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Anson Group adds Patrick Mooney, RAC as a Regulatory Consultant

(INDIANAPOLIS IN) June 11, 2010 – The Anson Group announces today the addition of Patrick Mooney to its growing team of experienced life science consultants. Mr. Mooney joins Anson Group as a Regulatory Consultant after his recent retirement from Eli Lilly and Company. He has worked in the pharmaceutical industry since 1982, and has had a range of responsibilities for a broad variety of pharmaceutical products.

Early in his career, Mr. Mooney worked as a molecular biologist in Lilly Research Laboratories, performing complex experimentation in gene cloning and expression to develop gene expression systems for bio-engineered proteins and to develop potential in vitro targets for drug discovery.

In 1991, he transitioned to a role as a Medical Writer, in which he served as part of teams of clinical researchers to analyze clinical data to write and edit complex clinical research submission documents in support of clinical trials and marketing applications. In his role as medical writer, he began his collaboration with cross-functional Lilly Research Laboratories and information technology teams to develop and implement electronic publishing and electronic submissions technology and business processes.

In the mid-1990s, Mr. Mooney transitioned to Senior Regulatory Associate role, serving as a regulatory submission coordinator in Global Regulatory Affairs at Lilly. He was responsible for the planning and development of submission documentation, and managed the publishing staff for numerous US IND, NDA, sNDA, and BLA submissions, as well as European, Canadian, and other regulatory submissions. This included early clinical and late/registration phase development stages for drug and biologics submissions across many therapeutic areas. In this role, he also established strategic direction, including policies and procedures, regarding the use of submission-document authoring and publishing and submission publishing software applications.

Mr. Mooney's work in the arena of complex submission processes led to a new role in which he served as business architect, subject matter expert, and consultant for submission publishing and authoring tools and processes. In this role as business architect, Mr. Mooney coordinated development and support activities between information technology and regulatory affairs, clinical research, CMC, toxicology research, and discovery biology research. He worked extensively in the development and integration of business processes and

software applications that supported many aspects of regulatory operations, including document creation, submission publishing, preparation of FDA-compliant electronic analysis datasets, regulatory response tracking and management, and CTD and eCTD compilation. In addition, he participated in due diligence activities with potential business partners, and he served as a consultant on submission issues for Lilly's external business partners.

"We are excited to have Pat join the Anson team and bring his skills and knowledge of regulatory information technology to the practice" states Anson Group Managing Partner, Colleen Hittle. "The importance of information technology in meeting the challenges of life science regulatory requirements are important talents and experience that Pat brings to Anson from his years of real world experience inside a major pharmaceutical company. That type of experience will be invaluable for our clients who are struggling to deal with the complexities of both data and software functionality involved in compiling an electronic submission."

About Anson Group

Headquartered in Carmel Indiana, Anson Group is a minority-owned independent consulting organization with over 14 years experience as a leading provider of services and strategies for FDA product approval and compliance for devices, drugs, biologics, and combination products. Anson Group's team of experienced industry experts tailors both enterprise strategies and clearly defined action plans that help its clients address crucial issues throughout the product life cycle. Anson works with clients in the United States, Europe, and Asia, from global pharmaceutical manufacturers to small pre-IPO or VC biotechnology and medical device start-ups.