The clinical evaluation is a critical element in the CE Marking regulatory pathway for placing a new medical device on the European market. It can be expensive, time-consuming and challenging. The recent revisions of the Medical Device Directives (MDD and AIMDD) place an even greater emphasis on a sound clinical evaluation as part of a technical document submission for all risk classes, especially high risk Class III and Active Implantable devices.

The manufacturer, prior to launching a device, is responsible for ensuring the clinical evaluation is thorough and objective in demonstrating valid clinical evidence of safety and performance. This places a substantial demand on the company to “get it right from the start”.

**BSI Clinical Strategy Review**

BSI Clinical Strategy Reviews help to ensure that the device manufacturer’s proposed Clinical Plan will be acceptable and sufficient to meet CE Marking requirements needed by the Notified Body. We offer this Service for the full range of Medical, Active Implantable and In Vitro Diagnostic Devices.

The clinical review usually takes place as part of the full technical documentation review submitted at the end of the process. Our voluntary Modular Approach allows BSI to conduct the review of the Manufacturer’s Clinical Evaluation Plan earlier—at the point when you have finalized your Plan but not yet started its execution.

**A High Level of Confidence**

Achieving agreement between the manufacturer and their Notified Body is essential in determining strategy and represents a major milestone in helping demonstrate the product launch is on target. This holds true whether you are a multinational corporation with substantial resources or a newly emerging company seeking capital.

Our highly trained BSI Product Experts have the knowledge, background and skill to conduct thorough reviews giving you a high level of confidence that your clinical strategy is on-track.

BSI provides a written gap analysis report supplying feedback on the manufacturer’s Clinical Strategy Plan, based on the latest European Regulations, Standards and Guidance. Optional onsite sessions are also available. The manufacturer can utilize this report in building their technical documentation giving them assurance in moving forward. In addition, knowledge upfront provides a cost-effective and timely opportunity to amend strategy if needed.

**Improved Time-to-Market**

As a manufacturer, you are in a much better position to meet or improve your time-to-market goals having your Clinical Plan reviewed prior to execution. It increases predictability, minimizes risks of unexpected questions, requirements or surprises just prior to the scheduled launch. If concerns are identified they can be addressed early.

**Benefits:**

- Gain a clear understanding of what the Notified Body expects early in the CE marking process with BSI
- Work with experienced and knowledgeable Product Experts
- Meet timelines by minimizing risks of unexpected questions or requirements just prior to your scheduled launch
- In the early stages, achieve a high level of confidence your clinical strategy is on-track
- Receive a BSI Report providing feedback on your clinical plan
- Emerging companies that reach clinical strategy agreement may use it as a milestone for next round of funding
- Modular Approach may afford a reduction of time towards full BSI CE Marking dossier review
The diagram gives a simplified overview of how the BSI Clinical Strategy Review fits into the manufacturer’s clinical evaluation process. Normally manufacturers wait until the end, after all the steps are completed, before submitting their Clinical Evaluation to the Notified Body. Most likely your company has already invested considerable time and resources. Unexpected changes at this late stage can result in unexpected costs and significant delays.

However, involving BSI sooner in the process you can gain a clear understanding of what the Notified Body expects. Whether you are conducting a Literature Review only or one in combination with a Clinical Investigation—you can attain a high level of confidence that your data will be sufficient to meet the Essential Requirements. This supports your company to reach its goals while staying within its budget.

Working with a Notified Body

BSI is a Notified Body governed by the highest of standards to ensure effectiveness, safety and independence. We are regulated by governmental agencies to provide objective certification that manufacturers’ products demonstrate compliance to the Directives.

Accordingly, we are not permitted to consult and must always maintain our objectivity for the good of all concerned. The voluntary BSI Clinical Strategy Review can be started at an earlier stage; however, it is still considered part of the normal review, subject to the same regulations.

The review is available only as part of the BSI CE marking process; only Manufacturers who have committed to CE marking their product with BSI can make use of the service. In line with BSI’s policy on consultancy, the early review is a gap analysis between what the manufacturer proposes and the requirements of the current Directives, Standards or Guidance.

**Full Service Notified Body**

- CE Marking
- ISO 13485 Quality Management
- Japan PAL
- Health Canada CMDCAS
- Risk Management Certification
- FDA Third-Party Programs
- Training
- Standards
- Speed-to-Market Programs
- Supply Chain Security
- Entropy
- and more

**BSI Clinical Strategy Review**

Manufacturer evaluates all relevant available Literature

Manufacturer determines if sufficient clinical evidence already exists to support CE Marking or if a Clinical Investigation is required

Manufacturer submits Clinical Evaluation Plan to BSI

**BSI conducts Clinical Review based on Plan**

**LITERATURE REVIEW**

BSI provides feedback on the manufacturer’s conclusion on their clinical data

**CLINICAL INVESTIGATION**

BSI provides feedback on proposed Clinical Investigation Plan

Manufacturer attains a High Level of Confidence

Manufacturer completes the final Clinical Evaluation Report based on analysis of all relevant data including from Literature, Investigation and Experience

Manufacturer submits full Clinical Evaluation Report to BSI as part of their normal Technical/Dossier Review

BSI conducts a full Technical/Dossier Review to determine compliance to the Directive. If consistent with above expectations, process would be streamlined. If certified by BSI, the manufacturer can then affix CE Marking

NOTE: The Clinical Strategy Review is based on the manufacturer’s successful achievement of its clinical plan, the version of the Directive and related guidance used at the time the review. Regulations and their interpretations may have changed by the time the clinical investigations are complete which may invalidate the review or require updating

For more information, please contact us at:

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 845 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group America Inc.
12950 Worldgate Drive, Suite 800
Herndon, VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

Copyright © 2014 The British Standards Institution. All Rights Reserved.