



Your partner  
in progress

# Structured Dialogue with BSI



# What is Structured Dialogue?

Structured Dialogue offers manufacturers an opportunity to better understand the Notified Body conformity assessment processes for medical devices and IVDs.

It may address procedural aspects of pre-application and application processes, Notified Body assessment procedures, high-level aspects of manufacturer's evidence of conformity or more complex combinations of clinical, technical, and regulatory conformity approaches while maintaining the impartiality of the Notified Body.



# Understanding Structured Dialogue

## What falls under Structured Dialogue?

- Procedural aspects of pre-application and application processes.
- Notified Body assessment procedures, administrative details.
- High-level aspects of manufacturer's evidence of conformity or more complex combinations of clinical, technical, and regulatory conformity approaches.

## What does not fall under Structured Dialogue

- Structured Dialogue is different from scientific advice which typically falls within the remit of the Expert Panels managed by the European Medical Agency (EMA).
- Structured Dialogue excludes the NB providing solutions to the manufacturer on how to comply with a specific legislative requirement(s).
- Structured Dialogue does not have any impact on future certification decisions for the device under application.

## What can be asked during Structured Dialogue?

### Open questions

Allow the Notified Body to provide feedback/questions to an approach.

### Allowed

- "Can you help us understand BSI interpretation of Clause X?"
- "We are pursuing Article 61 (10), does BSI agree with this approach?"
- "We are struggling to find state of the art information on our device and have agreed these performance objectives, does BSI think these are suitable?"
- "Our PMCF plan focuses on X aspects, does BSI agree these are suitable activities?"

### Closed questions

Any question focused on the Notified Body providing the solution to a problem will not be answered.

### Not allowed

- "Can you tell us how we can...?"
- "Can you guarantee us that if we choose assessment route X ....?"
- "Can you tell us the Class of our device?"
- "What is the correct route to collect clinical evidence?"

# Our structured dialogue

As a leading Notified Body, for over 20 years, BSI has been offering Structured Dialogues to enhance the efficiency and predictability of the conformity journey through all its phases, while respecting the independence and impartiality of the Notified Body.

Our approach to structured dialogue is highly collaborative. Various roles within BSI, including technical specialists, the commercial team, and scheme managers, engage at different stages of the process.

## Pre-application

### Examples of Dialogue topics

- Application process
- Conformity assessment process
- Lead times
- Project plan and client readiness
- Client information
- Indicative costs
- Organizational structure
- Transferring to BSI: the process

## Post-Certification

### Examples of Dialogue topics

- Ongoing technical and regulatory dialogue
- Ongoing Change Management Activities
- Project Management and general Client Support
- Compliance Management
- Recertification

## Application

### Examples of Dialogue topics

- Commercial contract management
- Project management
- Client engagement
- Certification process
- Submission requirements
- Change management

## Conformity assessment

### Examples of Dialogue topics

- Submission requirements
- Conformity assessment
  - Leveraging previous assessments
  - Conformity assessment activities and associated timelines
  - Clarification on assessment findings and missing data
- Completeness check
- Rounds of questions

**Our Structured Dialogue is suitable for various types of organizations including: Startups, SMEs, large organizations, global enterprises**

# Preparing your Structured Dialogue with BSI

BSI allows **an hour** to discuss procedural aspects, submission processes, conformity assessment challenges and much more.

## Before submission

Having conversations **before submission** of your documentation can help you understand:

- The Notified Body's processes, expected timelines, capacity and scope.
- Technical and clinical reviewers involved in the assessment & primary concerns with these devices.
- Ensuring that your approach to clinical evaluation is aligned to the Notified Body's interpretation of the legislation.

## During assessment

Having conversations **during the assessment** of your documentation can help you understand:

- Learning about the progress of your application can help understand any potential issues or concerns the Notified Body may have, helping you to address them sooner.
- Gaining clarity on questions raised during the assessment to better understand the intent of reviewers' concerns.
- What options exist for you to move forward, such as discussion around PMCF/PMPF plans and commitments, issuing certificates with conditions or limitations.

## After assessment

Having conversations **after the assessment** can help you understand:

- The requirements around certificate maintenance activities, PSUR and SS(C)P updates, expectations on PMCF/PMPF reporting or how to report significant changes.
- In the event of a refusal, a manufacturer can gain a better understanding of the reasons for refusal and what is needed to prepare for next submission.
- Where general improvements can be made next time for both the Notified Body and the manufacturer.

# Tips for your Structured Dialogue meeting



# Requesting a Structured Dialogue meeting

BSI allows **an hour** to discuss procedural aspects, submission processes, conformity assessment challenges and much more.

## Request a meeting

**If you're an existing client:** schedule with your Scheme Manager/Project Manager.

**If you've an ongoing conformity assessment:** schedule with the Technical Specialist /Product Reviewer/Clinical Specialists.

**If you're in pre-application phase:** schedule through our Sales Team.



## Scope the meeting

Identify the nature of the call, noting specifically what needs to be discussed and the questions you have related to the assessment.

This allows the Notified Body to select the relevant experts and team members to support the call.



## Availability

Suggest times to the organiser ensuring that different time zones are accommodated for both the Notified Body and manufacturer.

# Preparing for your Structured Dialogue meeting

Ensure that you prepare a clear and informative presentation outlining the points you wish to discuss with BSI. Ensure this does not last longer than 20 minutes to ensure there is time for meaningful discussion.

Ensure that you send your presentation to BSI well in advance of the meeting, this can ensure we can bring relevant experts to the meeting but can also allow for time for internal discussion to ensure agreement and to check the approach is acceptable.

Ensure that as a manufacturer you have all the relevant expertise from your team related to the query, (e.g., the medical director that can help provide further clarity if questions are raised from BSI's clinicians).

Asking for the meeting to be recorded or using transcript tools will be typically be rejected due to local IT Policy – be prepared to have someone recording minutes of the meeting.



# During the meeting



The first **20 minutes** are dedicated to manufacturers presenting on the topic and highlighting points they are seeking clarity on.

**Use your time wisely** – If there are many people on the call, it may be beneficial to only ask for introductions when people speak or to provide a slide with all names and roles listed.



The next **30 minutes** focus on the Notified Body providing its response to the presentation with additional questions being asked to the manufacturer on the topics presented.

**Pay attention to the questions asked** - the Notified Body cannot provide a solution but by asking questions the manufacturer should consider the intent behind the question.

Example – “Why have you not considered clinical data from the national Swedish registry on this device?”

The Notified Body may be requesting the manufacturer to consider this data to support the clinical evaluation.



The final **10 minutes** conclude the discussion with the noting of any actions or points that the manufacturer needs to explore.

**Opportunity to agree timelines on actions** – e.g., agreement on when additional documentation may be submitted to the Notified Body and the Notified Body agreeing a review timeline or deadline for responses to outstanding questions to be submitted.

# After the meeting

- Record meeting minutes.
- Share meeting minutes promptly with the NB to ensure the what discussed and agreed is available to both parties.
- Request the Notified Body to confirm meeting minutes correctness and agreement. This is helpful for later discussions.

**Note:** The Notified Body is entitled to change its decision if the evidence submitted later is not what agreed, or if there are changes in the regulatory landscape which may impact on the original agreement.



# Get in touch

Whether you're looking to discuss high-level aspects of evidence of conformity, Notified Body assessment procedures, QMS requirements, or more complex combination of clinical, technical, and regulatory conformity approaches and start your conformity journey.

Talk to us



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in progress

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