How to Streamline Your MDR or IVDR Review

2025-10-23

With us today...

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Poll
Question x2

Poll Questions

1. Have you applied to MDR or IVDR for any products?

- Yes, for my entire product range
- Yes, for a partial portfolio of products
- Not yet, but planning to
- No current plans for an application

2. Are you a BSI customer?

- Yes, I am currently
- No, but was previously
- I am interested
- No

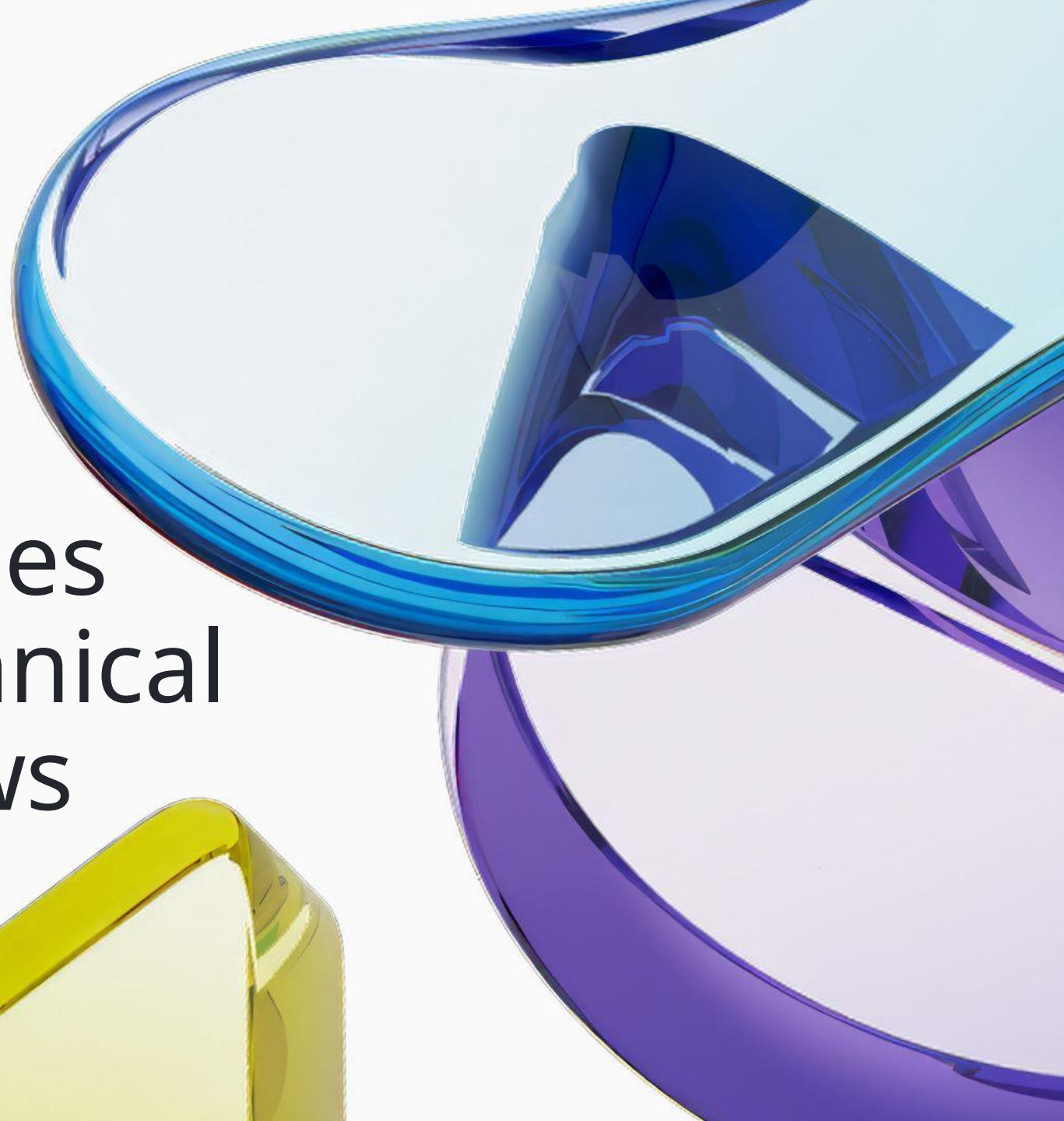
Agenda

01 Common Challenges and Delays in Technical and Clinical Reviews

02 How to Answer Questions Early with Structured Dialogue

03 Getting the Most out of Dedicated Interactive Reviews

Common Challenges and Delays in Technical and Clinical Reviews



What are Reviewers Looking for?

Reviewers are looking for evidence of conformity

- Notified bodies cannot tell manufacturers how to meet the requirements of the MDR / IVDR.
- Questions are typically structured to ask how the requirements of the MDR / IVDR have been met.
- Avoiding formal review questions can reduce the review duration by 1-2 months.

MDR Annex VII, Section 1.2.3

The Notified Body…**shall not offer or provide consultancy services to the manufacturer**, its authorised representative, a supplier or a commercial competitor…

Structure Files for Success

Document Submissions Tips - Save Time and Cost

- **Run a completeness check** before submitting.
- **Use searchable, bookmarked PDFs** for easy navigation.
- **Avoid** password protection, zip files, poor scans, and large numbers of individual documents.
- **Submit one PDF per part** as recommended in BSI Best Practice Guidance (Technical & Clinical)

Part A – Device description and specifications, including variants and accessories

Part B – Information to be supplied by the manufacturer

Part C – Design and manufacturing information

Part D – General safety and performance requirements

Part E – Benefit-risk analysis and risk management

Part K – Specific information for class III implantable devices…

MDR: https://www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf
IVDR: https://www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/bsi-md-ivdr-best-practice-documentation-submissions-en-gb.pdf

Intended Purpose Indications for Use

Common Issues

- Unclear distinction between intended purpose and indications for use.
- Misalignment across IFU, Draft DoC, CEP, CER, and SSCP causes review delays.
- Intended purpose must be consistent and updated on IFU, SSCP, and MDR certificate before issuance.
- Vague or broad intended purposes are hard to justify in CER/PER.

Clinical Evaluation Plan
Performance Evaluation Plan

Common Issues

- Missing required regulatory elements, often the Clinical Development Plan and PMCF.
- MDR GSPRs that require support from clinical data are not aligned to the GSPR checklist.
- Lack of a clear rationale for the level of clinical evidence to demonstrate safety and performance

Clinical Evaluation Report Performance Report

Common Issues

- Poorly defined state of the art (SOTA).
- Unclear or inconsistent safety/performance objectives.
- Insufficient clinical evidence.
- Equivalence not meeting MDR/MDCG 2020-5 requirements.
- IVDR equivalence requires identical devices.

Common IFU Issues

GSPR 23.1(g): Residual risks not aligned with CER and SSCP

GSPR 23.1(h): Symbols that are not harmonized must be described in the documentation provided with the device.

GSPR 23.4(b): missing patient target group and intended users.

GSPR 23.4(c): Missing or inconsistent clinical benefit. Can sometimes be indirect.

GSPR 23.4(e): Missing performance characteristics.

GSPR 23.4(u): Overall quantitative and quantitative information on materials for implants shown as percent rather than mass.

Electronic IFU

Common Issues

- Missing compliance to the eIFU requirement. Noncompliance with current eIFU regulations ((EU) 2021/2226, (EU) 2025/1234); *outdated reference to (EU) 207/2012.*
- Unable to access the Website (login required or unavailable).
- Reviewer cannot find or identify eIFU on website easily. Location of eIFU not clearly indicated or provided.

Requirement: GSPR 23.1: Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance…**if the manufacturer has a website**, be made available and kept up to date on the website.

Lifetime in Use and Shelf Life

Common Issues

- Device lifetime not clearly defined.
- PMCF/clinical data suggest longer lifetime use than classification rationale.
- Shelf-life testing focuses on packaging, not device performance.
- Testing overlooks temperature and humidity variations during transport/storage.

GSPR 6: The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the **lifetime of the device, as indicated by the manufacturer**...

Biological Safety

Common Issues

- Unclear if historical testing is compliant with current SOTA standards. Typically covered by a gap analysis rather than additional testing
- Missing information on processing aids and their impact on the biological safety assessment
- Device materials are not always clear. Especially for submissions with multiple device variants

Carcinogenic, Mutagenic or Toxic to Reproduction (CMR)

Common Issues

- Cobalt in stainless steel is considered a CMR material.
- Argument as to why design changes or alternative materials are inappropriate not included in justification (GSPR 10.4.2(c)).

GSPR 10.4.1: …Devices shall be designed and manufactured Devices, or those parts thereof or those materials used therein that:

> are **invasive and come into direct contact with the human body…**

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

Packaging Validation and Transit Testing

Common Issues

- Protocol and report for transit testing not clearly identified.
- Packaging validation and transit testing only demonstrates sterile barrier integrity. Device performance after transit testing not demonstrated.
- Transit testing not performed per ASTM or ISTA standards.

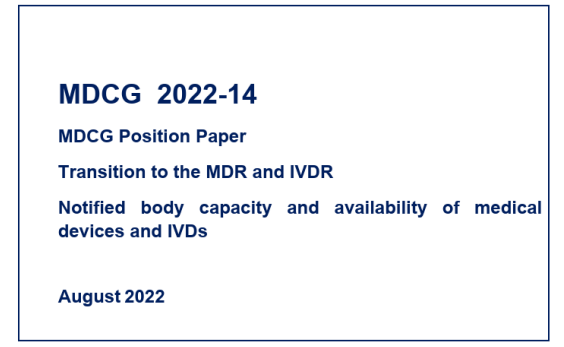
Requirement: GSPR 7, 11.3 and 11.4

GSPR 7: Devices shall be designed, manufactured and packaged in such a way that their **characteristics and performance** during their intended use are not adversely affected during **transport and storage**, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

Structured Dialogue

What is Structured Dialogue?

Per Annex VII (Section 1.2.3) Notified bodies are not permitted to provide services that may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they ***shall not offer or provide consultancy services*** to the manufacturer, or be ***linked to any organisation which itself provides consultancy services.***


MDCG 2022-14

MDCG Position Paper

Transition to the MDR and IVDR

Notified body capacity and availability of medical devices and IVDs

August 2022

MDCG 2022-14:
The MDCG encourages notified bodies and manufacturers to ***organise structured dialogues before and during*** *the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body. Such dialogues should not be considered consultancy service.*

What can a manufacturer ask in a Structured Dialogue Meeting?

Can you help us understand the notified body's interpretation of Clause X?

We are going to take this approach with our device, can the notified body provide any concerns with this approach?

Open questions that allow the notified body to provide their feedback or response to an approach and allowing for the notified body to ask questions are generally accepted.

Closed questions are often difficult because it can drive a simple response/decision without the need for an explanation.

Requesting a structured dialogue meeting

Typically, most notified bodies will allow an hour to discuss topics, submissions and issues with an assessment:

1

Step 1 – **Request a meeting**. This can be typically done through the Scheme Manager. If an assessment has already started this can often be organised with the Technical or Clinical Specialists. If the manufacturer is yet to have a contract with a notified body, then this meeting can be organised through the sales/commercial representative.

2

Step 2 – **Define the Scope.** Clearly outline the topics and questions to ensure the right experts are involved.

3

Step 3 – **Coordinate Availability.** Suggest suitable times, considering time zones for both parties.

Preparing for a Structured Dialogue Meeting

- Ensure that you prepare a clear presentation, no more than 20 minutes, outlining the points you want to discuss with the Notified Body.
- Include team members with relevant expertise (e.g. medical director).
- Send your presentation in advance to help the Notified Body prepare and ensure the right expertise are invited.
- Take your own notes. Recordings or transcripts are typically not allowed.

How to get the most out of Dedicated Interactive Reviews

BSI Service Levels

Technical Service Levels designed to meet the needs of our manufacturers.

Dedicated Onsite

Onsite interactivity with client is the most collaborative and efficient experience.

Requires travel and can be difficult to coordinate.

Clinical Oversight can be a limiting factor.

Dedicated Interactive

Simulates onsite with opening meetings, real-time conversation, explanations and responses to questions.

Pre-scheduled and coordinated.

Flexible and transparent.

Standard

Affordable for non-time critical reviews.

Review priority secondary to dedicated reviews.

All review questions provided as rounds of questions.

Advantages of Non-Conformities

Non-conformities are a useful tool to progress technical documentation assessments.

- ✓ All certificate types and legislations are eligible (including product certificates).
- ✓ A certificate *can be issued* with **minor** non-conformities + accepted corrective action plans which can significantly reduce time to certification compared with additional (potentially unresolvable) rounds of questions or file refusal and resubmission.
- ✓ **Major** NCs for safety or performance related issues must be closed prior to certification or renewal which effectively pauses the review. Still a preferred approach that saves time and cost compared with additional rounds of questions or refusal and resubmission.

Maximizing the Opening Meeting

Confirm Review Schedule: Clarify timelines and response expectations.

Identify Key Contacts: Establish main points of contact for both teams.

Explain Changes Clearly: Highlight any device or documentation updates.

Flag Complex Aspects Early: Note active components, animal tissue, medicinal agents or expanded indications that may affect review time.

Can be held **2-4 weeks before** the start of the review for complex reviews or manufacturers new to Dedicated Interactive.

Participating in Interactive Reviews

Review questions delivered interactively via dedicated MS Teams channel.

Responses should be provided by the manufacturer as they are available.

Manufacturer can respond to questions during the initial review **plus two calendar days** after the end of initial review.

Quick phone calls can be used to clarify complex topics.

Administrative posts in MS Teams, conference calls and email used to provide updates on the review.

Formal review questions used for open gaps to compliance or where additional time is required.

Maximizing Value:
Dedicated Interactive Review

- ***Subject Matter Experts Available to You & Your Team***: Having the right experts allows for immediate clarifications, faster decision-making, and fewer delays in the process.
- ***BSI's Continuous Engagement with Your Team***: Positive engagement at the opening meeting & throughout your review. This helps align expectations and address key concerns early to steer the review in a productive direction.
- ***Timely Responses to Questions***: Prompt answers are a game-changer. It keeps the review moving with clarity in real time and avoids bottlenecks and backtracking.

Final Tips - Engaging with your Review Team

- ***Request a call*****:** Don’t hesitate to reach out to us for clarification if any of the review questions feel unclear. *Clarity saves time*.
- ***Communicate early*****:** Speak with our BSI team before undertaking additional testing or reducing scope; this avoids unnecessary work and *ensures alignment*.
- ***Is More Time Needed?***: If timeline shifts due to testing or documentation updates happen; discuss with BSI *early* so we can explore options, *together*.

Poll
Question x2

Poll Questions

1. Do you feel more confident in applying for MDR or IVDR?
- Yes
- Somewhat, but still need more resources
- No
- Maybe

2. Do you feel comfortable interacting with BSI for Structured Dialogue or Dedicated Interactive reviews?
- Yes,
- Somewhat comfortable
- Not very comfortable

Q&A

Thank you!

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