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Julia O'Neill of Tunnell Consulting Shares Process Validation Insights at Pharma Conference

Presentation explores alternative approaches for specification setting, and recommends specific strategies for accelerated validation

King of Prussia, PA – May 15, 2017: Tunnell Consulting announced that Julia O'Neill, principal and statistician, will be sharing her insights in a presentation of "The Key Role of Specifications in Process Validation," at the Process Validation Summit 2017, May 18 and 19, at the Racquet Club of Philadelphia. The event will bring together leaders from the pharmaceutical and biotech industries to explore processes, strategies and new approaches to ensuring that they meet or exceed regulatory expectations and avoid costly FDA delays.

O'Neill also recently presented at the Regulatory Sciences for Biologics and Vaccines Conference in Leesburg, Virginia, which focused on accelerating and enabling manufacturing innovation. During that conference, which was held in April, the subject of O'Neill's presentation was "Lifecycle approach to validation supports accelerated approvals." She also took part in a panel discussion in April's Outsourced Pharma event in Boston, where she moderated discussions of "Winning workforce: A new generation in the supply chain." and "FDA, regulatory, and quality dynamics for innovative outsourcing."

As regulators require ongoing monitoring of processes throughout a drug product's lifecycle, pharmaceutical companies must modernize their validation and risk management approaches. This event will cover these issues, along with discussions of global technology transfer, process validation lifecycle management, and how the Drug Supply Chain Security Act relates to validation.

O'Neill's presentation explores alternative approaches for specification setting, and recommends specific strategies for both traditional and accelerated validation. "I am looking forward to attending this important industry event," said O'Neill, "It is especially vital for members of the industry to ensure they are compliant with the latest FDA requirements for validation." During her presentation, O'Neill will discuss the challenges of gaining information about true product requirements, and the challenges involved in breakthrough or orphan drugs, where data may be limited.

O'Neill is a CMC statistician with over 30 years of experience bridging statistics and chemical engineering, applied to a broad range of challenges in vaccines, biologics, pharmaceutical and chemical development and manufacturing. Prior to joining Tunnell, she was responsible for

development and deployment of process robustness strategy for manufacturing at Merck. She is an expert at resolving challenging problems using statistical, engineering, and Six Sigma methods.

About Tunnell Consulting

Founded in 1962 and serving many of the world's leading life sciences firms and government agencies, Tunnell Consulting, Inc. integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific credentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve. To learn more, visit us online at http://www.tunnellconsulting.com.