WHITE PAPER

YOUR FREE EU IVD REGULATION READINESS HEALTH CHECK

DO YOU WANT TO BE ON TIME OR IS IT TOO LATE? IF YOU WANT TO BE PREPARED, YOU HAVE TO DO SOMETHING DIFFERENT.

by Robyn Meurant, James Pink and Lukas Block

Many manufacturers are still underprepared for the new EU IVD regulation. Here are some of the big issues that NSF have found manufacturers struggling with:

- Not understanding which areas of the business are impacted by the new EU regulations
- Not knowing what a change in risk class means for their product and their portfolio (remember, a class change will impact about 80% of IVDs)
- Not yet having engaged a notified body and not understanding how Notified Body Operations Group (NBOG) codes are important in this process
- Unaware of the new requirements for the different actors in the supply chain and associated risk
- Lacking understanding in the role of the person responsible for regulatory compliance (PRRC)
- EUDAMED and unique device identifiers (UDI)
- The unrelenting drive to cut costs yet to remediate technical files for compliance with the new regulations
- Problems with data integrity as some companies ignore their moral compass (thankfully, only a very small minority, but we are all at risk of being painted with the same brush)
- The lack of expertise as those with the understanding of the new regulations are in short supply
- Knowledge of the new (multiple) reports required for compliance
- The need to reengineer quality systems built for a bygone era

Although these challenges are significant, the future offers unparalleled opportunities for those who are well prepared. We have found that best-in-class organizations have a few things in common:

- They prepare early.
- They realistically face the problems ahead; they do not ignore them.
- They invest heavily in skills and competencies. They educate, not train. They seek external expertise if it is not available in-house.
- They demonstrate excellent leadership and teamwork. One team, one purpose, guided by a moral compass that keeps everyone on track, no matter what. A piecemeal approach to the new regulations does not work.
- When mistakes are made, they learn from them, not repeat them.
- They focus on doing the basics (core competencies) very well and keep things simple.

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- Although they know what they are good at, they also know where they must improve.
- They implement improvements with precision and discipline. In these organizations, actions speak louder than words.

To help you prepare for the EU IVD regulation, our free "health check" is your opportunity to assess your EU regulation readiness, the first step for putting things in order. To be prepared for success, all you have to do is:

- Complete this simple health check questionnaire. It will take only 10-15 minutes, but covers each key element for implementing the regulation.
- Publicize it widely. Take it to your next team meeting. Leave copies in your coffee room. Circulate it on your intranet. Put it on your notice board. Ask as many people to complete it as possible. In our experience, you and your colleagues already know your readiness; you just didn't have an opportunity to share this information.
- Just answer each question with a yes or no.
- Any nos should act as a catalyst for action!

Impact Assessment **Have you…**	Yes	No
> Conducted a product portfolio impact analysis and now know which products are greatly impacted by the change to the MDR/IVDR?	Y ☐	N ☐
> Confirmed the new definitions and risk classification rules?	Y ☐	N ☐
> Mapped out the conformity assessment route(s) required and confirmed the notified body application requirements?	Y ☐	N ☐
> Considered how you will justify the amount and quality of clinical evidence for your products?	Y ☐	N ☐

Plans **Quality – Have you established a plan…**	Yes	No
> For the transition to EU IVDR considering the regulatory, registration, supply, quality management system and device technical documentation impacts?	Y ☐	N ☐
Risk Management – Have you established a plan that…	Yes	No
> Considers each device family?	Y ☐	N ☐
> Includes compilation of all assessments of benefit-risk ratios? Undertaken throughout the lifecycle such as design review, change assessment, postmarket surveillance trending, vigilance decision-making?	Y ☐ Y ☐	N ☐ N ☐
Performance Evaluation – Have you established a plan that…	Yes	No
> Takes into account the general safety and performance requirements and addresses the need for generation and gathering of data to support your product safety and performance?	Y ☐	N ☐
> Considers the state of the art in medicine and intends to make a determination of the clinical evidence for your product in order to understand the clinical benefit-risk ratio?	Y ☐	N ☐

Postmarket Surveillance – Do you have a plan for each device type that…	Yes	No
> Works within a postmarket surveillance system, is systematic and enables the active gathering of data as part of the performance evaluation plan, postmarket surveillance plan or postmarket performance follow-up?	Y ☐	N ☐
> Is based upon an assessment of the risk controls applied to the device and actively surveys post-production information to provide confidence that the controls are effective?	Y ☐	N ☐
> Interacts with the risk management and trending systems in order to 'trigger' decisions for benefit-risk and corrective/preventive action?	Y ☐	N ☐
Postmarket Performance Follow-Up – Have you established a plan that…	Yes	No
> Has methods and procedures for collecting data from clinical experience, feedback from users and the scientific literature?	Y ☐	N ☐
> Considers sources such as external quality assurance, other clinical and non-clinical studies, and genetic databases?	Y ☐	N ☐
> References the relevant parts of the PER and the risk management?	Y ☐	N ☐
Regulatory Compliance Strategy Plan – Have you developed a strategy that…	Yes	No
> Considers the potential changes in the European regulatory environment including delegating acts, implementing acts, guidance, harmonised standards and common specifications, as well as more general laws in Europe such as the data protection and cyber security requirements?	Y ☐	N ☐
> Is integrated into the design and development process to confirm that all design requirements include European laws, state of the art testing and clinical data?	Y ☐	N ☐
> Provides clear guidance on how to keep your products in compliance with the regulation through appropriate interactions with the PRRC?	Y ☐	N ☐
Business Continuity Plan – Have you…	Yes	No
> Secured an appropriate notified body that has been designated with a scope that includes your product portfolio?	Y ☐	N ☐
> Or are you in the process of communicating with your notified body to agree a submission timeline for continued supply of product after May 26 2022?	Y ☐	N ☐
> Undertaken a business risk analysis to determine what to do in the event of delay in receiving the IVDR certificate and explored your legal position?	Y ☐	N ☐

Resources **Have you…**	Yes	No
> Evaluated the additional tasks to be conducted to bring your quality management system, technical documentation, and regulatory and registration responsibilities into compliance with EU IVDR?	Y ☐	N ☐
> Estimated the resource impact for generating, gathering and compiling necessary evidence of conformity to the new regulation and communicated to your finance team for budget allocation?	Y ☐	N ☐

People **Have you determined who the person(s) responsible for regulatory compliance will be?**	Yes	No
> Are they capable of being able to supervise and control, as well as carry out the activities associated with being compliant with the EU IVDR?	Y ☐	N ☐
> Are they suitably qualified and experienced to understand the complexity of the regulation, the configuration items such as changes in laws and state of the art?	Y ☐	N ☐
> Are they suitably engaged in the day-to-day business in order to fulfil their duty and provide assurance that the product is in compliance with the regulation throughout its lifecycle?	Y ☐	N ☐
> Have they defined the roles and responsibility for each process in Article 10 and Annex IX Section 2.2C?	Y ☐	N ☐

Performance **Have you…**	Yes	No
> Implemented monitors and measures to track success, identify and manage risks and keep/get your products on the market in Europe?	Y ☐	N ☐
> Started internal audits and self-inspections against the regulation with suitably qualified auditors?	Y ☐	N ☐
> Have you initiated technical documentation mock reviews?	Y ☐	N ☐
• Performance evaluation	Y ☐	N ☐
• State of the art	Y ☐	N ☐
• Core risks and their control	Y ☐	N ☐

Technical Documentation **Are you aware of all the documentation you require to be compliant?**	Yes	No
> Device description and specification	Y ☐	N ☐
> Information to be supplied by the manufacturer	Y ☐	N ☐
> Design and manufacturing information	Y ☐	N ☐
> Information relating to the general safety and performance requirements	Y ☐	N ☐
> Risk management	Y ☐	N ☐
> Product and software verification and validation	Y ☐	N ☐
> A performance evaluation report, defined by a performance evaluation plan	Y ☐	N ☐

Technical Documentation (continued) **Did you know you also need to have:**	Yes	No
> A postmarket surveillance plan drawn up in accordance with Article 79 and Annex III?	Y ☐	N ☐
> Either a postmarket surveillance report or a postmarket update report (and what determines which one you need to have)?	Y ☐	N ☐
> And, if applicable, a postmarket performance follow-up plan?	Y ☐	N ☐
> Do you have an IVD that	Y ☐	N ☐
• Is placed on the market in a sterile or defined microbiological state?	Y ☐	N ☐
• Contains material of biological origin?	Y ☐	N ☐
• Has a measuring function?	Y ☐	N ☐
• Connects to other equipment in order to operate?	Y ☐	N ☐
> If you have answered yes to any of these last four questions, do you know the extra technical documentation you must have to comply with the IVDR?	Y ☐	N ☐

Performance Evaluation	Yes	No
> Do you know the three critical elements of a performance evaluation report and what is required to create them?	Y ☐	N ☐
• Scientific validity report, which demonstrates that the marker/(s) your IVD detects are correlated to the claimed (or inferred) clinical condition	Y ☐	N ☐
• Analytical performance report, which informs how well the IVD detects the markers and how the acceptance criteria for each one was established	Y ☐	N ☐
• Clinical performance report, which informs us how the clinical claims were derived	Y ☐	N ☐
> Do you know how to perform a valid literature search and which reports can benefit from information in the literature?	Y ☐	N ☐
> Do you know how to determine the risk-benefit ratio?	Y ☐	N ☐
> Do you understand the meaning of clinical benefit for an IVD and how it differs from that for a medical device or a medicine?	Y ☐	N ☐
> Do you know what state of the art is? And where you find evidence for what is accepted state of the art in medicine?	Y ☐	N ☐

Clinical Performance Studies	Yes	No
> Have you established the necessary level and quality of clinical data you need to generate or gather?	Y ☐	N ☐
> Do you know how to develop IVDR-compliant clinical performance study plans and reports?	Y ☐	N ☐
> Do you know the new requirements for interventional performance studies?	Y ☐	N ☐
> If you are the sponsor of a clinical performance study,	Y ☐	N ☐
• Are you aware of how long you should hold on to relevant documentation?	Y ☐	N ☐
• Have you identified a study monitor?	Y ☐	N ☐
• Are you based in the EU or have you assigned your duties to an authorised person?	Y ☐	N ☐

NEXT STEPS: SCORING

Write down the areas where you scored "No":

> Are these areas featured in this year's goals and action plan?	Yes ☐	No ☐

Write down who can help you address these areas of concern. What do you need to tackle these concerns?

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ABOUT THE AUTHORS

James Pink has over 20 years of experience in the medical devices industry including 10 years as a health care technology expert and lead auditor for a leading European notified body. He began his career as a product designer in the oil tools industry moving into medical physics and clinical engineering at the Royal Hallamshire Hospital in Sheffield, UK. Industry experience includes managing product development and quality assurance programs for active and non-active implantable and combination products. Mr. Pink is a contributor to several medical device standards committees including ISO 13485, ISO 14971 and various product-related standards.

Robyn Meurant has more than 30 years of experience in the field of IVDs, as a laboratory scientist and as a regulator with the Australian Therapeutic Goods Administration (TGA) and with World Health Organization (WHO) Prequalification. Ms. Meurant began her career working in several large diagnostic laboratories in the role of senior scientist. In her position at TGA, Ms. Meurant assisted in developing the new regulatory framework for IVDs. With WHO, she served as the lead technical officer for application evaluation and dossier assessment, and as lead for the development of guidance and technical specifications for IVDs in the scope of WHO Prequalification. In addition, she has contributed to standards development and has been a source of expert advice to the Australian government on IVDs. In 2009 she was awarded the Distinguished Service Award by the Australian Society for Microbiology.

Lukas Block has managed projects implementing Medical Device Regulation (EU) 2017/745 and has expert knowledge in the interpretation and application of the new regulatory requirements. He has worked with a wide range of medical devices throughout the entire product lifecycle and supported manufacturers in development, manufacturing, approval, monitoring and change management. He has also prepared technical documentation for national and international approvals, including risk management files, usability files and clinical evaluation reports.

We hope you find this health check useful. If you need any more guidance, help or support, please get in touch. That's what we're here for. Contact **healthsciences@nsf.org** or visit **www.nsfhealthsciences.org**

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