Jonathan Hughes - Interview Revisited

Jonathan Hughes - Credentials & Experience: *With 35 years of regulatory experience with wound care companies, Jonathan specialises in regulatory strategy, regulatory and clinical development pathways, worldwide regulatory submissions and training. He has worked with all the major international regulatory agencies, in particular US FDA, Japanese PMDA, Chinese NMPA, Notified Bodies and EU Competent Authorities. More recently Jonathan has worked on a range of medical devices across varied medical specialties covering active and non-active devices, IVDs and software such as medical apps (diabetes apps), decision support software and apps for asthma inhalers.*

Wound Market Consulting's Senior Regulatory Consultant Jonathan Hughes has revisited the Regulatory Landscape as of June 2024.

1. From experience what is one of the greatest barriers to entry into the wound care market?

Determining what clinical data is required. Is a clinical investigation required? The MDR has incorporated previous guidance such as MEDDEV 2.7.1 Rev 4, but this is now more rigid when companies are basing their applications on the argument of equivalence with another product. It is no longer sufficient to be 'similar' to previous products to use their data. Class III goes one step further; companies are only now permitted to use the equivalence argument if they have a contract with the competitor. This has meant more clinical investigations are now likely to be necessary.

2. What is the most common mistake often made by industry when submitting applications to notified bodies?

Although it sounds obvious, take the time to review your applications. Ensure that your technical documentation has been written with the audience – the reviewers - in mind and that it serves the purpose for what it was intended. Some notified bodies have their own templates that require specific formatting.

Try to step outside the box and ask yourself - Is it easy to read? To understand? To locate the relevant information that supports your application? Simple formatting errors can make what should be a simple application difficult to read. Reviewer resources are stretched and don't have time to search out information – they will issue a non-conformity if something is not obvious or easy for them to locate (even if they are there, somewhere). Make their job easier!

3. Have you found the level of detail required by the Medical Device Regulation (MDR) more comprehensive than that of the Medical Device Directive (MDD) for all classes?

Yes. The requirements are clearer in some respects but broader and more stringent. Many of the new regulations were already included previously in guidance documents but they have now been incorporated. In principle, many companies should have been following this guidance already.

The MDR has created a more level playing field for notified bodies. The notified bodies themselves are under more scrutiny and subsequently they are applying more rigour to their review of manufacturers and are less likely to take risks. Some feel that notified bodies have become less pragmatic and this has made it difficult to discuss and debate with them as a result. Prior to the MDR there were more than 70 notified bodies and now there are 49 (June 2024), with the MDR/IVDR resulting in a large recruitment drive for reviewer staff to meet demand. Unfortunately, this has subsequently meant that assessments now seem to be being completed on more of a "checklist" basis, as opposed to a more considered, pragmatic and informed approach taking all the evidence before them. The medical device classification system in most parts remains unchanged. There are some new classification requirements for certain devices (e.g.: devices containing substances that may be dispersed in/on the body, delivery devices and software) that have meant they have been re-classified (or "up-classified") from class I to class IIa or higher. Once classified, the conformity assessment route/pathway options are also broadly similar, with the higher risk-based classification requiring greater regulatory controls.

4. Quite often the notified bodies' response is to collect more evidence and data which is expensive and time consuming. Industry appears to be fighting tooth and nail to avoid this. Is this the sensible approach or should industry accept what notified bodies are asking of them?

Each case should be reviewed and judged on its own merit, so it is difficult to generalise. There is always going to be an element of back and forth with any notified body. Companies need to complete a strategic assessment of the likelihood of their application being successful. For some companies it might be quicker to complete any "big ticket" items such as clinical investigations before submission rather than run the risk of submitting without and incurring significant delays during the review process. This really depends on the business' appetite for risk. How much do you want to battle with the notified bodies? It could be more sensible to pick your battles. For significant issues, communicating with the notified body upfront is strongly recommended – while the notified body is not allowed to provide consulting advice, if presented with a plan they may be able to provide some degree of feedback as to likely acceptance of such plans.

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5.Is there an area of expertise/industry that still requires addressing in 2024? It still remains a difficult task to get "legacy devices" through the transition process to MDR/IVDR. The Commission eventually realised that this would lead to issues with device availability and ultimately impact patient care. They have issued some additional transitional arrangements, but they still remain difficult to interpret and follow. I suspect there will still be many companies and devices that will not meet the new transition arrangements and so the problem will not be resolved entirely. This is partly due to the additional, incremental requirements being demanded by the notified bodies, without alternative pragmatic approaches being considered. While improvements in the regulations were needed, some of the requirements that are being applied, especially to lower risk class devices, have increased significantly and have become too difficult or too expensive for some companies to manage. This may result in both a reduction in availability of legacy and innovative devices. Unfortunately, the loser here is not just industry but also patients. I believe the EU Commission still need to reform the MDR/IVDR to take account of the "over-regulation" of medical devices, and to allow a more pragmatic, scientific and risk-based approach to be applied. This needs experienced reviewers who are able to evaluate medical device risk benefit profiles, without relying simply on a rigid checklist-type approach.