QMS Aspects of the MDR (& IVDR)

Vicky Medley
Global QMS Manager – Medical Devices
October 2017
This Presentation

1. The clock is ticking!
2. Dates & priorities
3. BSI Assessments
4. QMS Items for MDR / IVDR
   - Immediate checks / post market
   - For full MDR / IVDR Application
5. Next Steps... some thoughts
The Clock is Ticking!

• What products currently on the EU market?
• What products on the market post 2024?
• What needs certification in 2022 / 2024?
• What is ‘in’ the MDR / IVDR that wasn’t previously? i.e. Will need CE Certification sooner?
• What is reclassified?
• What are your priority products?
MDR Transition (Article 120)

- **Entry into Force (OJEC + 20days)** (25 May 2017)
- **Adoption of MDR** (25 May 2017)
- **Date of Application** (26 May 2020)
- **Transition period** 3 years
- **MDD/AIMD certificate validity** (4 years)
- **MDR certificates**
- **Last MDD/AIMD certificates expire** (27 May 2024)
- **Annex IV certificates expire** (27 May 2022)
- **MDD/AIMD certificates (max 5-year expiry from issue/renewal date)**
- **27 May 2025** No more « placing on the market » of devices covered by MDD/AIMD certificates
- **NBs designation under MDR**
- **Date of Application** (26 May 2020)
- **Last MDD/AIMD certificates expire** (27 May 2024)
- **MDR certificates**
- **27 May 2025** No more « placing on the market » of devices covered by MDD/AIMD certificates
IVDR Transition (Article 110)

- **Entry in to Force**
  - 25 May 2017

- **Adoption of IVDR**
  - 05 May 2017

- **Transition period**
  - 5 years

- **Date of Application**
  - 26 May 2022

- **IVDD certificate validity (2 years)**
  - 27 May 2024

- **IVDD certificates void**
  - 27 May 2025

- **NBs can apply for designation**
  - 26 Nov 2017

- **NBs designation under IVDR**

- **IVDD certificates can be issued/re-issued/renewed**

- **No more « making available or putting into service » of devices covered by IVDD certificates**
BSI Assessments & Tools
Future

BSI QMS AUDIT

ISO 13485
MDSAP
ISO 9001
MDR / IVDD

Assessment Requirements

Assessment Requirements

‘Post market’ aspects
MDR – 26 May 2020
IVDR – 26 May 2022
BSI QMS Audits

- What is the procedure?
- Show me the process
- What is the defined and documented system for...
- Do you have evidence of?
No real changes as a result of MDR / IVDR. New frequencies already applied.

- Once per 3 years for Class III & Implantables.
- Once per 5 years for rest.
MDR / IVDR Pilot Audits

Quality System Audits

Microbiology & Sterilisation Audits
Class I Reusable Only

Technical Documentation Reviews

Pilot Audits to BSI Draft MDR / IVDR Processes and Procedures:

- DRAFT MDR / IVDR Assessment Procedures
- DRAFT MDR and IVDR Checklist (Approximately 100 items dependant on Devices, Conformity Assessment Route etc)
Volunteers Required!

Early Pilot MDR / IVDR QMS Audits (2017)
• Not a full formal audit, could be:
  • Section of site / system
  • Section of QMS
  • One product range
  • Sub-systems
  • Part Day / Remote audit

Later Stage Pilot QMS Audits (Q1 2018)
• Ideally of larger systems and full day(s) onsite

No charge!

• No non-conformities to MDR / IVDR (observations only)
• Assessment will not count (i.e. Further full MDR / IVDR QMS assessment required at later date)
• Check of process / systems and evidence as far as is reasonable / possible
• BSI accept full implementation will not be possible in all cases (e.g. SRN, UDI, EUDAMED etc)

bsi.

Charge at standard rates
BSI MDR Readiness Tool – Now Available

• Communication to All BSI Clients on 7 September 2017

• Available to non-BSI clients very soon!

• IVDR version coming soon!
Quality Management System

QMS Requirements to be assessed for ALL EXISTING CE Certifications from 26 May 2020

This includes:
- New requirements Vs MedDev 2.12.1 (Vigilance Reporting) i.e. maximum duration to report 15 days
- New requirements Vs MedDev 2.12.2 (Post Market Clinical Follow-up) i.e. increased frequency of updates
- Process/Procedure for communication with Competent/Notified Bodies to obtain SRN
- Registration of Economic Operators including Single Registration Number (Article 31)
- Systems for Market Surveillance (activities described in Article 33)
- Systems for Serious Incident, Field Safety Corrective Action (Article 87) and Trend Reports (Article 88)
- Systems for PMS Plan and Report (Article 84, Article 85)
- Systems for Periodic Safety Update Report (Article 86)

Additional QMS Requirements for MDR Applications

You will also need to document information on:
- All systems for any reclassified devices or devices new to the scope of certification (see previous sections)
- Economic Operators Registration (Article 30) and Single Registration Number (SRN) (Article 31)
- The new role of Person Responsible for Regulatory Compliance (Article 15)
- Agreement with EU Authorized Representative i.e. written mandate (Article 11), SRN (Article 11), and including Person Responsible for Regulatory Compliance (Article 12), QMS (Article 14)
- Importers i.e. SRN (Article 31), QMS (Article 13)
- Distributors i.e. QMS (Article 14)
- Strategy for Regulatory Compliance (Article 22) Unique Device Identification and Registration (Article 27, 29)
- Handling communication with regulatory authorities, Notified Bodies, Economic Operators
- Agreement with Importers/Distributors, including evidence of having met Article 12/14 respectively
- A process to identify Safety & Performance Requirements (SPR). See more below

Changes in Activity in BSI Audits

- All QMS audits to carry out or ask to witness physical/laboratory tests in order to check the QMS is working properly.
- In the case of Class III devices, tests that are essential for the integrity of the device shall be conducted on approved parts and/or materials.
- Unannounced Audits frequency at least once every five years.

- Includes key items for audit from 26 May 2020
- ALL CE Certified Manufacturers for post market processes
- + Key QMS Items for MDR Application
QMS Items for MDR / IVDR
- Immediate checks / post market
MDR Transition (Article 120)

- **Class I reusable**
- **Class III custom made implantable**
- **Devices with no Medical Purpose (Once Common Specifications available)**

---

**Adoption of MDR**

05 May 2017

---

**Transition period**

3 years

---

**MDD/AIMDD certificates can be issued/re-issued/renewed**

---

**Date of Application**

26 May 2020

---

**MDD/AIMDD certificate validity**

(4 years)

---

**MDD/AIMDD Annex IV certificates void on 27 May 2022**

---

**MDR certificates**

---

**27 May 2025**

---

**No more « making available or putting into service » of devices covered by MDD/AIMDD certificates**

---

**NBs can apply for designation**

26 Nov 2017

---

**NBs designation under MDR**

---

**bsi.**

---

**Date of Application**

26 May 2020

---

**MDD/AIMDD certificates void on 27 May 2024**

---

**27 May 2025**

---

**No more « making available or putting into service » of devices covered by MDD/AIMDD certificates**

---
However, the 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.
BSI QMS Audits from 26 May 2020 / 2022
For All EXISTING CE Certifications – 3 Main Areas

1) Registrations
   • Devices (Article 29)
   • Economic Operators (Article 30)
   • Manufacturers, authorised representatives and importers (Article 31)

2) Post Marketing Surveillance Systems
   • For Plan (Article 84) & Report (Article 85 – Class I)
   • Periodic Safety Update Report (Article 86 – Class IIa, IIb, III)
   • Vigilance Reporting requirements - Systems for Serious Incident, FSCA and Trend Reports (Article 87 & 88)

3) Market Surveillance (Article 93)
   • Provision / access to information, devices, sites by Competent Authorities
Registration of Devices & Economic Operators

- Devices (Article 29)
- Economic Operators (Article 30)
- Manufacturers, authorised representatives and importers (Article 31)
Economic Operators

Article 2 Definitions

• A manufacturer
• An authorised representative
• An importer
• A distributor
• Or the person referred to in Article 22(1) and 22(3)
• i.e. Provider of Procedure Packs or Parts & Components
Economic Operators

- Manufacturer – Article 10
- Authorised Representative – Article 11 & 12
- Importer – Article 13
- Distributor – Article 14
- Procedure packs or parts / components – Article 22 & 23
- Translation / Re-packaging / Re-labelling – Article 16*

*Need EC Certificate
### QMS processes and Economic Operators

<table>
<thead>
<tr>
<th></th>
<th>Manufacturer (Article 10)</th>
<th>Authorised representative (Articles 11 and 12)</th>
<th>Importer (Article 13)</th>
<th>Distributor (Article 14)</th>
<th>Assembler (Article 22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eudamed registration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical documentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design and development, Manufacture or assembly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling, storage and distribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconformities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSCA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDI/Labelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complaints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person responsible for RC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Throughout the lifetime of the device concerned the PSUR shall set out:

- Conclusions of the benefit risk determination
- Main findings of PMCF
- Volume of Sales
- Estimate of the size and other characteristics of the Population that use the device
- Where practicable usage frequency of the device

**Periodic Safety Update Report - Article 86**

- Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices
- Manufacturers of class IIb and III devices shall update the report at least annually
- Manufacturers of class IIa devices shall update the report when necessary and at least every two years
- For class III or implantable devices shall submit PSUR reports by means of the electronic system to the notified body
- Notified Body shall review, add its evaluation with details of any action taken, and make available to the Competent Authorities through the electronic system
Vigilance
Requirements for Reporting Serious Incidents & FSCAs – Article 87

New regulation wording on ‘Causal’ relationship between device and incident

- Systems
- Process
- Procedures
- Evidence

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>Directives</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Public Health Threat</td>
<td>2 days</td>
<td>2 days</td>
</tr>
<tr>
<td>Death or Unanticipated Serious Deterioration in the State of Health</td>
<td>10 days</td>
<td>10 days</td>
</tr>
<tr>
<td>Others</td>
<td>30 days</td>
<td>15 days</td>
</tr>
</tbody>
</table>
Any negative trends vs Risk Management Documentation

any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis ... and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.
QMS Items for MDR / IVDR

– Following application for certification
Initial MDR or IVDR Assessment

- For Brand New Initial Applications – Normal Initial Assessment Durations Apply

- For Manufacturers ‘Transitioning’ from MDD / AIMD to MDR likely 1 – 3 days Initial Assessment (in addition to current MDD durations)
 Clause 9 – The quality management system shall address at least the following aspects:

a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

b) identification of applicable safety and performance requirements and exploration of options to address these requirements;

c) responsibility of the management;

d) resource management, including selection and control of suppliers and sub-contractors;

e) risk management;

f) clinical / performance evaluation, including PMCF / PMPF;

g) product realisation, including planning, design, development, production and service provision;

ISO 13485:2016 – not covered

• Much already covered in ISO 13485:2016

ISO 13485:2016 – 7.3.3
ISO 13485:2016 – 5
ISO 13485:2016 – 6.1, 7.4.1
ISO 13485:2016 – 4.1.2, 7.1
ISO 13485:2016 – 7.3.7
ISO 13485:2016 – 7
Clause 9 – The quality management system shall address at least the following aspects:

- verification of UDI assignments, ensuring consistency of information provided;
- setting-up, implementation and maintenance of a PMS system;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
- processes for reporting of serious incidents and FSCA in the context of vigilance;
- management of corrective and preventive actions and verification of effectiveness;
- processes for monitoring and measurement of output, data analysis and product improvement.

ISO 13485:2016 – 7.5.8
ISO 13485:2016 – 7.2.3, 8.2.3
ISO 13485:2016 – 8.2.1, 8.5.1
ISO 13485:2016 – 8.2.2, 8.2.3
ISO 13485:2016 – 8.5.2, 8.5.3
ISO 13485:2016 – 8
Initial Assessment to MDR / IVDR... Some key areas we will be checking in BSI QMS Audits

- General QMS Requirements
  - Continual Improvement
  - Strategy for Regulatory Compliance
- Person Responsible for Regulatory Compliance
- UDI (+ Implant Card)
- Clinical processes – evaluation and investigation
- Post Market Processes – PMS Systems, PSUR, SSCP
Person Responsible for Regulatory Compliance

Article 15

• Required for both Manufacturers and Authorised Representatives
• Must have expertise in medical devices, including degree and four years’ professional experience
• Responsible for ensuring:
  => Product conformity checked via appropriate QA release
  => Technical documentation and DoC maintained
  => PMS & reporting obligations are met
  => Investigational devices: statement of safety and compliance with SPRs
• Note the concessions for small or micro enterprises with respect to requirements
UDI – Article 27 (24)

- On the label (not shipping containers)
- On vigilance reports ... the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.
- EU declaration of conformity - the Basic UDI device identifier (‘Basic UDI-DI’ as defined in Annex V Part C) of the device shall appear on the Doc referred to in Article 19.
- Technical documentation - Annex II
- Implant Card – Article 18
- Notified Body CE Certificate – Annex XII
# UDI Dates

<table>
<thead>
<tr>
<th>GS1, HIBCC and ICCBBA designated UDI issuing entities (Article 123,3i; Article 113,3h)</th>
<th>May 26, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI carrier on the label and higher levels of packaging (Article 123,3f; Article 113,3e)</td>
<td>May 26, 2021 - Implantable devices and Class III devices; May 26, 2023 - Class IIa and IIb (non-implantable) devices and Class D devices May 26, 2025 - Class I devices, Class B and Class C devices May 26, 2027 - Class A devices</td>
</tr>
<tr>
<td>UDI carrier on reusable devices (Article 123,3g)</td>
<td>May 26, 2023 - Reusable Class III devices; May 26, 2025 - Reusable Class IIa and reusable IIb (non-implantable) devices; May 26, 2027 - Reusable Class I devices.</td>
</tr>
</tbody>
</table>
Implant Card - Article 18

The manufacturer of an implantable device (not sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors), shall provide together with the device the following:

- device name, serial number, lot number
- Unique Device Identification, device model
- manufacturer name, address and website

- any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- any information about the expected lifetime of the device and any necessary follow-up;
- any other information to assure a safe use of the device by the patient
- including the information in Annex I, Section 23.4 (u) – qualitative and quantitative information on the materials and substances to which patients can be exposed
<table>
<thead>
<tr>
<th>Class</th>
<th>PSUR</th>
<th>SSCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Strictly N/A however Article 85 – Class I</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>PMS Report updated ‘when necessary’</td>
<td></td>
</tr>
<tr>
<td>Class Is / Im / Ir</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Class IIa</td>
<td>As necessary and at least every 2 Years</td>
<td>-</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Annual</td>
<td>-</td>
</tr>
<tr>
<td>Class IIb Implantable</td>
<td>Annual to NB (EUDAMED)</td>
<td>Annual to NB (EUDAMED)</td>
</tr>
<tr>
<td>Class III</td>
<td>Annual to NB (EUDAMED)</td>
<td>Annual to NB (EUDAMED)</td>
</tr>
</tbody>
</table>
Summary of Safety & Clinical Performance - MDR Article 32

SSCP shall include at least the following:

- Manufacturer + SRN
- Device + UDI-DI
- Intended Purpose, Indications, Contra-indications and Target Population
- Description, previous variant(s), differences, accessories, other products intended to be used in combination
- Possible diagnostic or therapeutic alternatives
- Harmonised Standards / Common Specifications
- Summary of the Clinical Evaluation Report + PMCF
- Suggested profile and training for users
- Information on residual risks, undesirable effects, warnings & precautions

- For implantable devices and for class III devices, the manufacturer shall draw up a summary of safety and clinical performance

- The SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via EUDAMED

Article 61 – Clinical Evaluation

For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance (referred to in Article 32) shall be updated at least annually with such data.
Witness Testing & Reconciliation

Annex IX Chapter I – 3.3 + 3.5

Class IIa, IIb, III

... At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly.

For class III devices surveillance assessment shall include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.
Witness Testing & Reconciliation

- New / strengthened requirement to carry out / request tests to verify proper functioning of the QMS.
- Currently routine in Unannounced Audits
- BSI Policy to witness where possible
- Focus on inprocess and / or final product inspection
- Reconciliation of materials for class III
Summary of Key Changes Impacting QMS Processes

**Systems / Process**
- Strategy for Regulatory Compliance
- Implementing & Delegating Acts
- PMS & Vigilance Processes (+ SSCP, PSUR)
- Communication with Regulators & Stakeholders
- Harmonised Standards, Common Specifications
- Clinical Evaluation & Investigation Processes
- Person Responsible for Regulatory Compliance
- Registration of Economic Operators and Devices

**Device Specific**
- No medical purpose
- Custom made (Class III)
- Nanoparticles
- Non-viable Animal or Human Tissues
- Software
- System & procedure packs
- Medicinal Substances
- Parts / Components

**Classification VS Conformity Assessment Route**
- Procedures for Clinical Evaluation
- Procedures for Technical Documentation
- SPR Checklist / Evidence
- DRAFT DoC
- Labelling, UDI
- Management of Changes

**Technical Documentation**
- SSCP & PSUR
Next Steps
Approaching the MDR & IVDR
Questions & Answers
bsi. ...making excellence a habit™