TRANSPERFECT
MEDICAL DEVICE SOLUTIONS

Intelligent Automation for MDR & IVDR Content:

Summary of Safety & Clinical Performance (SSCP), Summary of Performance (SSP), and Selected Labeling

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Background

The European Union's (EU) new Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) replace the previous EU Directives dating from 1993 (MDD) and 1998 (IVDD), respectively. In the words of the European Commission,

> *The objectives of these Regulations [MDR, IVDR] are to achieve a high level of protection of health for patients and users and to ensure the smooth functioning of the internal market for medical device products.*

The MDR rollout was developed in response to a number of high-profile device failures (including breast implants, power morcellators, and vaginal mesh) that resulted in patient injuries and tragic deaths. Unfortunately, a lack of both supporting resources (e.g., Notified Bodies, EUDAMED, etc.) and implementation guidance has caused regulators to push back mandatory compliance deadlines to avoid critical device shortages that would otherwise undermine the stated goal of "…a high level of protection of health for patients and users."

Due to the backdrop of patient safety concern, the resulting regulations were more proscriptive than would otherwise be the case. The cost of this proscriptive regulation is substantial: manufacturers are reporting a 10-times increase in costs to register legacy devices under the MDR (vs. MDD) due to the increased costs of compliance, including clinical data, post-market surveillance, and labeling requirements.

The tension between desired effect (patient/user safety) and undesired expense is best illustrated by a new class of documentation required by the MDR: **Summary of Safety and Clinical Performance (SSCP)** and IVDR: **Summary of Safety and Performance (SSP).** According to the guidance-writing Medical Device Coordination Group (MDCG), the SSCP is an important means to fulfill the MDR's objectives:

> *The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device… It is one of several means intended to fulfil [sic] the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information. (MDCG2019-9 Rev.1)*

In fact, the SSCP and SSP are a primary means for fulfilling the aims of enhanced transparency and adequate access to information. No other public-facing information produced by manufacturers or regulators contains as much intimate detail regarding the function and measured safety of a given device. Section 5 of the MDCG guidance describes several of these required details:

This section is intended to summarize, in a comprehensive manner, the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio. It shall be an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

In addition to producing an objective, detailed discussion of both favorable and unfavorable clinical evidence, the manufacturer is also obligated to discuss alternative treatments—options a patient or user might select rather than the manufacturer's device.

General Requirements and Guidance for Required Sections of the SSCP

MDCG 2019-9 is the primary source of guidance for the presentation, content and validation of the SSCP. It contains background information, general requirements, detailed guidance for each of the required SSCP sections and references, and a generic SSCP content (but not layout) template. Selected observations (by section) include:

Translations to Other EU Languages

- In addition to meeting all the prescribed content, requirements to create the SSCP, manufacturers must also translate and manage this content across multiple languages (typically 20+)—and at a considerable expense.
- Manufacturers should plan on using English as the source language for SSCP translations. The MDCG guidance states, *"If the selection of European languages for the SSCP does not include English, then an English translation of the document should also be provided."* Since the manufacturer must produce an English version of the SSCP, they can use this as the source language for their translations. In fact, the majority of qualified medical device translators work from English into their target language. More resources means greater availability at a lower cost— not to mention, lower risk.
- Manufacturers are required to exercise stringent supplier control under MDR—including a requirement that notified bodies audit a manufacturer's suppliers "...when the manufacturer cannot demonstrate sufficient control over its suppliers." To avoid this unwelcome attention to suppliers, it is recommended that manufacturers screen for "quality system parity" —an equivalent level of certification to the manufacturer itself—including ISO 13485 and ISO 14971. Further qualifications, specifically for translation suppliers, are discussed below.

- Because the SSCP and SSP are public-facing documents, the importance of translation quality cannot be over-estimated. In addition to potential patient/user miscomprehension and complaints from the field, manufacturers should be aware of the possibility of "competitive informing" —i.e, identification and notification of translation errors (to Competent Authorities or notified bodies) by competitors.

Validation of Updates to the SSCP Between Certification Activities

- The SSCP is a living document and requires regular updates in all languages. According to the MDCG, "The manufacturer has an obligation to keep the SSCP updated"—including updates originating from the Clinical Evaluation Report (CER) and the post-market Periodic Safety Update Report (PSUR). Notified bodies are obligated to verify that manufacturers have "appropriately updated the SSCP." Updated translations must be produced within 90 days of the "master" SSCP update.
- A system for updating SSCPs (and documenting updates) is necessary to demonstrate effective compliance; an automated solution for SSCP publication and maintenance is the best method for meeting this requirement. (see EnCompass Solution, below)

Quantitative Data

- Information related to "reciprocal interference with reasonably foreseeable external influences, medical examinations, or environmental conditions" must be included in the SSCP. This requirement forces manufacturers to think more expansively about warnings and precautions. For instance, one manufacturer was forced to recall and update instructions for a surgical device that could be inadvertently connected to a separate surgical system, leading to severe patient harm. Under MDR, potential mix-ups and foreseeable misuse are now in scope for risk management consideration.
- Information related to any field safety corrective action (FSCA) or field safety notice (FSN) for the device must also be included in the SSCP— this is another critical source of required updates.

The Summary of Clinical Evaluation as Referred to in Annex XIV and Relevant Information on Post-market Clinical Follow-up

Section 5 of MDCG 2019-9 is the heart of the content requirements for the user/healthcare professional:

> *This section is intended to summarise, in a comprehensive manner, the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of*

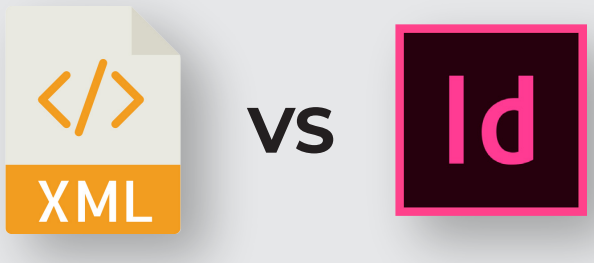
conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio.

It shall be an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

The requirement to divulge all clinical evidence and to objectively summarize all data, both positive and negative, in a balanced, objective manner is what makes the SSCP unique:

- Importantly, this section of the MDCG guidance requires *"a description of the documented clinical benefits for patients with relevant and specified clinical outcome measures, and the success rate for achieving the outcome measures."* In other words, measureable evidence of effectiveness.
- The focus on measureable evidence is central to SSCP content and, similarly, valid evidence must be presented for ANY type of claim: *"This should be described for all clinical claims the manufacturer presents in the IFU, and in any information, marketing, or promotional material that it distributes."*

This is a small subset of the content requirements outlined in MDCG 2019-9. And, while many MDR expenses (e.g. notified body audits) are unavoidable, the cost and risk of creating, translating, and managing SSCP and SSP (and some labeling) content can be dramatically reduced through automation technology, as discussed below.



Less with XML

20% less cost **22% less time** **50% less risk**

Services for SSCP & SSP Adaptation & Translation

In addition to automation technology, device makers typically engage other services in order to satisfy SSCP and SSP requirements. Under **General Requirements and Recommendations for the SSCP** (MDCG 2019-9), sections on translation, readability, and stylistic recommendations are included. Given the emphasis on the manufacturer's responsibility for outsourced processes under the MDR and IVDR, it is important that manufacturers thoroughly vet authoring and translation suppliers according to supplier control best practices, including:

Supplier Certification

Ideally, content and translation suppliers for SSCP, SSP, and other product-related content can offer "quality system parity" or equivalent levels of certification to their medical device clients. Together, the standards listed below provide a baseline for effective supplier control.

ISO 13485
medical device quality systems

ISO 9001
generic quality systems standard

ISO 17100
translation quality assurance

ISO 14971
medical device risk management

Authoring & Adaptation

Manufacturers may engage a service provider to help satisfy the readability and stylistic recommendations of MDCG 2019-9. The authoring and adaptation effort, like all controlled activities, requires distinct "doing" and "checking" phases carried out by qualified resources, taking into consideration reference guidance and enabling technologies. Ideally, the SSCP/SSP authoring and adaptation process includes the following:

- Qualified resources, including education and experience
- QA review to identify ambiguities or tortured English that may adversely affect adaptation
- Linguistic review of adaptation
- Separate SME review of adaptation
- Automated QC tools to verify spelling, grammar, punctuation, and terminological consistency
- Software tools to capture and reuse previously adapted content
- Resource guidance from key sources, such as *Summaries of Clinical Trials Results for Laypersons*

These key elements, combined under an ISO 13485-certified quality system, help to ensure a compliant result for adaptation of your SSCP and SSP content.

Technology for Adaptation Efficiency

- Software to capture previously adapted content
- Collaboration technology to ensure consistency across authors
- Automated QC tools to ensure accuracy and consistency

Translation

The SSCP and SSP are publicly available documents that fulfill the specific MDR and IVDR requirements of objectivity and transparency. They are also translated into all target languages where the product is sold. This exposes the manufacturer to translation scrutiny from not only patients and users but also competitors. Therefore, translations should be prepared with quality and accuracy as the primary consideration. Technologies that support this goal and reduce cost and risk are especially valuable for manufacturers struggling to manage large volumes of MDR and IVDR content.

The translation activity is best characterized as a professional service with two primary sources of risk: processes and resources. Process risk is best controlled through harmonized quality and risk management standards, specifically ISO 13485 and ISO 14971. Other standards, such as ISO 17100 and ISO 9001, provide further evidence of quality system compliance. ISO 18587 is important for AI-supported processes that can dramatically reduce cost and turnaround for SSCP and SSP content.

Resource risk is controlled by qualification, testing, and monitoring. For instance, TransPerfect Medical Device Solutions requires resources to be native-language and subject-qualified. Resources are tested using the only notified body-endorsed translation quality metric (an adaptation of the SAE J2450 standard) in 11 different subject matters (e.g., vascular intervention, dental, imaging, etc.) and two content types (labeling, marketing).

Controlling translation risk

Two sources of risk : resources and processes

Resources	Processes
Qualification: Native Language and Med Dev Experience	**ISO 13485**
Testing: Controlled and Approved	**ISO 14971**
	ISO 9001
	ISO 17100
	ISO 18587

Validated translation process technology is key for manufacturers who are struggling to contain the costs associated with MDR and IVDR, including:

- **Translation Management System (TMS)** – A robust TMS includes translation memory and integrated glossaries and is the most ubiquitous example of translation productivity tools. Translation memory allows device makers to recycle previously translated content (saving time and money) and includes "fuzzy matching" of close matches to further decrease cost and turnaround. By managing all translation efforts through a TMS, manufacturers can automatically generate reporting on spend, timeliness, quality, and other key metrics for improved performance.
- **Specialized AI Engines** – AI technology can provide an important productivity boost for certain languages and content types. For instance, IVD labeling generally performs well in an AI-supported process, whereas marketing/branding content generally does not. As noted above, ISO 18587 is the standard that provides guidance for AI-supported translation processes—suppliers working in this area should be certified. Manufacturers who successfully implement AI-supported processes in their labeling operations typically realize overall translation cost savings of 15% and turnaround reductions of more than 30%. Further, these engines can be used in other specialized applications, such as translation of inbound PMS reporting, which is set to increase dramatically under MDR/IVDR.

Intelligent Automation for SSCP & SSP Content Success

The SSCP and SSP are clear illustrations of the inherent tension between progressive regulatory goals (patient/user information, transparency) and the cost of implementation presented by the EU's new MDR and IVDR. Under these circumstances, manufacturers may feel they have no alternative other than to increase staff or budgets in order to meet changing regulatory requirements. However, the time provided by the MDR/IVDR's implementation delay gives manufacturers the opportunity to effectively manage increased content requirements and cost through "intelligent automation"—a combination of best-practice content strategies and process automation technology solutions.

Don't Wait, Automate!

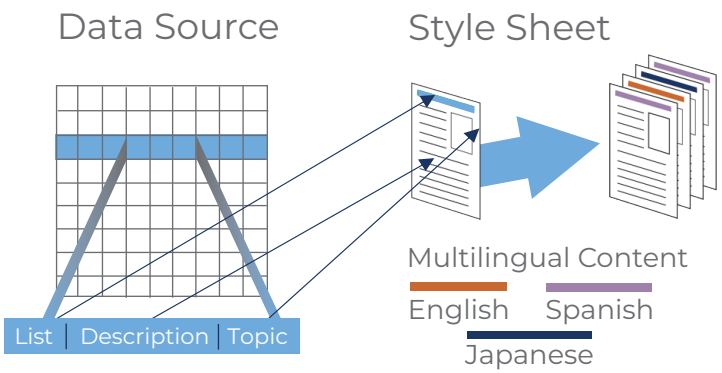
The challlenge of creating, translating, and maintaining SSCP and SSP content is compounded by traditional, document-based publishing—an expensive, time-consuming, and error-prone approach that costs the device industry more than $1 billion per year.

Typically, device makers manage IFUs, user manuals, surgical techniques, and other product-related content in document-based systems like Word and InDesign — along with repositories like Documentum. This means, for example, that a manufacturer with 50 SSCPs in 25 languages will need to create, translate/format, and maintain more than 1,200 discreet documents. For new SSCPs, formatting, and formatting QC, costs can run 15-20% of total translation expense. For maintenance updates, this can increase to 50% due to time-consuming manual processes. Manual processes also increase risk. Copy-paste formatting is one of the highest-risk activities in any manual documentation process and is responsible for up to 50% of typical translation errors.

Now, the EU's five-year MDR/IVDR delay gives manufacturers the chance to address the obstacles presented by document-based content. Specifically, an XML-based component content management system (CCMS) is the best way to reduce the costs, risks, and turnaround time inherent to document-based publishing. Content automation with a CCMS is accomplished by:

- Separating documents into individual, XML-tagged "topics" (logical blocks of content, such as "Warnings & Precautions" or "Contraindications"). Each unique topic is stored in the CCMS database, where it is available for use/re-use.
- Documents are created by assembling topics using a "map"—a file that points to the specific topics that define a particular document.

XML Structured Content



One Client's Story:

20%
Cost Savings

70%
Turnaround Savings

The Rest of the Story

Although an XML-based CCMS is a significant step towards achieving intelligent content automation, it is not the whole story. That's because MDR and IVDR changes dramatically increase the volume of translatable content (including SSCPs and SSPs) that device makers must create and manage. A CCMS helps control these costs by sending only new topics (not entire documents) for translation.

Automated publication processes also save significant time, cost, and risk. However, when tied to a translation management system (TMS) and supported by an advanced AI engine, manufacturers can realize true intelligent automation in their documentation processes.

The EnCompass Solution

Prior to the announced MDR and IVDR extensions, manufacturers struggled to produce SSCP content by the required deadline. Aside from the source English language authoring, the cost and time to translate and format this large volume of material presented a unique challenge. The obvious solution was an XML-based CCMS supported by a robust TMS and specialized AI engines. However, the cost, time, and overhead of a fully licensed solution has presented a barrier for many manufacturers.

In order to provide the cost, time, and risk reduction benefits of XML structured content for SSCPs and SSPs, TransPerfect Medical Device Solutions is pleased to introduce EnCompass—a subscription-based service that allows manufacturers to submit their final, English-language SSCPs or SSPs with TransPerfect handling the conversion to XML and system setup. Clients get access to a simple, secure web interface that allows them to make content updates and initiate publication processes. What they don't get is the burden of system licensing costs, system setup time, staffing of specialized personnel, and change management that comes with a full system implementation.

TransPerfect's EnCompass Solution is Composed of:

- **GlobalLink CCMS** – This is a validated component content system in use and delivering 10x productivity gains for global device and IVD manufacturers
- **GlobalLink Project Director** – This is a validated translation management system that automates workflows and provides unified, online translation memories and glossaries to reduce cost and increase quality. The system also has advanced reporting capabilities for cost, quality, and efficiency metrics across all suppliers.
- **GlobalLink AI** – Consisting of specially trained AI engines, GlobalLink AI provides high-quality draft translations that are edited by two independent, subject-qualified, native-language translators, according to the requirements of ISO 18587, to produce final, publication-quality, content.

Clients who have evaluated EnCompass for their SSCP translation and publication have seen a 15-20% decrease in overall project costs and up to a 70% reduction in turnaround times (vs. document-based), thanks to automated publishing.

EnCompass is billed as a quarterly subscription service with no charge for zero-use quarters to reduce overall costs when SSCP and SSP content is not being actively updated.

EnCompass for Labeling

For manufacturers with basic labeling formats (especially IVD), large-format manuals, or other standardized labeling sets, the EnCompass solution offers content automation without the the additional overhead costs of system licensing, implementation, and maintenance. For labeling implementations, additional style sheet development may be necessary to meet specific sizing requirements.

EnCompass Enterprise

For device makers with complex or frequently changing labeling requirements, TransPerfect offers a fully licensed version of the EnCompass solution. A client-side system implementation provides the maximum level of system control and content customization. It also offers manufacturers the opportunity to onboard valuable XML-based publishing know-how that can be extended to other groups, driving greater efficiencies company-wide.

Conclusion

The goal of the EU's MDR and IVDR is to "achieve a high level of protection of health for patients and users and to ensure the smooth functioning of the internal market for medical device products." The SSCP and SSP are documents required under the MDR and IVDR that help fulfill these regulatory goals by enhancing transparency and providing adequate public access to information.

Translation and maintenance of these documents in over 20 languages is a challenge both from a cost and quality perspective. Automation technologies can offer manufacturers some relief. For example, TransPerfect's EnCompass solution offers a subscription-based model for delivering content and publishing automation to medical device manufacturers without the costs and overhead of licensing and implementation. The results can be dramatic: up to 20% cost and 70% turnaround savings over traditional, document-based publishing.

The EnCompass solution can also be employed for certain types of medical device labeling—especially with IVD makers or wherever standardized formats are used. For complex or frequently changing labeling specifications. EnCompass Enterprise provides the necessary level of granular control.