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The Navigator for Enterprise Solutions

ENTERPRISE RISK MANAGEMENT SPECIAL SEPTEMBER 13, 2017 CIOREVIEW.COM

## 20 Most Promising Enterprise Risk Management Solution Providers - 2017

Enterprise Risk Management is taking the center stage in how companies run their business. Advancements in cognitive technologies, artificial intelligence and data analytics are helping organizations go beyond traditional ways of managing risks by using smart machines to detect, predict and prevent risks. Today, since the entire nature of the risk discipline and their consequences are evolving, organizations should look beyond regulation and cost-reduction and view risk management as a strategic element of their value chain.

Some of the smart devices that comprise the Internet of Things (IoT) and artificial intelligence (AI) have the capability to help organizations detect risk events, derive crucial risk insights and even take immediate actions—resulting in a real-time, pervasive, dynamic risk management environment. With a predicted 20.8 billion connected devices in use by 2020, new GRC challenges abound. IoT developers often overlook security. As cloud computing grows in popularity, the landscape is moving toward XaaS—everything as a service. This will transform business value chains, as data will be able to flow seamlessly

and securely across different platforms and infrastructures. The transition to the modern cloud and hyperconvergence not only strengthens their focus on data privacy and security, but also improve the transparency of audits, legal, and regulatory compliance, while refining business continuity planning. On the other hand the risk intelligence gathered from AI and machine learning platforms will also lead organizations to achieve higher levels of performance.

In recent years, since workforces become more mobile, businesses demands new frameworks to deal with the risks and requirements in terms of security, authentication measures, infrastructure security, data encryption, and country-specific regulations. Witnessing this growing challenge and opportunity, myriad of risk management solution providers have emerged to offer their powerful tools that is supported by latest technologies.

Our selection panel has evaluated hundreds of enterprise risk management solution providers based on the ability to assist CIOs and enterprise holders in overcoming the challenges in the sector.

We present to you CIORReview's 20 Most Promising Enterprise Risk Management Solution Providers 2017.



**Company:**  
GessNet™

**Description:**  
Software solutions and expert consulting in medical device safety, cybersecurity, quality and regulatory compliance risk management

**Key Person:**  
Fubin Wu  
Co-founder

**Website:**  
gessnet.com

## GessNet™ De-risking Medical Products

As network-connected medical products become a key cornerstone for modern healthcare systems, medical device and drug manufacturers are facing increased challenges to manage risks of safety, cybersecurity, quality and regulatory compliance. An effective risk analysis involves multiple tools, including Hazard Analysis, Fault Tree Analysis, Failure Mode and Effects Analysis, Risk Traceability Analysis and more. This makes it difficult to connect all output cohesively and maintain it together, reusable and in sync throughout the product life cycle. The connected medical products and its derivatives require risks can be managed at individual derivative product, subsystem, component, or use environment level, as well as be integrated and connected systemically. The complexity of today's medical products and its continuous evolving use environments make risk management error prone, which can lead to product recalls, new product regulatory approval delays, and/or other regulatory or legal problems. Addressing all these issues is GessNet™, a company founded by people who have worked in the medical industry for many years, providing software solutions and expert consulting for medical product risk management.



Fubin Wu

“Based on engineering science for safety, TurboAC™ is specifically designed for medical product risk management, and is highly flexible and configurable for generating various reports to meet various regulatory compliance or business practice needs”

Being equipped with all you need risk analysis tools, GessNet's TurboAC™ automates, streamlines safety and cybersecurity risk management activities, maintains records and results throughout the product life cycle. It makes it easy for manufacturers to adhere to industry standards (e.g. ISO 14971) and FDA requirements, and integrates safety assurance case method into the risk management process as needed. With TurboAC, multiple processes, including hazard analysis, security threat and vulnerability analysis, fault tree analysis, attack tree threat modeling, failure mode and effect analysis, safety and security risk assessments, assurance case development, post market product risk vigilance and risk management file maintenance, can all be performed jointly in one electronic system throughout a product life cycle. Also, the risk information

can be analyzed and reported in multiple formats to suit various needs. “Based on engineering science for safety, TurboAC is specifically designed for medical product risk management, and is highly flexible and configurable for generating various reports to meet various regulatory compliance or business practice needs,” remarks Fubin Wu, Co-Founder. In addition, the company's risk management consultants help manufacturers gain the latest insights for staying ahead of the curve in industry's best practices for safety, regulatory compliance, time to market, and engineering productivity.

As an innovative risk management solution, TurboAC has quickly gained recognition by professionals of medical device and pharmaceutical manufacturers ranging from large corporations (such as Medtronic PLC) to small startups across the globe. For instance, Cellnovo, a British mobile diabetes management system company, wanted to link Failure Mode and Effects Analysis (FMEA) with Hazard Analysis to ensure cohesiveness and transparency in information. “Cellnovo originally trialed a number of different risk management and safety Assurance Case software packages but quickly discovered there was no single package that fulfilled all of our needs,” says Ross Gunton, Safety Engineer, Cellnovo. “The automatic generation of Assurance Case Graphics and Fault Tree Analysis within the tool represents a huge augmentation in performance.” Gunton further states that since installing the GessNet TurboAC software, the training and customer support received from the team at GessNet has been of the highest levels. Online facilities, screen sharing and remote access tools were made available by GessNet to assist clients with any questions. More recognition can be found at <http://www.gessnet.com/testimonials>.

Having served many manufacturers over the years, GessNet's mission has always been to advance medical product risk management and make it a competitive advantage for the clients. Moving forward, the firm plans to build on their mission. Wu reckons that risk management is the central intelligence unit for medical product manufacturers to implement risk driven quality and business management systems, and risk management should be connected to any safety related systems or information intelligence centers to comprehensively manage risk. “Our future releases will continue expanding TurboAC's connectivity to other electronic systems or information centers,” concludes Wu. CR