NEWS RELEASE

Frank Falcione, EMBA, Joins Pittsburgh-Based Contract Research Organization, Clinical Research Strategies, LLC as Senior Executive Quality and Risk Management Consultant

Pittsburgh, PA – August 27, 2021. Clinical Research Strategies, LLC ("CRS"), a Pittsburgh-area-based, US-owned and operated contract research organization (CRO) and executive management consultancy for the life sciences industry is pleased to announce the addition of **Frank Falcione, EMBA**, Senior Executive Quality and Risk Management Consultant, to the firm. Frank has 30 years' experience as a senior executive working in domestic and international regulatory compliance, inspection-readiness, regulatory negotiations, quality management systems, and new product development within start-up medical device companies, military applications, and diagnostic instrumentation.

Photo by *Jen Worley*

Mr. Falcione has contributed more recently to the implementation of MDD Class IIb and III devices for CE approval, transition to EU MDR conformance, and FDA Class III Modular PMA submissions. Additionally, he led quality programs for inspection-readiness, on-site and virtual audits and inspections, and face-to-face regulatory meetings. He remains actively involved in teaching regulatory/quality and product risk management at local colleges and universities and contributing to the development of young entrepreneurs.

"Frank has significant experience in clinical, regulatory, risk management, and quality programs at a class III medical device company, and our clients will greatly benefit from the breadth of his knowledge, especially in the areas of risk management, domestic and international device submissions and registrations, quality systems and inspections," says Alethea Wieland, president and co-founder.

CRS co-founder and chief quality and regulatory officer, David Link, MBA, remarks, "As indicative or our global growth in consumer products, software as a medical device, Internet of things, digital therapeutics, federated medicine, and novel, *first-in-class* devices and diagnostics, Frank is a welcomed authority to accelerate growth of our quality and regulatory consulting practices at CRS."

About Clinical Research Strategies, LLC: CRS is a specialty CRO and executive management consulting firm that fits-for-purpose veteran life sciences executives, attorneys, regulatory scientists and strategists, clinical operations, project management, quality assurance engineers, and sales and marketing teams to take on the biggest challenges for start-up, mid-sized and large life sciences companies. Service areas are drug dossier submissions, clinical trials, Functional Service Provider (FSP) models, selection and management of CROs, regulatory compliance strategy and submissions, QMS, EU MDR and GDPR, rescue trials, TMF, risk mitigation and remediation, inspection-readiness, training high-performing teams, staffing solutions, and decentralized trials.

Indications represented are precision medicine, immuno-oncology, central nervous system, infectious diseases, respiratory diseases, orthopedics, de novo devices, digital health and mobile apps, reproductive health, regenerative medicine, cardiology, major depressive disorder, opioid-sparing pain, cannabis, radiology, and critical care. CRS is a qualified service provider for US federal grants.

CRS is an inclusive employer and does not discriminate in employment on the basis of race, color, religion, sex, gender identity, national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, education, membership in an employee organization, parental status, military service, or other non-merit factor. CRS does not tolerate censorship, surveillance, bullying, intimidation, retaliation, discrimination, or harassment of any kind.

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