TRANSLATION & CONTENT STRATEGY

EU IVDR

argos multilingual

Contents

How Will IVDR Implementation Affect Your Company's Content and Translation Strategy?

If you haven't done it yet, it's high time to look at in Vitro Diagnostic Regulation (IVDR) implementation.

IVDR was put in force by the European Union on May 25, 2017 as a replacement for the prior EU on In Vitro Diagnostic Medical Devices (98/79/EC). This latest regulatory change will control the sale, marketing, and use of in vitro medical devices in the European market.

The EU stipulated a five-year transition period under this new regulation, and IVD manufacturers will have until May 26,2022 to comply with all the requirements of the IVDR. In some cases, products already certified by a notified body under the prior IVDD regulation may be marketed an additional 2 years beyond this date, if no significant changes have been made and the notified body has mantained required surveillance.

Scope

Virtually all in vitro devices are affected, as is any software used to operate devices. Per IVDR (2017/746) Article 2(2), the following definitions apply:

- (2) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
- (a) concerning a physiological or pathological process or state
- (b) concerning congenital physical or mental impairments
- (c) concerning the predisposition to a medical condition or a disease
- (d) to determine the safety and compatibility with potencial recipients
- (e) to predict treatment response or reactions
- (f) to define or monitoring therapeutic measures

In addition to device software, this expanded scope now includes internet-based testing services as well as genetic and other testing that is intended to provide analysis of patient pre-disposition toward specified diseases. There are exclusions for products intended only for use in research, products intended for invasive sample gathering from the human body, internationally certified reference materials, and any materials used for external quality assessment.

Major Changes

IVDR is unprecedented in the number of new requirements and their overall complexity. The specific impact on your organization and its products is best assessed by your regulatory affairs department, as missteps may impede successful registration and the release of the new products as well as the reclassification and recertification of products already in the marketplace.

Here is a targeted list of the changes that may have the broadest immediate impact in terms of operations and labeling:

- Expanded product scope – especially noteworthy is the inclusion of device software, as the absence of any "grandfathering" provisions may require updates to fielded device software on any devices that are reclassified.
- The reclassification of devices according to risk, which includes reagents and other test chemistries used on the device. Theoretically, a higher classification for one of these could cause the entire device to be reclassified with a higher risk assessment as well, necessitating the updating of claims, the revision of customer facing documentation, or relabeling and re-registration.
- Notified bodies will provide more stringent oversight. Currently, approximately 80% of a company's in vitro products can be "self-certified" without intensive notified body involvement. IVDR is expected to invert this percentage, with 80% or more of IVD products requiring notified body involvement. This promises to create greater administrative burdens on companies and very likely will cause backlogs in access to the notified bodies as well. If you are not already engaged in IVDR preparation, the time to begin is now.
- There are no "grandfathering" provisions for existing IVD products. All approved products will need to be recertified within the framework of the new requirements and classifications.
- In addition to any print or on-device documentation, labeling information must be kept current and available on your company's website.

New Classifications

IVDR specifies four risk-based classifications for in vitro devices, A to D. The lowest risk classification, “A,” does not require notified body supervision. Any new or existing products that do not slot easily into a classification will automatically be considered a “B” level risk, requiring notified body supervision.

Class B, C, and D manufacturers will be subject to unannounced audits by notified bodies and will be required to have a quality management system and technical documentation review. If a device has multiple intended uses with differing risk classifications, the highest risk classification will be used for compliance with IVDR requirements.

Implementation Strategy & Checklist

Here are some possible approaches for successful IVDR implementation:

- First and foremost, regulatory affairs (RA) interpration of any new regulation is critical and should guide all facets of your implementation. If you do not have RA access in your company, please consider using the services of a consulting firm specializing in IVDR to avoid fines, importation delays, or other obstacles.
- Work with your RA representatives to determine how many devices and related products must be reclassified.
- Once you have the list of affected products, what are the revenue implications for each?
- Should you prioritize by existing sales, or by the potential value of new markets or regions?
- Can you arrive at a general statement to minimize verbiage and insert the name of the affected products as a “wild card” element?

- If you still generate documents using desktop publishing, is it feasible to create an addendum with the changed classification that can be referenced with a small addition and then placed on your website? Can you modify only those document sections referencing the classification?
- Do you have documentation that can be updated with a reference sticker or addendum placed within the product packaging or accompanying labeling? Can you utilize regional distribution centers to overlabel containers? Can this overlabeling include a website reference for the customer to access the complete updated risk classification information?
- For device software, can new intended use statements etc. be delivered as part of a software patch? Would it be feasible to require acknowledgement of these updates to authorize the newly installed software?

Projecting New Content Costs

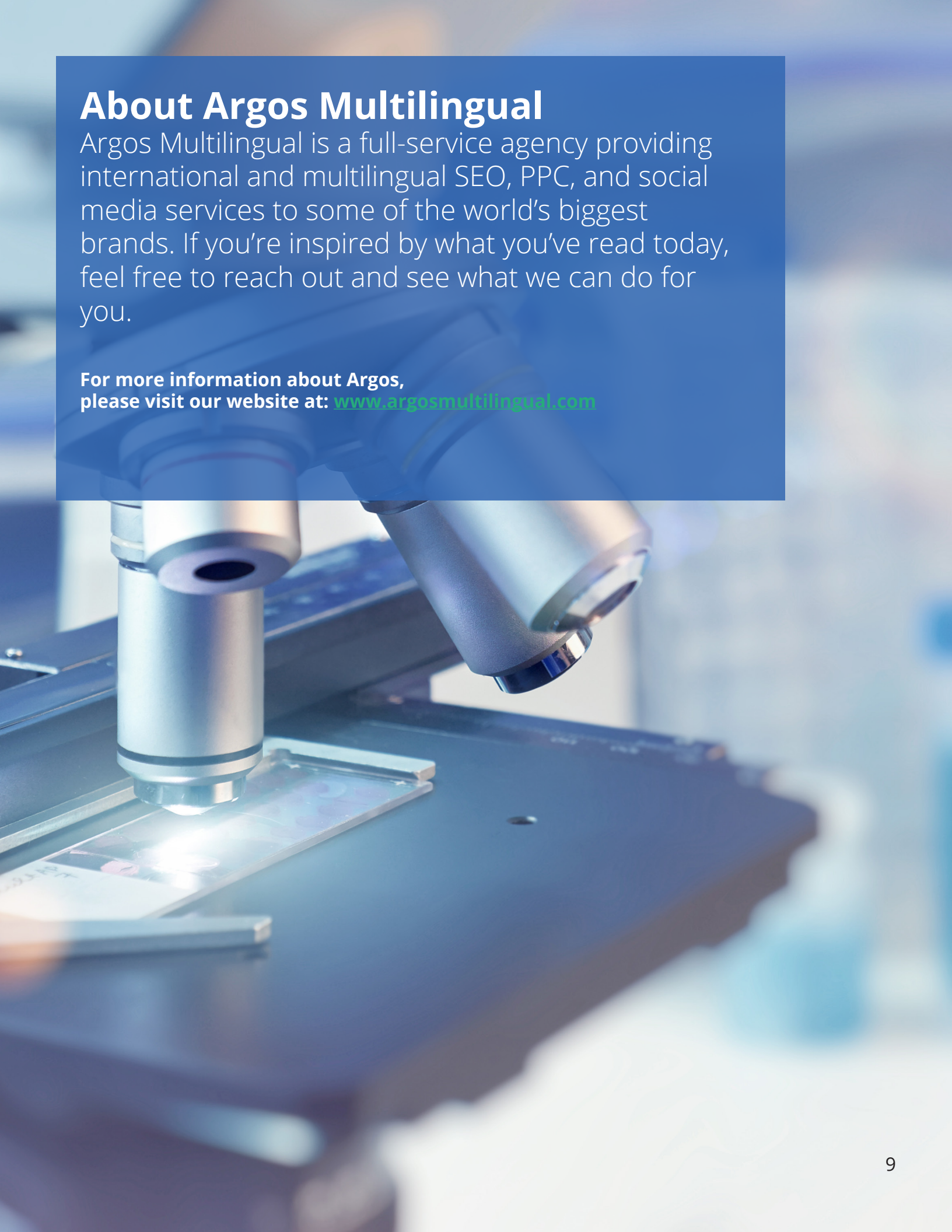
Having done this critical assessment, you can now project the cost by adding up the number of words from your new intended use statement(s) and multiplying by languages involved using per word costs from prior invoices. If DTP is also involved, use the per page cost for all pages to be updated. If you are forced to republish paper manuscripts, web content, or software updates, include the reprinting costs as required.

Future Considerations

Finally, use this latest regulatory challenge to assess the effectiveness and maturity of your overall content strategy. Are you best served by using desktop publishing? Or would a content management system make future updates more automated and therefore less painful and expensive? Are you maximizing the messaging and reuse of your source material by harmonizing your terminology? Are you standardizing authoring to promote a unified message to your customers and reduce your translation costs overall? Is there true parity between your web content and the rest of your documentation?

The only certainty in the field of life sciences is the certainty of many more challenging regulatory changes. Why not prepare to meet those challenges now?

Additional Information
https://www.ivdreurope.com/



About Argos Multilingual

Argos Multilingual is a full-service agency providing international and multilingual SEO, PPC, and social media services to some of the world's biggest brands. If you're inspired by what you've read today, feel free to reach out and see what we can do for you.

For more information about Argos, please visit our website at: www.argosmultilingual.com