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### **Tunnell Consulting Joins Top Industry Experts at ISPE Conference** *Tunnell Consulting experts bring thought leadership on driving innovation to advancing patient therapies at key industry event*

**KING OF PRUSSIA, PA** August 16, 2017: [Tunnell Consulting](#) announced today that four of the firm's thought leaders will be taking part in sessions at the [ISPE Annual Meeting and Expo](#), to be held October 29 through November 1 in San Diego at the Marriott Marquis San Diego Marina. The event's theme is "Driving innovation to advance patient therapies."

The ISPE Annual Meeting and Expo will feature several interactive education sessions, focused on significant trends in the pharmaceutical engineering field. This year's event highlights current industry initiatives designed to transform new medicines and emerging technologies from vision to reality.

Tunnell's Dr. Philippe Cini will lead a session on Monday, October 30 as part of the event's Product Development and Production Systems track. The discussion, "Process capabilities as they apply to the pharmaceutical and biotech industry," is an insightful follow-on to the ISPE Process Capability Workgroup's earlier article on how process capabilities drive process improvement and compliance. "During this session, attendees can learn more about the work done by the ISPE Process Capability Workgroup, and how pharmaceutical and biotech companies put those programs into action in their own companies," said Dr. Cini.

Also on Monday, Tunnell's Greg Anthos will share his insights as he leads the "Quality systems integration for acquisitions/mergers and suppliers" panel, as part of the Quality Systems and Regulatory track. "After a merger, firms need to look at whether their quality systems are in need of an update," said Anthos. "In any case, quality systems often evolve or have many small revisions over time, and eventually become cumbersome. As part of this session, we will look at how one company redesigned their quality systems in roughly one month, and implemented the new design within six months." The session will be especially useful for leaders responsible for quality systems, and will include an interactive audience discussion.

As part of the event's Information Systems track, Tunnell's Kip Wolf will take a role in the "Data Integrity Concepts – A Broader Approach" session on Tuesday, October 31. During the session, Kip will have copies of his article on data integrity from Life Science Magazine available. During the panel discussion, Kip and other industry thought leaders will explore how key quality principles and processes are the foundation of data integrity assurance for cloud based systems. Techniques for evaluating cloud providers, specifying requirements, and implementing the correct client-side controls will be included as part of a case study, and innovations in information governance will also be discussed. "The impact of cloud-based systems requires a renewed look at data integrity needs and controls," said Wolf. "During this informative session, we will look at the relationship that exists between recent trends and information governance, and highlight some of the newer opportunities and

innovative strategies that can be put into place to reduce risks and improve data integrity in this new environment.”

Also on Tuesday, Julia O’Neill’s session, “Clinically relevant specifications for drug substance and drug product impurities: The why and how,” in the Quality Systems and Regulatory track, looks at the potential drawbacks of current practices, and the benefits of decoupling the voice of the patient from the voice of the process. “The current practice of setting specifications based on variability observed in limited clinical batches, without considering the impact on the patient, may reward poor manufacturing process,” said O’Neill. “Drawbacks of this approach include the fact that it may reject a batch that could have met patients’ needs, and it may also lead to drug shortages and higher costs.”

The Tunnell thought leaders participating in the event are at the forefront of the industry, guiding the most important decisions pharmaceutical and life sciences companies must make. The speakers not only understand the industry as it is now, but where it is going in the years to come.

### ***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>.