EU MDR & IVDR CHECKLIST
FOR TRANSLATION

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With all the things your company is doing to get ready for MDR and IVDR, it's easy for translation-related items to fall through the cracks. Translation is often an afterthought in big projects, and planning for MDR/IVDR is not likely to be much different. If you're a part of your company's localization strategy, considering these challenges in advance will help you get ahead of some of the more problematic items before they take you by surprise in the middle of a project.

PORTFOLIO RATIONALIZATION

- Work with your regulatory team to review your company's product list and determine whether any product registrations will be allowed to expire without seeking MDR/IVDR approval. If so, phase out these products, inform customers, and consider reallocating ICR/SMEs to other product lines.
- Consider aligning submissions to your notified body with registration expiration dates. Since there have been concerns about bottlenecks due to past shortages of notified bodies, a blanket strategy of "submitting everything simultaneously" might not be optimal for your business in the current landscape.

CONTRACTS

- Make sure your supplier carries enough insurance to cover intentional or accidental breach of sensitive information. This is crucial for devices that are still in the approval process and may need translation of technical details or safety and performance information.
- Verify that your supplier's NDA covers the intentional or accidental breach of sensitive information and that their supply chain is also secure.
- Confirm that your supplier contract includes a strategy for urgent compliance translation requests and clear guidelines for handling questions from regulatory authorities.
- Verify that your supplier contract is clear on expectations regarding feedback from distributors.
- Spend time establishing the best procedures to translate different types of information such as clinical reports, technical information, notified body questions/submissions, and other types of content.
- Review your rates to make sure they are adequate to support the translators and other resources you'll need for notified body submissions and responses.

NOTIFIED BODIES

- While notified bodies have shown increased capacity recently, it's essential to remain informed and alert for bottlenecks during the regulatory process.
- Evaluate your market and submission readiness for each region. Consider whether you will need new notified body representation in Turkey, the UK, or the European Free Trade Association (EFTA).
- Confirm with your regulatory team that your notified body is either approved or is actively seeking approval and has not opted out.
- If selling in the UK, ensure your notified body will be able to do parallel submissions in the UK and the EU after Brexit.
- Confirm that your notified body accepts content in your business's operational language. If your company prepares documentation in English, does the notified body accept English documentation?
- If your notified body does not accept content in the language you do business in, create a translation strategy for your submission documents and factor these issues into your MDR/IVDR timeline. You may also consider re-evaluating your authoring strategy to create documents in the appropriate submission language.
- Begin planning for post-Brexit UK submissions and determine if you will pursue multiple markets or reconsider your product position in the UK.
- Identify how Brexit impacts your translation strategy or notified body strategy. For English-speaking businesses, it could reduce the number of English-native expert opinions and increase the translations needed for expert evaluations.

CLINICAL

- Ensure your clinical plan complies with European regulations and establish a translation strategy for clinical documentation.
- Prioritize the ease of translation for clinical reports, particularly those concerning the safety and performance of the device. Proactive translations will shorten response times.

LANGUAGE QUALITY

- Has your style guide been reviewed and approved internally? Since notified bodies and member states may request a wide variety of documentation, a clean, approved style guide will be essential for maintaining quality.
- Is your terminology list clear? This clarifies specialist terminology for suppliers, facilitates high-quality translations and enables quick turnarounds.
- Evaluate how your source content will be handled prior to translation and ensure translation queries can be addressed quickly during translation.
- Review the translator profile for your documentation. You may need specialized linguistic resources to translate technical documentation. Consider offering product training to help translators understand the product better.

PROCESS

- Review your translation processes to ensure they're adaptable to these regulations. Work with your supplier in advance to strategize on how to respond to feedback provided by the distributor or notified body post-market. Consider if a single process for all content will suffice or if you will use different processes for different levels of documentation, such as:
    - EUDAMED content
    - Materials for patients
    - Feedback from distributors or notified bodies
    - Requests for technical documentation
    - Member state-specific translation requests for technical documentation
- Evaluate what type of training internal stakeholders will require to understand any new processes for translation.

QUALITY

- Make sure your suppliers clearly understand your procedures and that they cover the complexities of translation.
- Review your supplier qualification requirements and how they manage translations. Work with your supplier quality team to determine if translation is properly categorized.
- Understand how you are qualifying your translation suppliers and assess their audit risk.
- Check that your translation supplier is audit-ready with supplier audits and follow-up training if needed.
- Evaluate whether quality management system changes or procedure updates are needed to support the MDR requirements.

SUPPLY CHAIN

- Ensure your translation partner works with translators who are appropriately qualified for technical documentation and that your budget is sufficient to work with those suppliers.
- Make sure your EC reps are still located within the EU after Brexit.

DISTRIBUTORS

- Determine if distributors need additional training to conduct their new responsibilities.

TRANSLATION MEMORY STRATEGY

- Decide if new patient materials should be integrated into your standard translation memory or kept separate from technical documentation.
- Assess the sensitivity of technical documentation and evaluate whether this content should go in the standard translation memory or if it should be segregated from the standard documentation.

Navigating the EU MDR and IVDR regulatory processes can feel overwhelming, but you're not alone. Let the experts at Argos Multilingual help you navigate the complexity with our full suite of consulting services.

ABOUT ARGOS

Argos Multilingual is a global language solutions provider with experience in the life sciences, industrial manufacturing, and software/hardware industries. Our business is built on three core values - quality at source, a partnership approach, and technology agnostic solutions. We are committed to giving you freedom of choice while providing customized strategies to fit your business needs, and we are ISO 9001, ISO 17100, EN ISO 13485, and ISO 27001 certified. With production centers in Krakow, Poland and Colorado, USA, we provide value through dedicated customer service and subject matter expertise in your industry.

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