Panel Discussion: EU-MDR, MDSAP and ISO 13485:2016: How Are They Interconnected and What You Need to Know

Moderator: Robert Ruff, Executive Director of Medical Device Education and Training, NSF Health Sciences; former Medical Device Specialist and Senior Investigator at ORA and International Team Lead at CDRH, FDA

Panelists
• Dan O’Leary, President, Ombu Enterprises LLC
• Florianne Torset-Bonfillou, Regulatory Affairs and Education, Senior Lead Auditor & Senior Design Dossier Reviewer, GMED North America
• Marc-Henri Winter, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA
Connections –
EU-MDR, MDSAP, & ISO
13485:2016

Dan O’Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com
Topics

- Status of the EU-MDR implementation by EU
- Article 120 Transitional Provisions
- ISO 13485:2016 and the EU-MDR – CEN/TR 17223:2018
- ISO 14971:2019 and the EU-MDR
- Status of NBs
- Status of harmonized standards and common specifications
- Status of Eudamed
- Potential hurdles for manufacturers and how to prepare for them
- Questions
Status of the EU-MDR Implementation
The Expectation

• Expectation: The EU will have all of the mechanisms in place for a device manufacturer to apply the CE Mark before the Date of Application, May 26, 2020.

• Assumption: Given the complexity of the EU-MDR and limited Notified Body capacity, a manufacturer will need about one year from application to an MDR CE Mark

• Conclusion: Time is running out!!
MDR Transition Time Line

3 Year Transition Period

- May 26, 2017: Enter into Force
- May 26, 2020: Date of Application
- Nov 26, 2017: Notified Bodies, Competent Authorities, Medical Device Coordination Group
- Jan 2018
- Jan 2019
- Jan 2020

Published: Nov 26, 2017
MDR Transition Time Line

- May 2017: Entry into Force
- May 2018
- May 2019
- Apr 2019: Date of Application
- May 2020
Corrigendum

• On March 13, 2019 the EU published Corrigendum #1

• It has 14 changes
  – They correct typographical errors such as changing “trademark” to “trade mark”.
  – One of significance deals with devices that incorporate non-viable animal tissue or derivatives
Article 120
Transitional Provisions
The Work Around

• Article 120 allows a hybrid system to keep devices on the market after May 26, 2020

• The hybrid system is the “soft transition”

• Put simply, the soft transition requires:
  – A valid MDD device certificate
  – The manufacturer complies with the MDD, with exceptions
  – The NB continues to audit the manufacturer following the MDD rules
  – The manufacturer replaces certain part of the MDD QMS with MDR QMS requirements
  – The manufacturer follows certain MDR registration requirements
MDR Soft Transition Time Line

May 26, 2020
NB notifications to the MDD and AIMD are void

May 26, 2020
Date of Application

May 27, 2022
MDD Annex IV and AIMD Annex 4 certificates are void

Jan 2021
Jan 2022
Jan 2023
Jan 2024

May 27, 2024
NB certificates issued after May 25, 2017 are void

Devices with a valid MDD or AIMD certificate remain on the market:
- Complies with the directive
- No significant changes in design or intended use
- Implement the MDR for PMS, vigilance, registration of economic operators, and registration of the device

Date of Application
May 26, 2020

Ombu Enterprises, LLC
Article 120
Soft Transition Simplified

• QMS
  – Develop a hybrid QMS with some elements from the MDD (or AIMD) and some elements form the MDR
    • Economic operator registration

• Device
  – Maintain each device following the requirements of the MDD (or AIMD) including the Essential Requirements
    • Maintain a valid NB device certificate
  – Apply the hybrid QMS to each device
    • Device registration
    • Post-market surveillance
    • Market surveillance
Article 120
Transitional Provisions

• Article 5(1) says, “A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained, and used in accordance with its intended purpose.”
  – However, Article 120(3) provides an exception

• Article 120(3) says that a device with a certificate issued under Article 120(2) may remain on the market after May 26, 2020 under certain conditions:
  – The device complies with the MDD or AIMD
  – The MDD or AIMD NB remains responsible for surveillance
  – There is no significant change in the design or the intended use
  – The QMS implements the MDR requirements for PMS, Market Surveillance, and Vigilance
  – The manufacturer completes the MDR economic operator registration and device registration
ISO 13485:2016
EU-MDR
CEN/TR 17223:2018
Article 10

- The EU-MDR Article 10 lists the obligations of the manufacturer

- One of the obligations, in Article 10(9) is to implement an effective QMS
  - Article 10(9) requires that the QMS address 13 specific areas

- In some cases the areas are complex
  - Example: Setup, implement, and maintain a post-market surveillance system in accordance with Article 83
ISO 13485:2016 & Friends

• ISO 13485:2016 is the international standard, issued by ISO, that provides regulatory requirements for a medical device QMS

• A requirement of ISO 13485:2016 is:
  – Identify the roles a company plays in each regulatory area
  – Determine the corresponding regulatory requirements
  – Implement process to meet these requirements
  – Develop quality objectives related to the process

• A MDSAP audit checks that the company meets the requirements
  – The focus is on the five MDSAP countries: Australia, Brazil, Canada, Japan, and the US
ISO 13485:2016 & Friends

• EN ISO 13485:2016/AC:2018 is an EU standard, issued by CEN, that provides regulatory requirements for the MDD, IVDD, and AIMD
  – Each of these directives includes QMS requirements that are not in ISO 13485:2016

• EN ISO 13485:2016/AC:2018 includes an Annex for each directive
  – The annexes include tables for each conformity assessment path that explain whether or not ISO 13485:2016 satisfies the directive

• Example:
  – ISO 13485:2016, 4.2.3 requires a medical device file and lists the minimum contents
  – EN ISO 13485:2016, Table ZB.1 says that the medical device file must include statements about human blood derivatives and tissues of animal origin
ISO 13485:2016 & Friends

• EN/TR 17223:2018 is an EU technical report, issued by CEN, that provides information on the relationship between ISO 13485:2016 and the MDR (and the IVDR).

• The technical report is about 85 pages. Most of the pages are divided between two tables – and MDR table and an IVDR table
  – Assume about 35 to 40 page long tables for each regulation
• Example
  – Article 10(9.g) require the QMS to cover “product realization, including planning, design, development, production, and service provision”
  – This flows through Annex IX, chapter 1, 2.2 paragraph 2 c) indent 6
  – This leads to ISO 13485:2016 4.2.3a) 7.3.3b), and 7.5.1e)
  – Partially covered. ISO 13485:2016 includes a general requirement for design inputs to include applicable regulatory requirements and for the medical device file to include the labelling, including instructions for use. Specific requirements of Chapter III of Annex I are not included explicitly

Ombu Enterprises, LLC
ISO 14971:2019
and the EU-MDR
ISO 14971:2019

• The current international version is ISO 14971:2007

• The current EU version is EN ISO 14971:2012
  – It is harmonized to each of the three directives: MDD AIMD, & IVDD

• ISO plans to issue a new international version in 2019

• CEN plans to issue a new EU version in 2019
  – It will have five Annexes
  – Three (ZA, ZB, & ZC) will cover the existing directives
  – Two (ZD & ZE) will cover the regulations

• The Annexes are in the conventional format referring to clause of the corresponding Annex I

• The Content Deviations are gone!
Status of NBs
Notified Bodies

• The list of NBs for the MDR and the IVDR are on the NANDO website

• IVDR
  – None listed

• MDR
  – NB 0086 BSI Assurance UK Ltd
  – For a list of the Product family, product /Intended use/Product range follow the links to their Notification document
Harmonized Standards
Common Specifications


Status

• Request for harmonization
  – Not yet issued

• Number of harmonized standards required – Unknown
  – Number of standards harmonized – 0

• *Common Specifications* (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process, or system. [Art. 2(71)]

• Number of common specifications required – Unknown
  – Number of common specifications issued – 0
Status of Eudamed
Eudamed

- Eudamed includes the following electronic systems:
  - Electronic system for registration of devices referred to in Article 29(4)
  - The UDI-database referred to in Article 28
  - The electronic system on registration of economic operators referred to in Article 30
  - The electronic system on notified bodies and on certificates referred to in Article 57
  - The electronic system on clinical investigations referred to in Article 73
  - The electronic system on vigilance and post-market surveillance referred to in Article 92
  - The electronic system on market surveillance referred to in Article 100.
Functionality

• The Commission, collaboration with the MDCG, draws up the functional specifications for Eudamed.
  – The implementation plan is due by May 26, 2018
  – The Commission intends that Eudamed is fully functional so it can be announced by March 25, 2020

• The Commission, on the basis of an independent audit report, informs the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications

• The Commission, after consultation with the MDCG, publishes a notice in the Official Journal of the European Union.

• If Eudamed is not fully functional on May 26, 2020, the requirements apply six months after the date of publication in the Official Journal
Status

• On Feb. 28, 2019 the EU published the first draft consolidated version of functional specifications for Eudamed (version 4.1)

• Example:
  – FS-PUB-ACT-001: Search and view actor details
    • FS-PUB-ACT-001.01: List all Economic Operators and Sponsors (only those with authorized application for CI/PS) whose registered actor details match a set of search criteria provided by the user
  
  • FS-PUB-ACT-001.02: Display registered actor details (excluding the confidential information) of an Economic Operator or Sponsor (only those with an authorized application for CI/PS) designated by his/her Single Registration Number/Actor ID or by some other combination of criteria allowing his/her unique identification

• CI/PS means Clinical Investigation / Performance Studies Module
Manufacturer’s Potential Hurdles
Time

• Assume (generously) one year:
  – Update the QMS
  – Create new technical files
  – Contract with an NB
  – Pass the NB audit
  – Prepare the DoC
  – Put the EU-MDR CE Mark on the device

• For the Article 120 soft transition:
  – Update the QMS
  – Pass the NB audit

• Many NB announced a cutoff at the end of March for the Article 120 soft transition
Standards

• To prepare the new technical files, manufacturers will need the MDR harmonized standards – There are none!

• The solution is:
  – Identify the Annex I requirements that apply to your device
  – If you will use a standard for conformity, identify the current EN standard
    • Note that the current EN standard may not be the MDD harmonized standard
  – Determine the clauses in the standard to apply
  – Prepare the documented evidence in the Annex II Technical Documentation

• Cost – At some point you will need to buy the EN standard with the Annex for the MDR
  – Assume $150 per standard for each standard you use for the MDD
Economic Operators

• There are six kinds of economic operators
  – Identify each of them associated with your company

• For each one, you will need to put a contract in place

• Be sure to read and understand the MDR requirements for each economic operator
  – This is the basis for your contract

• The Authorized Representative needs current copies of all the technical documentation, NB certificates, etc.
  – Determine the best method to keep a current copies available in the Authorized Representative’s office
QUESTIONs

Ombu Enterprises, LLC
ISO 13485:2016 as Foundation of the MDSAP Audit Model

Marc-Henri Winter

FDA | CDRH | OC | DICO

[OPEQ Pilot: Office of Regulatory Programs | Division II | Inspections and Regulatory Audits Team]
MDSAP - Vision

Regulatory Authorities (RA)

Audit and Certify

Assess and Recognize

Share Audit Report

Manufacturers

Audit and Certify

Other Info

Regulatory Decisions

MDSAP

Interface MDSAP - Other RA-specific Regulatory Processes

Auditing Organizations (AO)
Audit Model

- QSIT: Quality System Inspection Technique developed by the FDA in 1999 for medical device inspections against 21 CFR 820 + 803/806. Implemented.
- ISO 19011: Guidelines for auditing management system. No systematic audit trail.
For each of the 7 processes
  - Purpose
  - Outcomes
  - Audit tasks (90 in total)
    - Statement of task
    - Relevant ISO 13485:2016 clause
    - Relevant regulatory requirements
    - Additional country-specific requirements, beyond ISO 13485
    - Linkages between tasks / processes → trail
    - Relationship with risk management
    - Guidance
Audit Model

• 90 audit tasks covering
  – All ISO 13485:2016 requirements
  – Relevant regulatory requirements

• Clarifying annexes:
  – Audit of technical documentations
  – Considerations relative to the audit of the controls of the sterility

✓ Verify that the audited manufacturer has defined and implements controls to ensure the safety and performance of medical devices [Quality / Compliance]
Audit trail

• That term is not defined and has different possible meanings:
  – Pre-determined sequence of audit tasks or steps (~ audit plan).
  – [Preferred] Identification by the auditor of audit findings of significance and weighing on their judgment-based sampling when selecting a product, process, document or record to evaluate.
  – Chronological record of the discussions and finding of the audits (~ auditor’s notes).
What the Audit Model is Not...

• A regulation
  – MDSAP does not introduce any new requirement applicable to manufacturers
  – It is an auditing tool → Auditors are to perfect their regulatory competence through other means.

• An inflexible auditing strategy
  – Auditors are expected to plan their audit to be most effective considering
    • The specifics of the organization being audited;
    • The size of the audit team and the competence of its members;
    • Other applicable constraints...
  – This may justify deviating from the order of the tasks as presented in the audit model, provided the specified task linkages are used to highlight audit trails.
ISO 13485:2016 and “Regulatory Requirements”

- ISO 13485 uses the term “regulatory requirement” 58 times.
  - The requirements of the standard are incomplete without the applicable regulatory requirements
- “Regulatory requirements” encompasses requirements for the QMS and the safety or performance of the medical device contained in any law applicable to the user of the standard.
  [paraphrase from ISO 13485 Introduction]
- An organization is expected to:
  - identify its role(s) according to applicable medical device regulations;
  - identify the regulatory requirements that apply to its activities under these roles;
  - incorporate these applicable regulatory requirements within its QMS.
Main regulatory requirements embedded in the audit model

- Medical Device File
- Document and Record retention
- Notification of changes
- Marketing Authorization
- Facility Registration
- Provisions for exclusion of design controls
- Requirements for safety and performance of the device
- Use of recognized standards
- Clinical evaluation
- Identification (UDI)
- Traceability (device tracking)
- Post market surveillance
- Complaint handling
- Reporting of adverse events and advisory notices
Regulatory Requirements Not Incorporated in the Audit Model

• Additional QMS requirements applicable to some medical device only e.g. combination products subject to pharma-GMPs → specific auditor competence required.

• Regulations not specific to medical devices e.g. US regulation for radiation emitting devices → not audited under MDSAP; subject to FDA inspections.
Status of the Program

- 11 AO recognized
- 2 AO authorized to audit
- 1 new applicant

- 2,880 certification holders
  - 3,702 facilities (including “campuses”)
  - 4,251 individual addresses

Current, as of 2019-04-17
Audit and FDA Inspection Progression

MDSAP Audits and FDA Inspections during fiscal years 2017 and 2018
Audit Model and Europe

• Europe is an MDSAP observer (not a participating member) 
  ➔ The MDSAP audit model does not incorporate European requirements
• However Auditing Organization perform combined audits 
  ➔ Auditing Organizations can create a version of the audit model incorporating the European requirements
• Annexes Z of EN ISO 13485 identify the EU requirements that are not fully addressed by the standard and can help complement the MDSAP Audit Model with European specific regulatory requirements.
• The MDSAP Audit Report forms enable recording non-MDSAP findings, especially for CE Marking. Considerations for making future revisions of the forms more generic, less MDSAP-centric.
Additional Information

• Additional information on MDSAP is available at [https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm](https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm)

• Contact the MDSAP team at [MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)
EU-MDR, MDSAP AND ISO 13485:2016: HOW ARE THEY INTERCONNECTED AND WHAT YOU NEED TO KNOW

FLORIANNE TORSET-BONFILLOU, DIRECTOR REGULATORY AFFAIRS AND EDUCATION, GMED NORTH AMERICA
- EU MDR – TRANSITION STATUS

- AUDIT OF EU MDR COMBINED WITH MDSAP AUDIT
EU MDR – TRANSITION STATUS

Timelines for NB

Entry into force
May 25, 2017

Q3 2019
NB Designation

May 26, 2020
Date of application

May 26, 2024
Expiration date of all MDD certificates

Preparation and Implementation

Transition
EU MDR – TRANSITION STATUS

Timelines for Certificates validity

May 26, 2017
Entry into force

May 26, 2020
Application

May 27, 2024
End of validity Certificates MDD

“Soft Transition”

Directives Certificates issued before May 26, 2017 = Normal expiration date (max 5 years)

STOP Issuance Directives certificates

Directives certificate issued starting May 26, 2017 = Normal expiration date but maximum May 27, 2024

Art 120
ARTICLE 120– TRANSITIONAL PROVISIONS

A medical Device covered by a valid certificate issued in accordance with directives 90/385/CEE or 93/42/CEE can be put on the market or put in service after May 26, 2016 only if:
- it continues to comply with either of those Directives
- provided there are no significant changes in the design and intended purpose

Requirements of this Regulation relating to:
- post-market surveillance,
- market surveillance,
- vigilance,
- registration of economic operators and of devices
shall apply in place of the corresponding requirements in those Directives

→ The notified body that issued the certificate shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified
TRANSITIONAL PROVISIONS / TRANSITION TO MDR

QMS impact / ISO 13485:2016

- Applicable regulatory requirements
  - changes, impact management
  - Post Market surveillance procedure
  - Economic Operators identification/registration

- ISO 13485:2016 harmonization status

Annex ZA (informative)  Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices
[OJ L 189] aimed to be covered ................................................................. 4


Annex ZD (informative)  Relationship between this European Standard and the General Safety and Performance requirements of Regulation (EU) 2017/745 aimed to be covered..................................................................................................................... 24

Annex ZE (informative)  Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered..................................................................................................................... 37
AUDIT OF EU MDR COMBINED WITH MDSAP AUDIT

AO / NB Perspective

- **Common baseline:** ISO 13485:2016

- **Upcoming harmonized EN ISO 13485**
  - Table ZD.1 – Correspondence between this European standard and the requirements of Article 10 of Regulation (EU) 2017/745
  - Table ZD.2 – Correspondence between this European standard and the requirements of Annex I Chapter 1 of Regulation (EU) 2017/745
  - Table ZD.3 – Correspondence between this European standard and the requirements of Annex IX of Regulation (EU) 2017/745
  - Table ZD.4 – Correspondence between this European standard and the requirements of Annex XI of Regulation (EU) 2017/745

- **EU MDR Audit / MDSAP Audit**
  - Combined
  - Mixte
THANKS FOR YOUR ATTENTION

G-MED NORTH AMERICA, INC.

6550 Rock Spring Drive, suite 280
Bethesda, Maryland 20817 - USA
Office: (301) 495-0477
E-mail: contact@lne-america.com
FDAnews 16th Annual Medical Device Quality Congress
April 23, 2019

EU-MDR, MDSAP and ISO 13485:2016: How Are They Interconnected and What You Need to Know
Article 10(9) Components
Basic Quality Management System Requirements

NOTE
The blue boxes depict entirely new requirements/processes. Others will require evaluation and change in order to comply with the new requirements within the EU MDR.
Quality Management System Correspondence Table: EU MDR, MDSAP Audit Model Tasks and EN ISO 13485:2016

Description:
Article 10 of the European Medical Device Regulation (EU) 2017/745 describes a robust set of general obligations that a manufacturer must assume. The following tabulations have been developed to provide the user with a guide to the general obligations and to correlate those obligations to both EN ISO 13485:2016 requirements and MDSAP chapters and tasks.

Reference: PD CEN/TR 17223:2018
<table>
<thead>
<tr>
<th>Article 10 Ob.</th>
<th>Requirement</th>
<th>MDR Article / Annex</th>
<th>Typical QMS Process / Procedure</th>
<th>EN ISO13485:2016 Clause(s)</th>
<th>MDSAP Chapter and Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>When placing their devices on the market or putting them into service,</td>
<td>Article 5</td>
<td>Design and Development</td>
<td>7.3</td>
<td>Chapter 5</td>
</tr>
<tr>
<td></td>
<td>manufacturers shall ensure that they have been designed and manufactured in</td>
<td></td>
<td>Product Realisation (P&amp;SC)</td>
<td>7.1, 7.5.1</td>
<td>Chapter 6</td>
</tr>
<tr>
<td></td>
<td>accordance with the requirements of this Regulation.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Manufacturers shall establish, document, implement and maintain a system for</td>
<td>Annex I S3</td>
<td>Risk Management</td>
<td>4.1.2 b), 7.1</td>
<td>Ch1, T7</td>
</tr>
<tr>
<td></td>
<td>risk management as described in Section 3 of Annex I.</td>
<td></td>
<td></td>
<td></td>
<td>Ch3, T3 - T7, T9, T12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ch5, T8-T10, T12 – T13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ch6, T10 – 11, T16, T21,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>T21, T22, T28</td>
</tr>
<tr>
<td>3.</td>
<td>Manufacturers shall conduct a clinical evaluation in accordance with the</td>
<td>Article 61 Annex XIV</td>
<td>Clinical Evaluation</td>
<td>7.3.7</td>
<td>Ch5, T11</td>
</tr>
<tr>
<td></td>
<td>requirements set out in Article 61 and Annex XIV, including a PMCF.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Manufacturers of devices other than custom-made devices shall draw up and</td>
<td>Annex II Annex III</td>
<td>Technical documentation</td>
<td>4.2.3</td>
<td>Annex 1 (Audit of</td>
</tr>
<tr>
<td></td>
<td>keep up to date technical documentation for those devices. The technical</td>
<td></td>
<td></td>
<td></td>
<td>technical documentation)</td>
</tr>
<tr>
<td>Article 10 Ob.</td>
<td>Requirement</td>
<td>MDR Article / Annex</td>
<td>Typical QMS Process / Procedure</td>
<td>EN ISO13485:2016 Clause(s)</td>
<td>MDSAP Chapter and Task</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
<td>---------------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.</td>
<td>Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.</td>
<td>Article 83</td>
<td>Post market surveillance / feedback (MA&amp;I)</td>
<td>8.2.1</td>
<td>Ch3, T12</td>
</tr>
<tr>
<td>11.</td>
<td>Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.</td>
<td>Annex I S23</td>
<td>Labelling, Claims and IFU’s (Design and Development)</td>
<td>4.2.1 e 4.2.3 7.3.3, 7.3.4, 7.3.6, 7.3.7</td>
<td>Ch5, T5-11 Ch6, T25</td>
</tr>
<tr>
<td>12.</td>
<td>Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.</td>
<td>Article 56 Article 87</td>
<td>Field Safety Correction Recall procedures Vigilance reporting (MA&amp;I)</td>
<td>8.3.3 7.2.3 8.2.3</td>
<td>Ch3, T12 Ch4, T1-T2</td>
</tr>
<tr>
<td>13.</td>
<td>Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88.</td>
<td>Article 87 Article 88</td>
<td>Feedback Complaints Vigilance (MA&amp;I)</td>
<td>8.2.1 8.2.2 7.2.3, 8.2.3</td>
<td>Ch3, T1- T2, T12 Ch3, T2, T12, T13 Ch4, T1-T2</td>
</tr>
</tbody>
</table>
1. MDSAP
Verify Processes, Quality Manual & QMS Documents
Article 10 s9, Annex IX, s2

2. MDSAP
Management Rep appointment
Article 15

3. MDSAP
Quality policy and objectives established

4. MDSAP
Organisational Structure and Competence
Article 10 s9(c), Annex IX s2.2 (b)

5. EU MDR
Verify that the roles and responsibilities of any economic operators and the person responsible for regulatory compliance are documented in the organization’s quality management system.
Article 11 through 16

5. EU MDR
If an authorized representative is required, verify that the manufacturer has assigned an appropriate mandate to the authorized representative and assures conformity to Article 11.
Annex IX s2.2 b