Preparing for

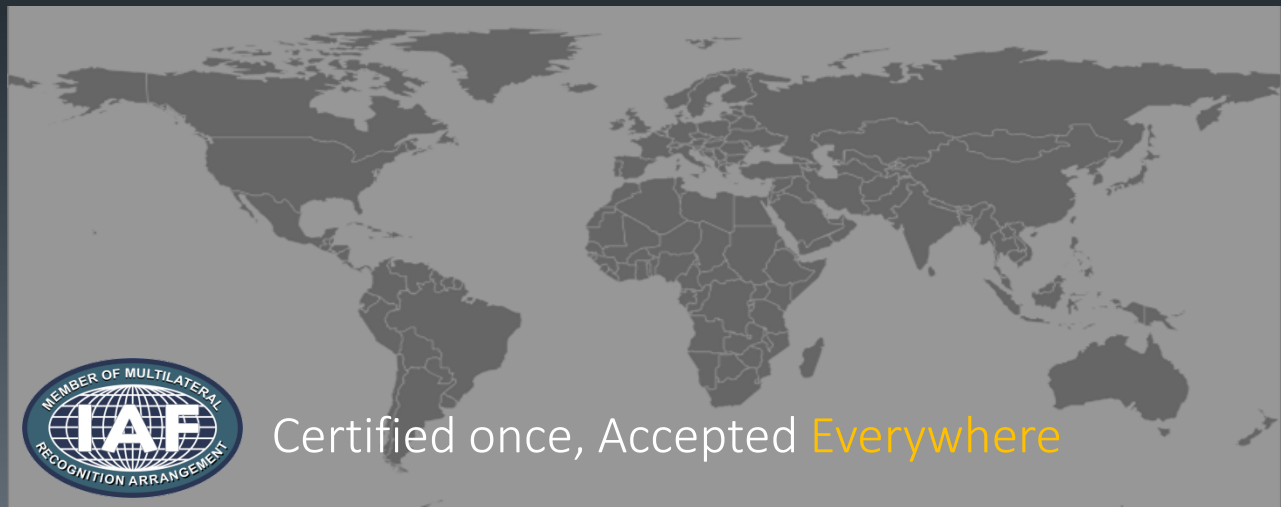
ISO 13485:2016

Further Reducing Risk to Public Health

Worldwide

Providing for Healthcare Everywhere

From Medical Devices Made Anywhere



Certified once, Accepted Everywhere

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

So what's the difference!

ISO 13485:2016

Biggest Changes

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Biggest Changes

*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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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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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

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Quality System Section 4.

4.2.3 “Medical device file” (MDF)

The Medical Device File is not unlike the FDA Device Master Record (DMR) of Part 820.181. The MDF contains parts of the “Technical File” required for CE marking as well.

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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?

Secure patient information!

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Management Responsibility 5.0

…….documented procedure for management review

……. Management review

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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"

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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

What makes Competent users?

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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 design and development inputs;

←Design Review

Design Documentation should link these activities

Design input→ | Design output→ | Verification→ | Validation

Design Transfer →

Plan to ensure traceability

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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**

Reduce risk of 'Use errors'

Scale 'usability' effort
consider IEC 62366
To eliminate unacceptable risk

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7.3.6 Design and Development Verification

7.3.7 Design and Development Validation

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

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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7.3.8 Design and Development Transfer

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

Can you Build what you Designed?

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7.3.9 Design and Development Changes

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

Does Change Affect…?

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

Check your Changes

Biggest Changes

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7.3.9 Design and Development Changes

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

Does Change Affect…?

- ✓ *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 Changes

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Biggest Changes

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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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!

Biggest Changes?

Many little Changes

= Big Change

Manage risk of suppliers' product

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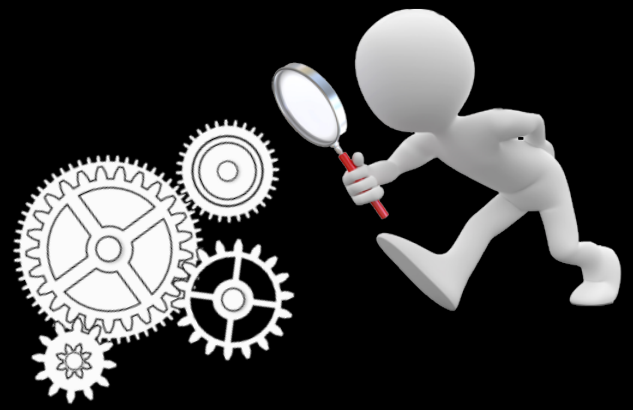
Biggest Changes

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

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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 input to improve…

Servicing

"Complaints" during Servicing?

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7 Product realization

7 .5 Production…

Process Validation

7.5.6 Validation of processes for production and service provision.

The organization shall document procedures for validation of processes, Including…statistical rationale for sample size

~~Revalidation~~

g) approval of changes to the processes

Simply More Clarity?

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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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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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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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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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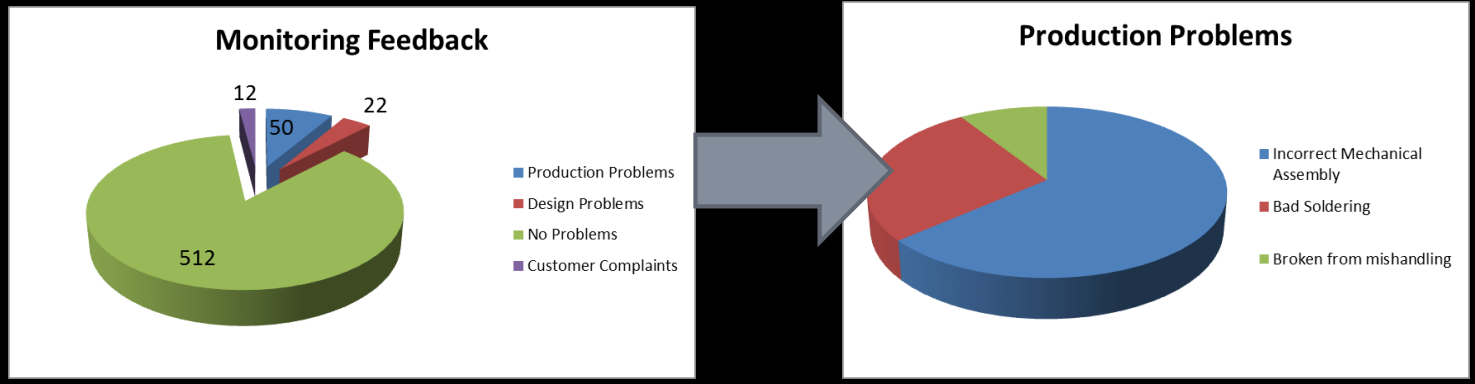
8.2.1 Feed back

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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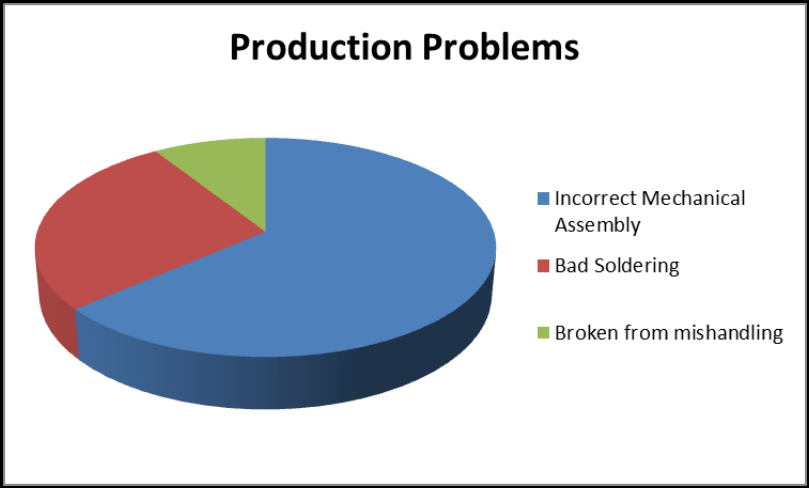
8.2.1 Feedback

shall serve as potential input into risk management



Patient safety issue??

Does the Quality Present a Risk?

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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

1) Adds *"audit of applicable regulatory criteria*
2) Connects better with "CAPA" process

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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

More Documentation, Records and Traceability

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Biggest Changes

8 Measurement Analysis and Improvement

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 in the documented procedure

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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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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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Biggest Changes

8.4 Analysis of data

More data to be reviewed, including

e) Audits

f) Service reports (as 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 for Expected

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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 device need improvement?

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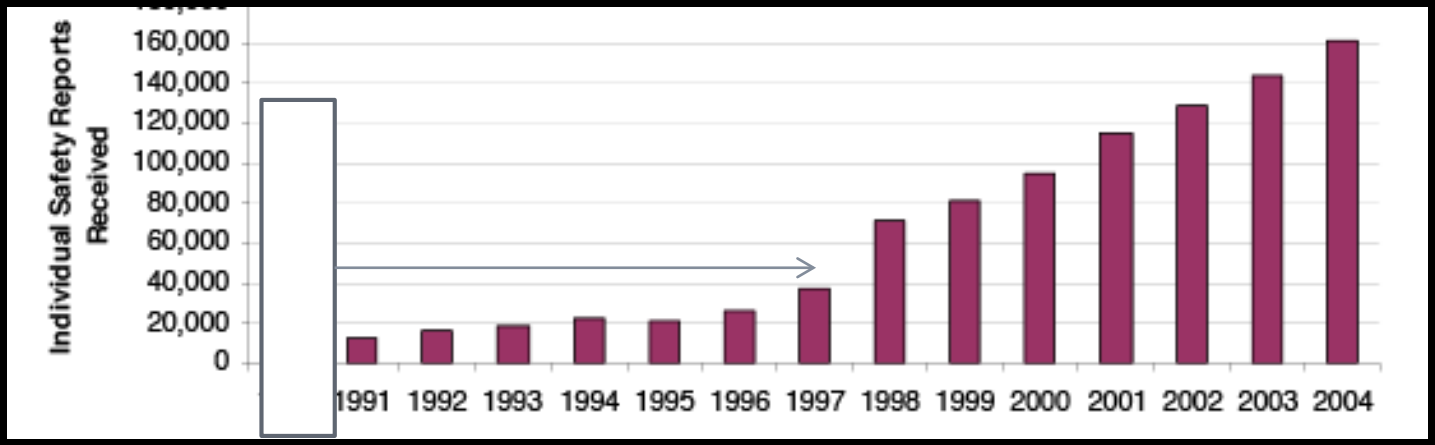
8.5 Improvement

8.5.1 General

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



Add Feedback from Field Data

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8.5.2 Corrective Action

8.5.3 Preventive Action

Verify the (….) action does not adversely affect
…applicable regulatory requirements
…safety and performance of the medical device;

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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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Thank You

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