



BOSTON SCIENTIFIC CASE STUDY

ENHANCING EFFICIENCIES THROUGH CENTRALIZING SSCP AND LABELING TRANSLATION WORKFLOWS

17 SSCP
TRANSLATION PROJECTS

100%
ON-TIME-DELIVERY

36.26%
REDUCTION IN TRANSLATION COSTS



THE CHALLENGE

The Global Regulatory Affairs team at Boston Scientific entrusted Lionbridge with its centralized management and execution of an extensive SSCP translation program.

As a world leader in developing high-risk implantable devices, Boston Scientific is required to publish Summaries of Safety and Clinical Performance (SSCP).

The SSCP is a mandatory document under Article 32 of the EU Medical Device Regulation (EU MDR) 2017/745 for all high-risk Class III devices and Class II implantable medical devices. It plays a vital role in providing transparent, accessible, and updated information on the safety and performance of medical devices for users, patients, and healthcare professionals. The SSCP is validated by Notified Bodies as part of the Conformity Assessment of the device and translated into local language.

The language scope of the SSCP is equivalent to the IFU and other labeling information supplied with the device.

Since the SSCP is a regulated and public document disclosing essential safety and performance characteristics of the device, language accuracy must go hand in hand with optimization efforts. The regulatory team faced increasing pressure to deliver a high volume of high-quality SSCP translations across all EU languages under tight timelines and budget constraints. Maintaining consistency with labeling content and minimizing duplication of effort were critical to success. To ensure global accessibility and regulatory compliance, the SSCP must be authored in clear, unambiguous language for the intended user and translated under controlled workflows into local languages.



ABOUT THE CUSTOMER

Boston Scientific Corporation is a global medical technology company headquartered in Marlborough, Massachusetts. Founded in 1979, the company specializes in developing and manufacturing innovative medical devices for a wide range of interventional medical specialties, including:

- Cardiology
- Endoscopy
- Neurology
- Oncology
- Urology
- More

Lionbridge has been a long-standing, trusted partner to Boston Scientific. We support Instructions for Use (IFU) and global labeling translations, providing a commitment to delivering precise, compliant content across international markets.

THE SOLUTION

With our strong partnership with Boston Scientific, Lionbridge identified opportunities for optimization across content streams. Our medical device team collaborated with Boston Scientific's labeling team to help drive incremental efficiencies. Additionally, having specialized in language outcomes under the EU MDR since its 2017 publication, Lionbridge understood the SSCP is a document sourced from the technical dossier and the Instructions for Use (IFU) (already translated for Boston Scientific by Lionbridge).

These documents carry a significant content overlap, which isn't always clear to individual document owners across different functional areas in the MedTech enterprise. By aligning the SSCP translation workflow with the existing labeling translation process, we implemented a content reuse strategy allowing Boston Scientific to:

- ▶ **Leverage previously translated IFU content** for SSCPs using translation memory.
- ▶ **Streamline the translation process** by sequencing SSCP translation after IFU completion.
- ▶ **Ensure accuracy and consistency** in terminology and tone across both document types.
- ▶ **Adopt a robust quality assurance process** for better accuracy and language consistency.
- ▶ **Reduce turnaround time** via minimizing redundant translation steps.
- ▶ **Lower costs through increased content reuse** and reduced translator workload.
- ▶ **Seamlessly manage future updates** of the SSCP and its interdependent technical documents.



METHODOLOGY

LANGUAGES:

- ▶ Bulgarian
- ▶ Croatian
- ▶ Czech
- ▶ Danish
- ▶ Dutch
- ▶ Estonian
- ▶ Finnish
- ▶ French
- ▶ German
- ▶ Greek
- ▶ Hungarian
- ▶ Icelandic
- ▶ Italian
- ▶ Latvian
- ▶ Lithuanian
- ▶ Norwegian Bokmal
- ▶ Polish
- ▶ Portuguese
- ▶ Romanian
- ▶ Slovak
- ▶ Slovenian
- ▶ Spanish
- ▶ Swedish
- ▶ Turkish

PLANNING

- ▶ Project scope and success criteria
- ▶ Roles and responsibilities
- ▶ Detailed schedule and communication plan

MULTIDISCIPLINARY TEAM

- ▶ 1 Global Account Executive
- ▶ 1 Global Program Director
- ▶ 1 Program Manager
- ▶ 1 Project Manager
- ▶ 1 Project Coordinator
- ▶ 1 Language Team Leader
- ▶ 1 Language Lead
- ▶ 1 Desktop Publisher

COMMUNICATION

- ▶ Weekly meetings within the Operations team
- ▶ Daily communication ad-hoc
- ▶ Focused troubleshooting emails, internal and external



THE RESULTS

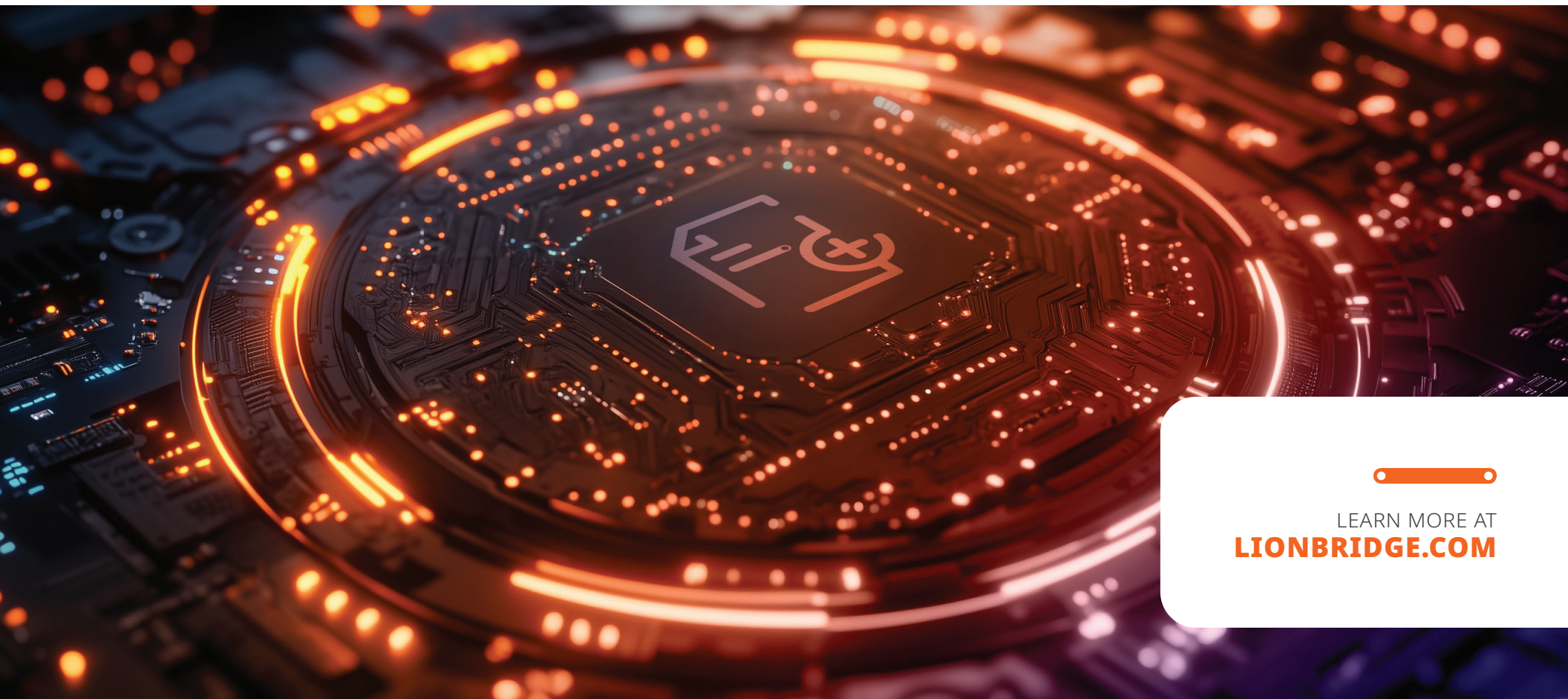
Lionbridge identified synergies and drove results for Boston Scientific's language outcomes. The integrated approach in this program demonstrates that cross-functional collaboration and smart content reuse can achieve these goals in medical device documentation:

- Increased efficiency
- Reduced costs
- Language consistency
- Language quality

It's critical to have a robust, centralized translation workflow across interdependent technical documents to fully leverage the benefits of

technology and language assets. A risk-based language strategy for the full content life cycle of the medical device can further optimize, including large-scale adoption of Artificial Intelligence (AI). Our overall work for Boston Scientific included:

- 17 SSCP translation projects completed
- 24 Languages covered
- 17,064,072 Total word count:
- 100% On-time delivery
- 34.52% Average leverage of translation memories
- 36.26% Reduction in translation costs
- 0 Quality concerns



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