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Bill Enos is the Americas Senior Commercial Director, Medical Devices and has been with BSI for more than 15 years. Bill is responsible for leading BSI activities in the medical devices regulatory sector for the Americas region including EU Notified Body, ISO 13485 Certification, Health Canada/ SCC CMDCAS accreditation and MDSAP Auditing Organization recognition. His responsibilities include auditing quality systems and review of technical files and other certification activities related to sterile medical devices. Previously Bill was the Global Head of Microbiology at BSI.

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BSI: Three Tips from the Top European Notified Body

Medical device and *in vitro* diagnostics manufacturers, along with European notified bodies, are all navigating the unprecedented, tumultuous waters of the MDR and IVDR, with the over-arching goal being patient safety. Bill Enos, from notified body BSI, describes his firm's experience and strategy, and provides valuable advice for device manufacturers working to certify products in the challenging and rapidly evolving EU environment.

This year marks a historic time in the European medical device regulatory space. The Medical Device Directive (MDD), originally written in 1993 to harmonize the laws relating to the safety and performance of medical devices within the EU, is being replaced by the Medical Device Regulation (MDR; and the new IVD Directive, initiated in 1998). And, notified bodies (NBs)—organizations designated by EU countries to assess the conformity of certain device products before being placed on the market—are working under unprecedented and still-evolving circumstances. As of January 7, there have only been nine MDR (2017/745) and three IVDR (2017/746) designations, compared to a peak of about 80 NBs that were operating under the MDD in the early 2010s. According to EU Commissioner for Health and Food Safety, Stella Kyriakides, the goal of 20 NBs is anticipated to be reached during the first quarter of 2020. (See *"New EU Health Chief Maintains May MDR Commitment, and Offers Eudamed, Expert Panel Updates,"* Market Pathways, *December 16, 2019*.)

This small handful of organizations is operating amidst a challenging backdrop that includes the looming May 26 MDR deadline, several ongoing designation applications under MDR/ IVDR, manufacturers requesting early renewals of Directives certificates (to take advantage of an MDR grace period for devices with a valid CE mark), a busy pipeline of MDR applications including for higher-risk products, and a general increase in regulatory oversight and scrutiny of NBs by designating authorities.

BSI, a key player in this space, has been proactively preparing to meet the new regulatory assessments, and provide support, input, and oversight to device manufacturers. *Market Pathways* caught up with Bill Enos, BSI's Americas Senior Commercial Director, Medical Devices. "We're working with our manufacturers and clients to set the right expectations for the new requirements and navigate the tumultuous waters that we're all in together, with regard to the MDR and the IVDR. There's no shortage of opportunity for notified bodies in this space," he says. "The big takeaway here is that manufacturers aren't alone in this season of change."

In January of last year, BSI in the United Kingdom (UK) became the first NB to be officially designated under the EU MDR, followed by IVDR designation in October. (Note that the IVDR deadline is two years following MDR—May 26, 2022; the *in vitro* diagnostics space is an unprecedented story of its own, as previously only about 20% of manufacturers were required to have NB oversight of their products, but under the new regulation that number is booming to approximately 80%.) Last September, BSI certified the first device, a Class IIa device (previously classified as Class I), to the MDR via its UK notified body. Its Netherlands-based NB (established by BSI to ensure that could accommodate device companies regardless of the outcome of Brexit) received the MDR designation this past November, and received IVDR designation on December 24. Now, both of its notified bodies—UK and Netherlands—have full scope designation to the IVDR and the MDR. Around one-third of the medical device products

placed on the European market have been assessed by BSI.

The established business improvement and standards company, which handles a variety of sectors beyond medical devices, is being very strategic about where it allocates and grows its staff so that it balances existing and upcoming device and diagnostics customer needs with new business opportunities, says Enos. "At the end of the day, nobody wants to be the bottleneck to safe products being out there on the market for patients. Our desire is to learn and grow and be as expedient as we can, but also as quality-minded as possible so that we're only allowing manufacturers to place the best and safest products on the market under BSI's certification, and protecting public safety."

As Enos explains, the level of clinical and patient safety requirements has increased over the past several years in preparation for the new medical device regulations. "It's been a step-wise approach, and we've seen that as we've been audited as a notified body from our competent authorities," he says. "They increase the level of expectation on the notified bodies incrementally every time they come and audit us. As we then transition those requirements to manufacturers, the hope is that they have increased their level of compliance along the way so it's not as big a shock as it could have been."

In terms of moving products ahead under the MDR, there are some challenges, especially for those products that may be up-classified, says Enos. "Custom-made implants and advanced software as a medical device (SaMD), for example, are now considered as a different classification under the new set of requirements. Manufacturers have a very short timeframe in order to get those products approved and get a certificate in hand to continue to stay on the market in the European space," he says. (Note that a "corrigendum" was finalized in mid-December that gives these up-classified devices more leeway to rely on Directive certificates for up to four extra years; see "*Pathways Picks,*" Market Pathways, *December 18, 2019*).

BSI is not only dealing with the institution and implementation of the MDR, with the IVDR right on its heels, but as a British-based NB it also has been gearing up for Brexit. With its Netherlands-based NB, the certificates it has issued will still be valid whatever the outcome of Brexit and future trade negotiations. "The past few years have been challenging in terms of not only getting our UK notified body designated to MDR/IVDR but also setting up a new notified body in the Netherlands and getting that designated to the three medical devices directives and more recently the MDR and IVDR regulations," said Enos. "In 2020, what I see as a result of that is BSI being positioned extremely well to support the market in getting devices safely into the European space under the medical devices regulation."

He cautions device companies not to be fearful of Brexit. "It just presents different challenges, and hopefully everyone comes together to find ways to navigate those challenges and make trade and other arrangements possible." (*See "Brexit Prep: Five Things Device Firms Must Know if No Deal is Reached,"* Market Pathways, *October 15, 2019.*)

Enos and John Bis, BSI's VP of Medical Device Solutions Sales, who also spoke with *Market Pathways,* offer three key pieces of advice to *Market Pathways* readers trying to compete in the new EU MDR environment:

1 Thoroughly review and understand the full content of the MDR:

The requirements for applications under the new regulation require a higher level of documentation than the old set of directives. The BSI team spends a significant amount of time working with its clients, both existing as well as prospective, to set the right expectations about what the new requirements bring, says Enos.

"Manufacturers can benefit themselves most by taking the time to truly understand what the requirements look like. That will give them a better basis for conversations with their notified bodies, with their own regulatory teams, marketing teams, and quality teams. The better and more well-versed they can be internally with the new, higher level of documentation requirements will certainly help them be effective externally."

2 Submitting first isn't necessarily best:

"Take the time to thoroughly review your technical documentation before you submit to a notified body. The last thing that a manufacturer should want to do is try to race to get that submission in, only to have it come back with questions or potentially having an incomplete file which gets rejected. What manufacturers can avoid is a lot of wasted time and budget in thoroughly preparing ahead of time to ensure that their files are complete before they send them. This preparation will also serve manufacturers well going forward, because then they can apply those lessons learned to all of their subsequent files," says Enos.

3 Invest in yourselves:

In many cases, where there are gaps or weaknesses, there are opportunities out there for manufacturers to look at things like training. "The key to success here is in educating themselves as well as educating those all the way up through their organization, including management," explains Bis. "This can often require that companies invest more in themselves: more regulatory experience, more clinical data, more quality management," he says.

"Having well trained, knowledgeable internal teams will go a long way because notified bodies aren't allowed to consult," adds Enos. "We really only have the opportunity to provide a list of gaps, not necessarily solutions. So the better trained and the more well-informed the manufacturing staff is then that makes the entire review process more streamlined. When it's streamlined, I think at the end of the day, hopefully it costs less, it takes less time and products are to the market and to patients more efficiently."