Your partner
in progress

MDR
Article 117

Drug-device combination
products application process

Overview

Article 117 requires manufacturers placing drug-device combination products onto the market as an integral device and marketing them as a medicinal product to seek a Notified Body Opinion (NBOp). The Notified Body then confirms whether the device is compliant with the relevant General Safety and Performance Requirements (GSPR) and provides an NBOp Report to the manufacturer to be included in the Market Authorisation Application (MAA).

What is the role of the Notified Body?

A Notified Body, such as BSI, is designated by its National Designated Authority to conduct a conformity assessment under the relevant EU legislation. For specific drug-device combination products, the conformity assessment requires a review of the relevant Technical Documentation provided by the manufacturer in support of the safety and performance claims for their medical device. The Technical Documentation is assessed against the GSPR of the EU regulations, taking into consideration the relevant guidance set out by the EU.

Focusing our attention on Article 117

BSI has formed a dedicated Medicinal and Biologics team to provide guidance on Article 117. The team has over 80 years' combined experience in drug development, Good Manufacturing Practice (GMP) systems and controls, and Quality by Design (QBD). The team also has extensive experience in conformity assessments of medical devices with ancillary medicinal substances (MDR Rule 14).

BSI was the first Notified Body to issue an NBOp under Article 117 of the MDR.

Some drug-device combination devices requiring NBOp:

- Autoinjector
- Inhaler
- Pre-filled nebuliser
- Pre-filled pen
- Pre-filled syringe

“Having a dedicated team in place allows us to focus our attention on this challenging area of EU regulation, delivering excellence to our clients”

Theresa Jeary, Global Head of Medicinal & Biologics, Regulatory Services, BSI

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

FAQs on Article 117 process

How long does the Article 117 process take?

The duration of the entire process depends on the quality of the documentation submitted by the manufacturer, the number of questions BSI needs to ask for each round, and the manufacture's responsiveness in answering questions. An estimated timeline for Article 117 reviews can be consulted on page 3. The process is typically expected to take between two and six months to complete, although this can vary during busy periods.

Is there an expedited service available?

There is no expedited service. However, our team will work closely with you to complete the reviews within the estimated timelines provided on page 3.

Which documents do I need to supply?

Annex II of the MDR provides guidance on the documentation required. BSI also offers **Article 117 Documentation submission best practice guidelines** for further guidance. As part of the Article 117 process, there will be a thorough review of evidence of conformity to the GSPR. For this reason, supporting technical data will be required.

What is the output of the process?

BSI will issue an NBOp Report providing an opinion on the conformity of the device part with the relevant GSPR set out in Annex I to the MDR. To avoid any duplication of the reviews, this report will be detailed enough to demonstrate to the Competent Authority what data have been reviewed and to assure them conformity has been appropriately assessed.

What is the role of BSI during the question stage of the MAA process?

On rare occasions, there might be questions from the Competent Authorities for the Notified Body during the MAA process. BSI will be available to answer these, mindful of the fact that there is a clock stop.

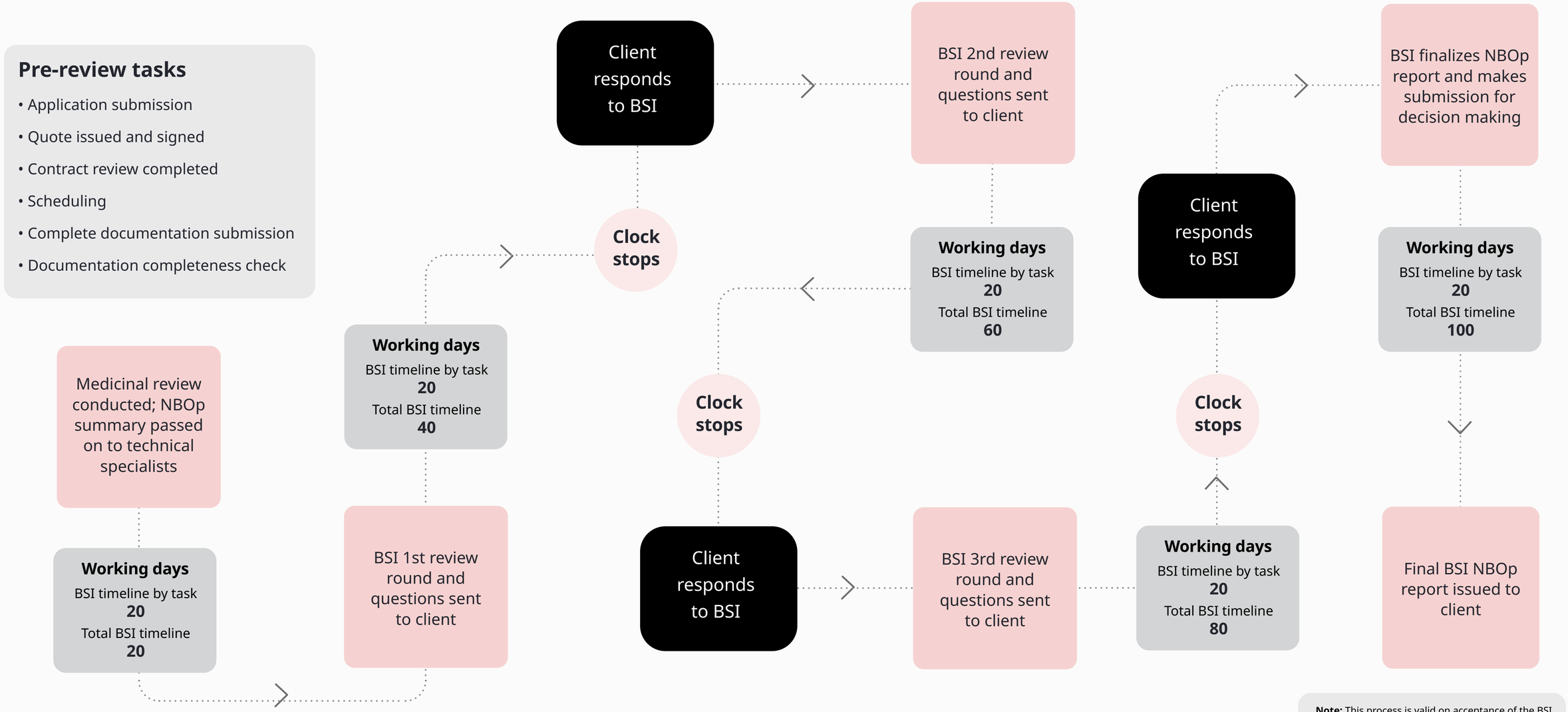
How much clinical data is required?

The safety and efficacy of the medicinal substance is reviewed by the Competent Authority. As a Notified Body, BSI will need sufficient data to demonstrate the device part of the combination device performs as intended. Clinical data may be required if there are specific device-related clinical claims or safety concerns.

I'm making a change to an already marketed drug-device combination product. Does this require an NBOp?

Significant changes to your product that could affect the performance and safety characteristics of the medical device will require an NBOp as part of the medicines variation process as described in Directive 2001/83/EC. As an independent Notified Body, BSI is not able to advise or provide consultation to manufacturers on whether specific changes require an NBOp.

Estimated timeline for Article 117 reviews



Note: This process is valid on acceptance of the BSI Netherlands Terms of Service by the Manufacturer

Download the **BSI Netherlands Terms of Service**

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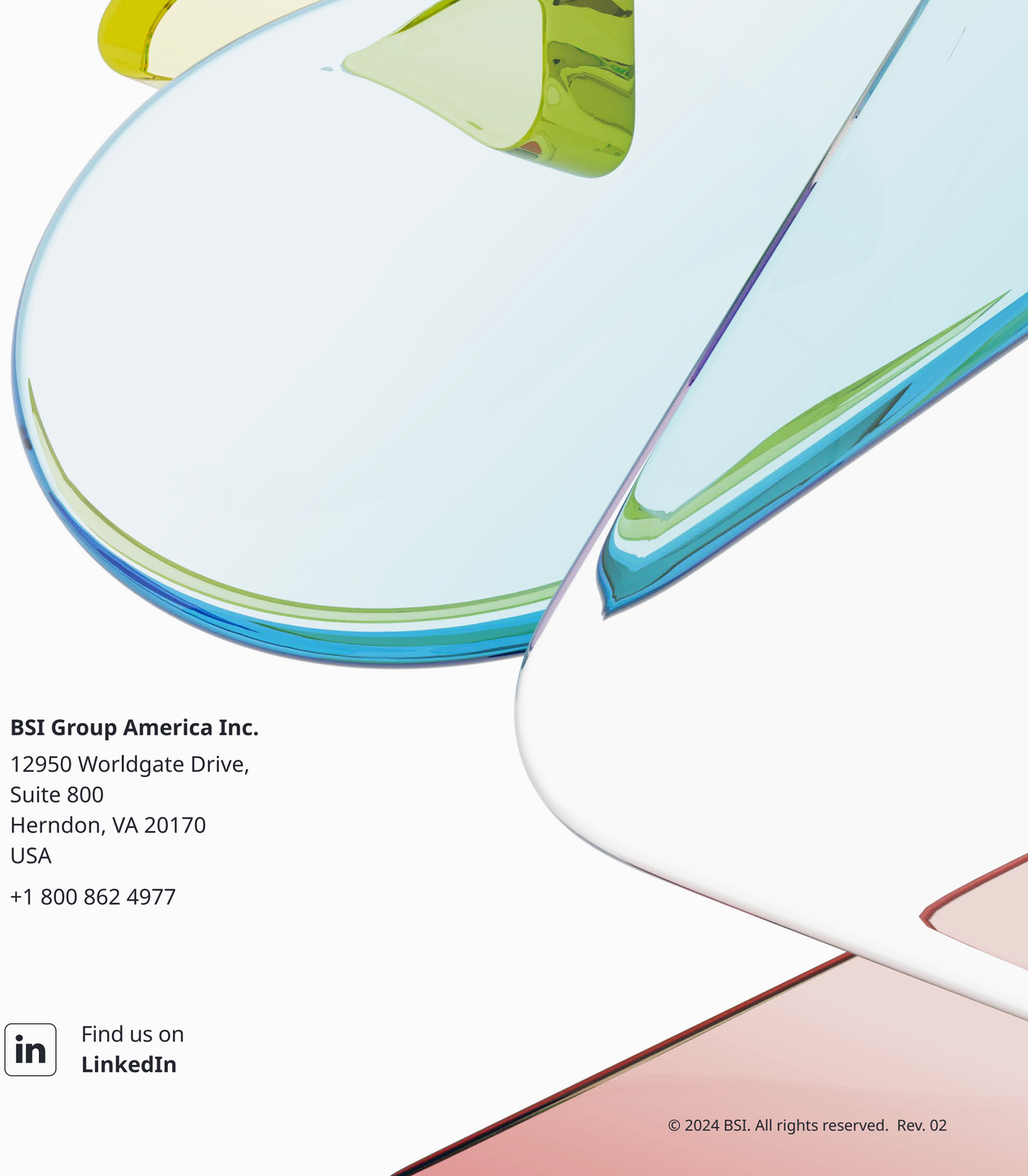

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