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A SMART WAY TO TACKLE REGULATORY COMPLIANCE

EVNIA

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CEO

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A SMART WAY TO TACKLE REGULATORY COMPLIANCE

By Stacey Smith

"There are in fact two things, science and opinion; the former begets knowledge, the latter ignorance." — Hippocrates

The Life Sciences industry is at an inflection point, particularly in today's pandemic-stricken world. From data-driven technologies to the integration of artificial intelligence, innovation is the key driver of progress for this sector, especially when dealing with medical devices. However, innovation without proven safety is non-applicable. This is why strict regulations have been enforced by governments globally to ensure both patients and medical personnel are protected. While these regulations aim to eliminate risk and enhance transparency, they also put a major dent in the time to market of novel products—something that is being felt in the current COVID-19 crisis.

Dr Efstathios Vassiliadis, the founder and CEO of Evnia, a leading-edge consulting company in the regulatory and clinical affairs, observes, "Manufacturers often have systemic gaps in several parts of the medical device value chain, such

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as research and development, clinical evidence, and documentation production. This results in lengthy and expensive remediation activities that also result in significant delays." He also notes that many products that are already in the market–often for years–lack clinical evidence to support the safety and performance claims or have gaps in their technical documentation. As a result, the slew of incompetencies hampers the quality of those products and, ultimately, the quality of patient care. To address these compliance-related issues and help new products reach patients faster, Dr Vassiliadis emphasises the importance of proactive clinical activities.

This is why he started Evnia–to help medical device companies bridge regulatory gaps and ensure patient safety. The company specialises company specialises in clinical evaluation, regulatory and technical documentation services, as well as regulatory management for medical devices and in-vitro diagnostics. Evnia, which in Greek means smart and articulate thinking, intelligently supports manufacturers' efforts in introducing innovative devices to the market and ensuring that their existing devices fulfil all regulatory expectations.

Dr Vassiliadis firmly believes that innovation and quality must always be inseparable and that the way to realise this is through compliance. He adds, "When compliance and clinical evidence are proactive and well thought through, the cost and time to market are significantly reduced, while patient benefits are maximised." On this premise, Evnia transforms clinical and technical data into actionable intelligence that is used to create a robust compliance base for organisations. Once on solid ground, they are able to innovate at optimum cost and in a time-efficient manner, while enhancing the trust and transparency for both the caretakers and patients. "We act as a catalyst for organisations, helping them bring novel solutions to patients faster and in a compliant way. We also help ensure that existing products are safe and performing as intended," states Dr Vassiliadis.

Our CER process consists of a proven set of templates and procedures, executed by industry experts, to cover all of the regulatory expectations of an organisation

The core competency of Evnia includes developing and maintaining compliant clinical evaluation reports (CERs), together with supporting documentation for medical devices of all classes to help organisations comply with MEDDEV 2.7.1 REV4 and the upcoming MDR. CER is one of the most crucial documents, as every medical device company that currently sells or sponsors products in the European Union needs to produce and maintain a compliant clinical evaluation report throughout the product lifecycle.

Evnia offers a holistic solution for conducting efficient clinical evaluation plans, reports, and supporting documents. "Our CER process consists of a proven set of templates and procedures, executed by industry experts, to cover all of the regulatory expectations of an organisation," assures Dr Vassiliadis. Be it Summary Technical Documentation (STED) or a customised

structure, Evnia's technical documentation covers the full spectrum. Dr Vassiliadis adds, "Technical documentation was, often, a moving target for us because, in order to conduct our primary objective of developing compliant CERs, we needed those documents in a compliant state. Hence, we took the onus of developing the complete set of technical documents that medical device manufacturers need to submit to the regulatory authorities to ensure the optimal outcome."

To complicate the matters more, on 25th May 2017, In Vitro Diagnostic Regulation (IVDR) came into effect, now requiring in-vitro diagnostic (IVD) medical device manufacturers to update their technical documentation and comply with the new, more stringent regulation by May 2022. The new regulation addresses some of the challenges posed by the In Vitro Diagnostics Directive (IVDD), including a new rule-based classification system for products, superseding the current list-based approach. So, Evnia provides IVDR services that consist of a Performance Evaluation Plan (PEP) and a Performance Evaluation Report (PER), enabling IVD manufacturers to continually demonstrate their scientific validity and enhance analytical and clinical performance of an IVD device, while exposing any potential gaps or risks.

"We are working extensively on the IVDR to help our clients keep up with the enhanced regulatory requirements for their IVD devices," says Dr Vassiliadis. Meanwhile, the company also guides manufacturers through the preparation of the respective technical documentation (as per Annexes II & III) to achieve IVDR compliance. Finally, Evnia offers project and regulatory management services to establish effective collaboration between multiple processes and departments for a seamless and streamlined workflow.

A Team of Like-Minded Individuals with Cross-Functional Capabilities

What makes Evnia a leading solutions provider for all regulatory and clinical related issues that medical device and IVD manufacturers may experience is its team. A team of experts with different competencies who work together synergistically. Unlike competitors that only have medical writers to develop CERs, Evnia boasts of a cross-functional team—medical writers, medical doctors, usability and validation engineers, and biocompatibility experts—who help bring innovative solutions to market safely and efficiently. "Evnia is an organisation of like-minded people who are all committed to patient safety and quality of care," states Dr Vassiliadis.

Evnia's cross-functional team works on every detail of complex regulatory processes to safeguard an organisation's interests. For organisations that already have the technical know-how to develop CER themselves, Evnia acts as a second pair of eyes to ensure that critical information related to the safety or performance of devices on the market is included.

Since 2015, Evnia has completed more than 300 CERs for companies operating in the Life Sciences industry. Dr Vassiliadis shares a customer success story of a client that required a vast number of clinical evaluation reports in a short amount of time after new regulations for medical devices came into effect. Evnia offered a model of previously refined templates and processes that were compliant with the regulations, enabling the client to fulfil all criteria for safety and performance faster. "Our team delivered a large number of clinical evaluation reports in record time, always within budget and with a compliant outcome," adds Dr Vassiliadis.

With its extensive experience in developing clinical and technical documentation, Evnia is now focusing on initiating clinical investigations and clinical trials to generate evidence that can support its evaluation process. "We are committed to creating the necessary data and evidence to ensure that the circle of trust is always complete so that the patients can always receive better quality of care," concludes Dr Vassiliadis. Ph

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