

3Analytics Partners With AssurX to Revolutionize IMDRF Coding Using AI

The IMDRF Coding solution integrates seamlessly into AssurX EQMS, ensuring compliance with EU MDR and FDA guidelines while reducing costs by up to 72%.

SILICON VALLEY, CA, UNITED STATES, March 10, 2025 /EINPresswire.com/ -- 3Analytics, the first AI

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Dr. Dharani, CEO and Co-founder of 3Analytics

enabled eMDR solution, today announced a strategic alliance with AssurX, Inc., a renowned provider of regulatory compliance software for quality management system (QMS), to enhance the complaint handling process using IMDRF coding.

International Medical Device Regulators Forum (IMDRF) coding is an integral part of Medical Device Compliant Handling. The complex process involves referring different annexures and finding the accurate code for the issue manually, by an experienced professional.

3Analytics' IMDRF Coding Solution simplifies medical device complaint management with AI-driven automation. By assigning accurate IMDRF codes in real-time, it minimizes human errors, handles multiple allegations effortlessly, and ensures compliance with evolving regulations. Adaptable to EU MDR and FDA guidelines, this solution integrates seamlessly into existing workflows, enhancing safety signal detection, efficiency, and regulatory accuracy while cutting costs by up to 72%.

This innovative solution is integrated within the AssurX Enterprise Quality Management System (EQMS) software and generates six codes for each annexure based on contextual understanding rather than mere keyword extraction. Some benefits include minimal human intervention, enhanced processing efficiency, and 100% compliance with the EU MDR guidelines in real time.

Dr. Dharani, CEO and Co-founder of 3Analytics, recognized that by automating the complex process of IMDRF coding he could significantly minimize the amount of time required to find the accurate code. It currently is done manually by a professional that involves a level of expertise of understanding the IMDRF codes and adapt to updated version releases twice a year.

“The IMDRF coding process is a time-consuming process which requires human intervention to

understand the given context and interpret the exact code from the annexure,” said Dharani. Having an eQMS software partner that can help us deliver this unique yet powerful solution to the market was critical to our success. AssurX was the right vendor choice.”

“Working with skilled compliance experts like 3Analytics gives our mutual customers the advantage of more than just having compliance guidance and a comprehensive software package; this synergy ensures that compliance activities are designed to leverage the integration and automation possible with AssurX eQMS,” says Eric Cooper, AssurX Chief Technology Officer.

ABOUT 3ANALYTICS

Founded in January 2020 in Silicon Valley, CA, 3Analytics Inc. is dedicated to making drugs, vaccines, and medical devices safer while saving lives through the power of Artificial Intelligence (AI), global data aggregation, and a team of passionate multidisciplinary experts. The company’s GxP-compliant AI-driven platform revolutionizes patient safety by offering advanced solutions for literature surveillance, signal management, IMDRF coding, and complaint processing. With automation powered by AI/ML/NLP, multilingual support in over 100 languages, and seamless integration with public safety data sources, 3Analytics delivers tailored solutions across drug safety, medical devices, cosmetovigilance, and vaccines, ensuring proactive risk management and global regulatory compliance. At its core, 3Analytics is committed to transforming healthcare by leveraging innovation and fostering collaboration to drive patient safety and industry excellence. To learn more about 3Analytics IMDRF Coding solution, [visit www.3analytics.com](https://www.3analytics.com)

ABOUT ASSURX INC.

With decades of expertise built into our extensive quality management and regulatory compliance software, the [AssurX Quality Management Software](https://www.assurx.com) Platform helps companies maintain quality and compliance standards, streamline workflow and better manage any enterprise. Our configurable software and understanding of users’ needs produce a unique system that easily adapts and scales as a customers’ business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. To learn more, [visit: www.assurx.com](https://www.assurx.com).

Colleen Nugent

AssurX

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