# EU MDR & IVDR CHECKLIST FOR TRANSLATION REQUIREMENTS

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With all the things your company is doing to get ready for MDR and IVDR, it's easy for some 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 have a hand in your company's localization strategy, the list below 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, designate products for obsolescence, alert customers, and evaluate whether any internal ICR/SMEs can be reallocated to other product lines.
- Prioritize submissions to your notified body based on registration expiration date. Most experts agree that the notified body shortage will be the biggest bottleneck in this new process, so following a "submit everything at once" strategy may not be what's best for your business.

# CONTRACTS

- Make sure your supplier carries enough insurance to cover intentional or accidental breach of sensitive information. This is especially necessary for new/not yet approved devices that may need translation of technical details or safety and performance information.
- See 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 contains a strategy for managing urgent translations for compliance requests and that it also contains clear guidelines for handling regulatory body questions.

- Verify that your supplier contract is clear on expectations regarding feedback from distributors.
- Spend time determining the best process for the different types of information such as clinical reports, technical information, notified body questions/submissions, and other types of translations.
- Review your rates to make sure they are appropriate for the translators you'll need for notified body submissions and responses.

# NOTIFIED BODIES

- Create a company-wide strategy around the likely shortage of notified bodies.
- Evaluate your market/submission readiness for each region. Consider whether you will need new notified body representation in Turkey, the UK, or EFTA regions.
- Confirm with your regulatory team that your notified body is either approved or is actively seeking approval and has not opted out.
- Make certain that 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 the language your business runs in. 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, determine a translation strategy for your submission documents and build that work into your MDR/IVDR timeline. At some point, you may also wish to re-evaluate your authoring strategy to create documents in the appropriate submission language.
- Begin planning for UK submissions post-Brexit and determine if you will take a parallel path or stop selling in the UK.
- Identify whether Brexit will impact 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 that your clinical plan for Europe complies with the new regulations and that there is a strategy for the translation of clinical documentation.
- Consider the ease of translation of your clinical reporting as it relates to the safety and performance of the device. Pre-translation will shorten response time.

# LANGUAGE QUALITY

- Has your style guide been reviewed and approved internally? Since notified bodies and member states have more leeway to request new/different documentation, a clean, approved style guide will be essential to quality translations.
- Is your terminology list clear? This will set clear quality guidelines and clarify specialist terminology with suppliers while facilitating high quality/quick turnaround translations.
- Evaluate how your source content will be handled prior to translation and make sure the translation teams will have quick access for queries during translation.
- Review the translator profile for your documentation. You may need specialist translation resources for translating technical documentation, so prepare training materials at the product level to help the translators familiarize themselves with the device.

# PROCESS

- Evaluate your process to see if it is suitable for the changes affecting translations. Work with your supplier in advance to determine how you will handle any feedback provided by the distributor or notified body post-market. Consider the following changes and whether you will use the same process for all content or if you will use different processes for different levels of documentation:
  - EUDAMED content
  - Patient-facing materials
  - Distributor or notified body feedback
  - Requests for technical documentation
  - Member state translation requests for technical documentation
- Evaluate what type of training internal stakeholders will require to understand any new processes for translation.

# QUALITY

- Make sure that your procedures are clear to your suppliers and that they adequately cover the nuances of translation.
- Review your supplier qualification requirements and where translation fits in. Work with your supplier quality team to determine if translation is properly categorized.
- Understand how you are qualifying your translation suppliers and if they will be at risk for audit.
- See 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

- Confirm with your translation partner that they have translators 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

- Determine whether you want to incorporate new patient materials in standard translation memory or if they should be separated from technical documentation.
- Determine 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.

This list can seem overwhelming, which is why it pays to let the experts at Argos Multilingual and Global Simple help you with your transition. We offer a full suite of consulting services to get your localization team MDR and IVDR ready.

# ABOUT ARGOS MULTILINGUAL

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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