MethodSense Welcomes Medical Device Innovator Dr. Anna Galea as Senior Regulatory Strategist

Life science veteran to guide clients through complex submissions and accelerate development of AI/ML-enabled medical technologies

MORRISVILLE, NC, UNITED STATES, August 7, 2025 /EINPresswire.com/ -- MethodSense, Inc., a leading provider of regulatory, quality and technology solutions for the life-science industry, today announced that Anna M Galea, PhD has joined the firm as Senior Regulatory Strategist. Dr. Galea brings more than two decades of experience guiding breakthrough devices and combination products from concept to market across the United States, Canada and the European Union. Her portfolio includes 45 U.S. patents, 23 peer-reviewed publications and leadership of global, multi-disciplinary teams at BlueRock Therapeutics, United Therapeutics and other high growth innovators.

As Senior Regulatory Strategist, Dr. Galea will serve as a primary client interface on complex submissions, mentor MethodSense's growing consulting team and shape regulatory strategies for emerging technologies such as AI/ML-enabled devices and advanced combination products. She will also collaborate on product road-map priorities for LuminLogic®, MethodSense's compliance-management SaaS platform.

During her tenure as Vice President of Device Development & Manufacturing at BlueRock Therapeutics (a Bayer company), Dr. Galea directed global partners across eight sites, managed

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> *Dr. Anna Galea, MethodSense Senior Regulatory Strategist*

the organization's largest development budget and led device components of cell-and-gene combination products. Previous roles include Senior Director & Chief Scientist at United Therapeutics' Lung Biotechnology PBC, where she advanced a total artificial lung program from early concept to clinical readiness.

"MethodSense's philosophy of embedding with each client team and treating their challenges as our own, mirrors how I've worked my entire career," Dr. Galea said. "With LuminLogic, we can pair that mindset with a platform built for AI-ready, machine-readable submissions and help companies navigate the FDA faster, with less risk."

"Anna's rare blend of engineering depth, regulatory vision and team-building skill strengthens every dimension of our practice," said Rita King, CEO of MethodSense. "Her arrival underscores our commitment to pairing seasoned expertise with modern tools so innovations can reach patients sooner."

In addition to her industry achievements, Dr. Galea has secured 66 U.S. research grants and contracts, partnering with more than 30 clinical and academic groups worldwide. She holds a PhD in Biomedical Engineering and an MS in Quantitative Physiology from Harvard University, an MS in Electrical Engineering from MIT and a BS in Biomedical Engineering from the University of Toronto.

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About MethodSense
MethodSense is a regulatory and quality consulting firm specializing in the medical device and life sciences industries. With deep expertise in FDA, EU MDR, and global regulatory pathways, MethodSense helps companies achieve compliance, accelerate market entry, and ensure product quality. Its LuminLogic® compliance management platform integrates regulatory processes, quality management, and lifecycle documentation into a seamless solution for achieving regulatory success.

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