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Penny Northcutt, RAC, FRAPS, CQA**,** President/CEO, **REGSolutions, LLC** has more than 37 years as a regulatory affairs professional. She provides regulatory solutions and quality systems for the medical device industry, supporting both large and emerging medical device companies. Penny has managed a team of independent consultants ranging from 1-12 which adds another 80+ years of technical experience to her team. She has successfully led REGSolutions teams to service greater than 100 clients in the 12 years REGSolutions, LLC has been in business. Visit our website at www.pennynorthcutt.com.

Penny's company, REGSolutions, specializes in unique regulatory strategies where skillfully written submissions speed the process of bringing new medical devices through hurdles in this ever changing regulatory environment. Penny Northcutt is an expert in US device submissions [510(k), IDE, HDE, PMA, and DeNovo] and interface with the FDA administrative processes and regulations. Her reputation has led to many companies enjoying an expedient pathway to US market. Penny also has many years of experience with EU CE mark, EU MDR and Technical File builds where a success-to-market pathway and strategy must often be negotiated with the Notified Bodies. As EU Medical Device Regulation comes about in 2020, REGSolutions is assisting clients transition their systems, legacy products, training, and product registration to compliance from MDD to EU MDR.

The other arm of her business is devoted to creating and implementing ISO 13485 quality management systems and working with small companies to create their technical files and obtain CE marking. Recently a number of projects have also required Quality Programs with compliance to 21 CFR 1271 and AATB Guidances. REGSolutions, LLC has successfully built their reputation on successful medical device registration submissions for market entry in the USA, Canada, European (EU) and various Rest-of-World countries. Penny and her team have helped numerous companies transition from a paper-based Quality Management System to electronic software-based. The software-based systems are known to strengthen a company's compliance capability. Additionally, Penny's experience in regulatory/quality compliance has recently been valuable in CAPA remediation projects to bring companies and their quality systems into compliance when they are faced with an FDA 483, Warning Letter violations, or Consensus Decree.

Penny holds a Bachelor of Science degree from Mercer University. Penny was appointed as a RAPS Fellow (FRAPS) in 2009; a distinction only senior regulatory professionals receive for their continued significant contributions and leadership in advancing the profession. She has received two Regulatory Affairs Professional Society (RAPS) certifications (EU and US) and is active in the regulatory affairs profession as the RAPS Atlanta Chapter Chairperson for the last 8 years. She is also a Certified Quality Auditor (CQA) through the American Society for Quality (ASQ). In 2007, Penny was awarded the Leonard Stauffer Award from RAPS. This award is given to an individual that goes above and beyond in mentoring and professional training in the regulatory field.

Ms. Northcutt's vast experience as a subject matter expert in product development/design control/quality systems (including with Greenlight Guru Software) for medical devices (Class II and III) and client liaison project management skills along with the REGSolutions. LLC team's expertise would be very beneficial for any product development efforts from a start-up to well establish companies.

She can be reached at *penny@pennynorthcutt.com* or 678-428-6978.