MDR Implementation Challenges from a Material Supplier Perspective

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Agenda

• MDR Transition Timeline
• Supplier References in the MDR

From the Manufacturers Perspective
• Supplier Selection and Control
• Supplier State of the Art
• Supplier Influence on the Finished Device

From the Suppliers Perspective
• Planning for a Notified Body Audit
• Dealing with Data Requests
• Substance Concentration Limits
• MDR V ISO 13485:2016
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Mar 2016</td>
<td>ISO 13485:2016 released</td>
</tr>
<tr>
<td>26th May 2017</td>
<td>MDR was published in the Official Journal of the European Union</td>
</tr>
<tr>
<td>1st Mar 2019</td>
<td>All organisations must be certified to ISO 13485:2016</td>
</tr>
<tr>
<td>26th May 2020</td>
<td>Official application date of the MDR</td>
</tr>
<tr>
<td>25th May 2025</td>
<td>Date for which devices CE marked under the MDD can no longer be sold in Europe</td>
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</table>
Supplier References In The MDR

There are a number of references to suppliers in the MDR. Key ones include:

- **Article 10 – General Obligations of Manufacturers, Para 9b, section d.**
  
  “The quality management system shall address at least the following: Resource management, including selection and control of suppliers and subcontractors”

- **Annex I – Chapter 1 - General Requirements**
  
  “Devices shall achieve the performance intended by their manufacturer …… taking into account the *generally acknowledged state of the art.*”

- **Annex VII – Requirements To Be Met By Notified Bodies, para 4.5.2b**
  
  “If not already covered by the audit programme, audit the control of processes on the premises of the manufacturers suppliers, when the *conformity of the finished devices is significantly influenced by the activity of suppliers* and, in particular when the *manufacturer cannot demonstrate sufficient control over its suppliers.*”
Supplier Selection and Control

- Audit
- ISO Status
- Metrics
- Specification
- Agreements
Supplier State of the Art

- Technical Awareness
- Investment
- Competitor Analysis
- New product/service introduction

Innovation
Capability, Quality, Cost
Understand the competitive landscape
Portfolio of class leading products or services

State of the Art
Supplier Influence On The Finished Device

- Bespoke
- Off The Shelf

Complexity of Material / Service

Device Risk

Class I

Class III

Supplier Control Required
Supplier Management
In Summary

• Manufacturers will need comprehensive, documented processes for supplier selection, monitoring and control

• Suppliers should be able to demonstrate:
  • An understanding of the state of the art in their industry
  • Plans and activities that move the supplier in that direction

• Where a manufacturer cannot show an adequate level of control, it is more likely that an NB will audit the supplier

• This is especially true where the product or service supplied has a significant impact on the finished device

• All suppliers need to be risk assessed – not just the obvious ones
From the Suppliers Perspective

• Planning for a Notified Body Audit
• Dealing with Data Requests
• Substance Concentration Limits
• MDR v ISO 13485:2016
Planning for a NB Audit

• The decision by a NB to audit a supplier is a function of:-
  – the manufacturers perceived control over the supplier
  – the risk posed by the supplied material or service to the compliance of the finished medical device
  – the performance of that supplier

• Theoretically different NB’s could audit the same supplier in a very short space of time

• Suppliers need to recognize that there is a possibility of an audit from the manufacturers NB

• It is in the suppliers interest to fully understand the impact the product or service has on the finished medical device and to plan accordingly
Planning for a NB Audit

Be Prepared!

<table>
<thead>
<tr>
<th>Before</th>
<th>On the Day</th>
<th>After the Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Document the process</td>
<td>1. Verify auditors identity</td>
<td>1. Work with customer to address any N/C’s</td>
</tr>
<tr>
<td>2. Define the team (first &amp; reserves)</td>
<td>2. Establish audit scope</td>
<td>2. Emphasize joint CA</td>
</tr>
<tr>
<td>3. Ensure the organization is aware of the</td>
<td>3. Agree product and process areas to be reviewed</td>
<td>3. Demonstrate supplier &amp; customer working as a team</td>
</tr>
<tr>
<td>possibility of an audit</td>
<td>4. Agree boundaries</td>
<td></td>
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<tr>
<td>4. Highlight differences between NB and ISO</td>
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<tr>
<td>audit</td>
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NB Audit Planning – Other Points

- Costs for NB audits of suppliers are borne by the manufacturer
- Nonconformities are raised against the manufacturer who must work with the supplier to ensure effective and timely closure
- The introduction of the MDR will result in more requests of suppliers for customer audits / questionnaires
- Close partnership between manufacturer and supplier is mutually beneficial for many reasons, including reducing the likelihood of supplier audits by NB’s
Dealing with Data Requests

• All technical files will be reassessed against the requirements of the MDR (no grandfathering)

• There is an increased focus on the supporting test data included in the technical file submission – especially related to clinical evaluation

• Anecdotal evidence suggests that previous assumptions as to the validity of data is being rejected, specifically on grounds of age and its relevance to a specific device design

• Biological testing requirements to meet ISO 10993-1 are increasing because of changes in interpretation
## Biological Testing Requirements

Extract from ISO 10993 - 1 (2003) – Biological Evaluation of Medical Devices

### Table A.1 — Evaluation tests for consideration

<table>
<thead>
<tr>
<th>Medical device category by</th>
<th>Biological effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>nature of body contact</td>
<td>Cytotoxicity</td>
</tr>
<tr>
<td>(see 5.2)</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Contact</td>
</tr>
<tr>
<td>Surface device</td>
<td>Mucosal membrane</td>
</tr>
<tr>
<td>Breached or compromised</td>
<td></td>
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</tbody>
</table>
What does this mean for Suppliers?

• Re-use of older test data is no longer acceptable

• Test data for a “generic” design shared with multiple customers is no longer acceptable

• This means the onus for material testing is moving from the supplier to the manufacturer

• Additional testing costs are significant

• One outcome is likely to be a rationalisation of device types to minimise regulatory compliance costs
Substance Concentration Limits

- Annex 1, Chap 2 – Requirements Regarding Design and Manufacture (10.4.1)
  “Devices, or those parts thereof or those materials used therein……….
  shall only contain the following substances in a concentration above 0.1% weight by weight where justified………
  substances which are carcinogenic, mutagenic or toxic…..”
Substance Concentration Limits

- Suppliers will face requests for confirmation as to the level of these substance categories within their materials.
- The total value relates to the finished medical device.
- The device manufacturers process needs to be assessed to ensure the finished device meets these limits (or that an appropriate justification is acceptable).
- Appropriate ongoing checks will need to be made.
- Potentially some older product families may no longer meet regulatory approval and will have to be withdrawn.
MDR v ISO 13485:2016

- Many suppliers who do not manufacture medical devices, are themselves certified to ISO 13485 so as to align their QMS with the principles of the MDR.

- ISO 13485 certification is a statement of intent by a supplier to support customers in meeting their MDR requirements.

- It therefore puts many of the same obligations on the supplier / sub-supplier relationship as at the top level.
Para 7.4.1 Purchasing process

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

a) based on the supplier’s **ability** to provide product that meets the organization’s requirements;

b) based on the **performance** of the supplier;

c) based on the **effect** of the purchased product on the **quality** of the medical device;

d) proportionate to the **risk associated** with the medical device
Sub-Supplier Selection and Control

- Audit
- ISO Status
- Specification
- Metrics
- Agreements

Sub-supplier
ISO 13485 – Supplier Impact

Table A.1 – 7.4.1. Purchasing Process

Focuses the supplier selection criteria on the effect of the supplier performance on the quality of the medical device, the risk associated with the medical device, and the product meeting applicable regulatory requirements.
Cascading Requirements

- Medical Device Manufacturer
  - Selection, control, oversight, risk.
  - Reporting, data, feedback, mitigation

- Tier 1 Supplier

- Tier 2 Supplier
Final Conclusions

• Partnerships between supplier and manufacturers are vital to regulatory compliance

• Supplier involvement with new device development should start at an early stage

• Suppliers should play a key role in providing input to the manufacturers risk assessment

• Consideration needs to be given as to how requirements are cascaded appropriately down the supply chain
Thank you for your attention.

Any questions?