping containers;

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

US FDA 21 CFR Part 820.130

Design/Construct control of packaging

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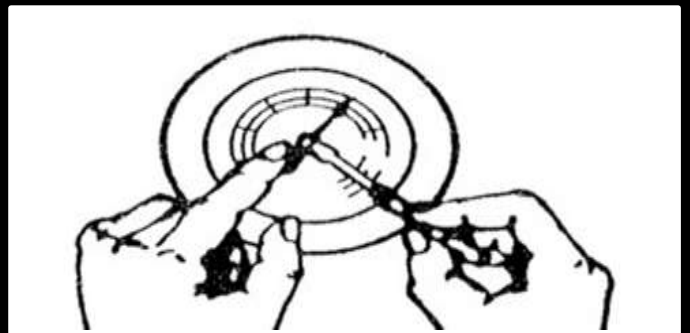
What changed?

7.6 Control of Monitoring and Measuring Equipment

…adjustments shall be recorded (see 4.2.5);



Record Adjustments

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What changed?

7 .6 Control of Monitoring and Measuring Equipment *…document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements.*

Software
Validation
Procedures
Must also cover (MME)

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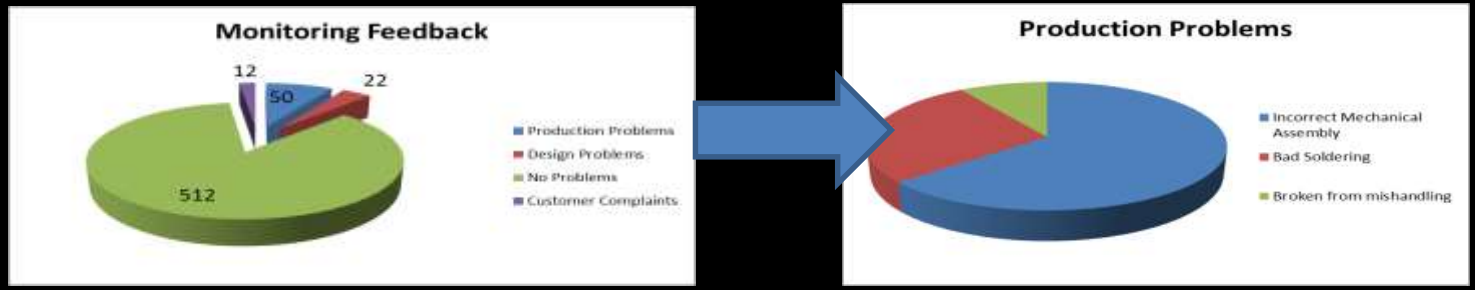
What changed?

8.2.1 Feedback

shall document procedures for the feedback process… to gather data from production as well as post-production activities



Monitoring Data From Production

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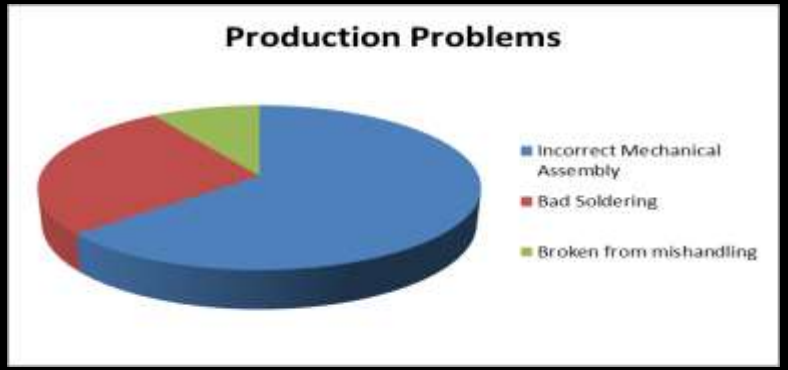
What changed?

8.2.1 Feedback

shall serve as potential input into risk management



Patient safety issue??

Does the Quality "Issue" Present a Risk?

Biggest Changes

Preparing for
ISO 13485:2016

8.2.2 Complaint handling

"The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements"

"Complaint"

Evaluate for reportability

0 12 24 36 48 60 72 84 96 108 120

Biggest Changes

Preparing for
ISO 13485:2016

8.2.3 Reporting to regulatory authorities

Records *of medical device reporting to regulatory authorities shall be maintained.*

"Complaint"

Evaluate for reportability

Reporting

0 12 24 36 48 60 72 84 96 108 120

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Article 87

Reporting of serious incidents and field safety corrective actions (FSCA)

(a) any 'serious incident' involving devices made available on the Union market, *except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;*

'serious incident' – immediately to 15 days.

'serious public health threat', no later than 2 days.

See Article 2 definitions to apply Article 87 properly

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What changed?

8.2.4. Internal Audit

…audit of applicable regulatory requirements

Records of the processes and areas audited and the conclusions, shall be maintained

…necessary corrections and corrective actions are taken

Audit regulatory criteria
Connect clearly with "CAPA"

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What changed?

8.2.5 Monitoring and measuring processes

When planned results are not achieved, correction and corrective action shall be taken, as appropriate. ~~to ensure conformity of the product.~~

Focus no longer on product conformity alone

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What changed?

8.2.6 Monitoring and measuring product

As appropriate, records shall identify the test equipment…

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

Annex IX 2.2 (e)

(EU) 2017 745

Traceability of Product to Test Equipment to Calibration

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What changed?

8.3 Control of nonconforming product

8.3.1 General requirements

Now requires

....the documented procedure shall define the controls and related responsibilities and authorities "for the identification, documentation, segregation, evaluation and disposition of nonconforming product."

More requirements in the "NCP" procedure

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What changed?

8.3 Control of nonconforming product

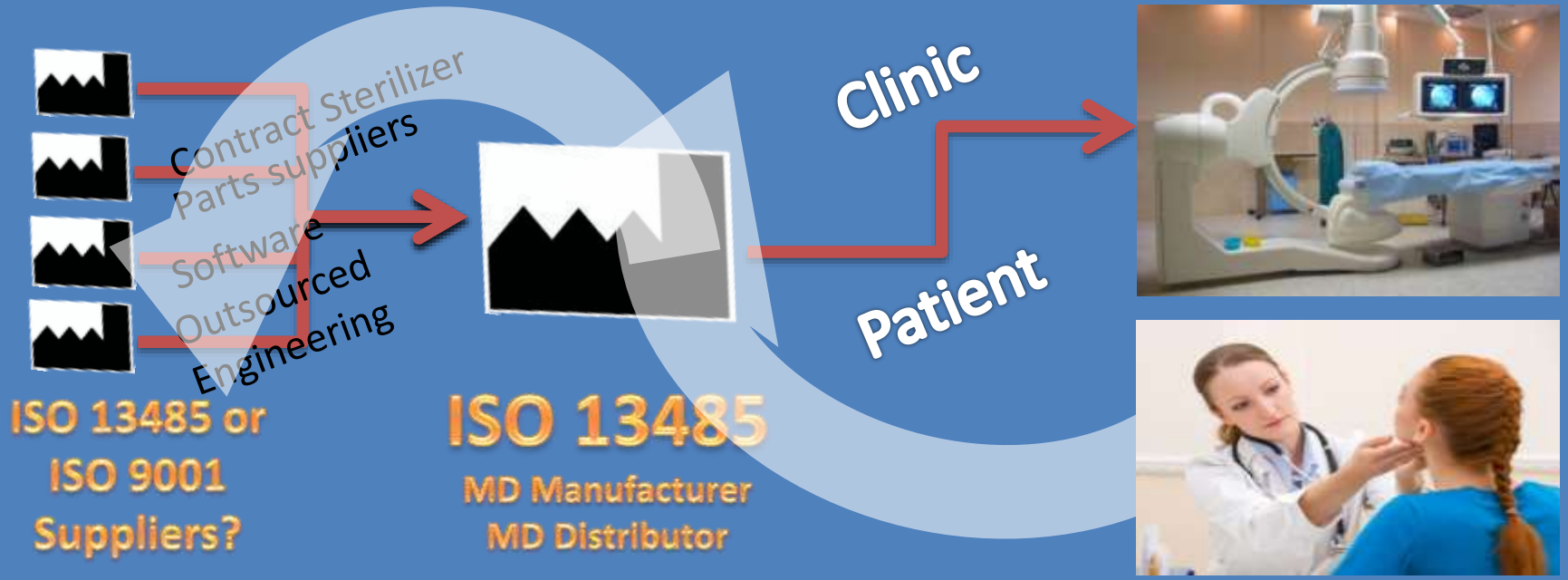
8.3.1 General

adds evaluation …shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Investigate further?
Notify supplier?

Preparing for
ISO 13485:2016

1 MORE INVOLVEMENT WITH THE SUPPLY CHAIN



What changed?

8.3 Control of nonconforming product

8.3.1 General

Record

…nature of the nonconformity

…subsequent action taken, including the evaluation

…investigations

…rationale for decisions

More details in NCP records

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What changed?

8.3.2 Actions in response to nonconforming product detected before delivery

Adds *…nonconforming product is accepted by concession only if the justification is provided,*

Must Record Justification

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What changed?

8.3.3 Actions in response to nonconforming product detected after delivery

Must have procedures for implementing and issuing Advisory Notices

[Moved to 8.3.3 in ISO 13485:2016 from 8.5.1 in ISO 13485:2003]

3.1 'advisory notice'

notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:
— use of a medical device,
— modification of a medical device,
— return of the medical device to the organization that supplied it, or
— destruction of a medical device

Must Keep Records of Advisory Notices

Biggest Changes

Preparing for
ISO 13485:2016

8.3.4 Rework

Adds *…after rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. …Rework records must be maintained*

"How did you fix it?"
RECORD IT!

New Section "Rework"

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What changed?

8.4 Analysis of data

More data to be reviewed, including

e) Audits

f) Service reports (s appropriate)

If …data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement…

More Data to be Reviewed

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What changed?

8.5 Improvement

8.5.1 General

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability; adequacy and effectiveness of the quality management system as well as medical device safety and performance.

Does the product need more help from the QMS?

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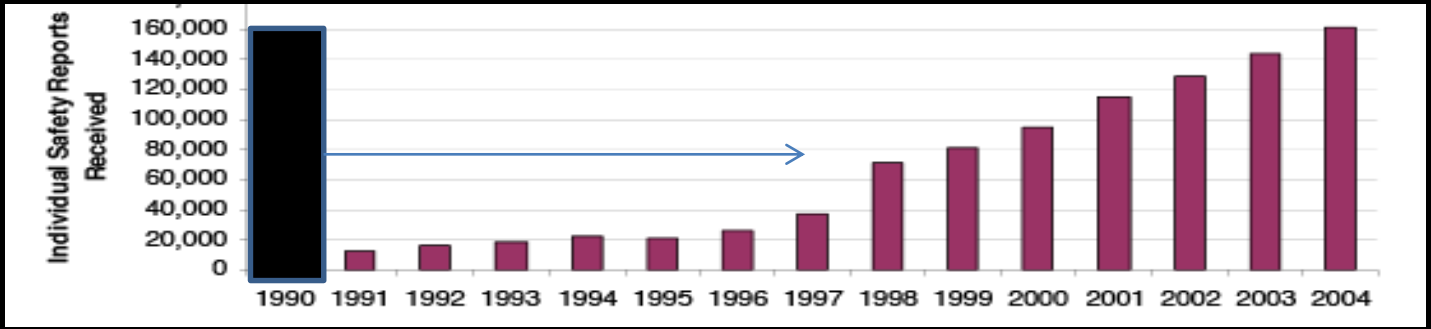
What changed?

8.5 Improvement

8.5.1 General

*Adds through the use of …*post market surveillance*…*



Add Feedback from Field Data

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What changed?

8.5.2 Corrective Action

Adds

"Any necessary corrective actions shall be taken without undue delay".

"Incident"?
"Serious incident"?
"Serious public health threat"?

Article 87

(EU) 2017 745

Don't Delay Reporting Serious Incidents!

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What changed?

8.5.2 Corrective Action (e)

Verify the corrective action does not adversely affect the ability to meet

…applicable regulatory requirements

…safety and performance of the medical device;

"Switching to the plastic screw to manage corrosion will interfere with electrical grounding" –
Corrective Action Plan - REJECTED

Does the CA have unacceptable consequences?

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What changed?

8.5.3 Preventive Action (d)

Verify the preventive action does not adversely affect the ability to meet

…applicable regulatory requirements

…safety and performance of the medical device;

The more fire retardant plastic is too brittle, and will cause the electrical enclosure to crack too easily–
Preventive Action Plan REJECTED

Does the PA have unacceptable consequences?

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Top Takeaway 2016

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ISO 13485:2016

Food for thought

1) Applicable QMS regulations must be integrated
2) Much stronger complaint handling and reporting
3) More control over suppliers
4) More of the “risk based” approach
5) New Documented Procedures
   - for Validating software
   - for Rework

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Preparing for **ISO 13485:2016**

Further Reducing Risk to Public Health Worldwide

Thankyou!

Presented by: Grant Ramaley
ISO 13485 Working Group
International Accreditation Forum

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