



## **Tunnell Consulting CMC Statistician Julia O'Neill to Present at PDA Conference**

### ***O'Neill to Take Part in Session on Control Strategy for Gene and Cell Therapies***

**KING OF PRUSSIA, PA** November 16, 2017: Tunnell Consulting announced today that principal and statistician Julia O'Neill will be a speaker at the 2017 [PDA Cell and Gene Therapy Conference](#). She will take part in the "Development of a process control strategy" session, presenting "Developing control strategy for gene and cell therapies – Journey of unique challenges."

The event, which will take place December 5 and 6 at the Manchester Grand Hyatt in San Diego, follows the successful Cell and Gene therapy Workshop in April. This conference expands on the latest and most comprehensive information on a broad range of topics in the field, and will bring together the industry's top medicine, regulatory, quality, facilities, and engineering experts. Topics will include the role of multi-'omics' and application of big data, management of unique regulatory requirements, and considerations for scaling of processes and processing spaces.

"Cell and gene therapy products are creating exciting opportunities to serve patients with new and more effective treatment options," said O'Neill. "These new options mean that we will need to overcome new challenges, while also changing well-established paradigms."

The session will provide an inside look at ways to redefine the approach for development of a process control strategy, which will ensure consistency of process performance, and deliver products which meet quality requirements. During the session, speakers will present examples of the challenges the industry is facing, and specific strategies to overcome them.

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>.

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