



Tunnell Consulting and its sister company, Turesol Staffing Solutions, leads development of ISPE's Process Capability Maturity Model (PCMM)

Model identifies organizational strengths and weaknesses, with published survey results showing maturity levels of pharma and biotech firms

KING OF PRUSSIA, PA, March 21, 2018: [Tunnell Consulting](#) and its sister company, [Turesol Staffing Solutions](#), announced that a process capability maturity model specific to the pharmaceutical and biotech industries has been recently developed and published in ISPE's Pharmaceutical Engineering Magazine. They are grateful to have had the opportunity to lead and contribute to this important industry effort.

Taking part in the development of the article's deep insights were Philippe Cini, PhD, Leader of Turesol Staffing Solutions and Tunnell's CMC Statisticians Julia O'Neill and Michael Thomas. The three Tunnell thought leaders were joined in penning the article by industry experts from some of the most prominent organizations in pharmaceuticals and biotech, including Gretchen Allison of Pfizer, Aaron Goerke, PhD of Roche, Gerald Leister of Eli Lilly, Eda Ross Montgomery, PhD of Shire, Paul Stojanovski of Therapure, and Arne Zilian, PhD of Novartis AG.

In the article, the authors have defined nine distinct areas of consideration, which will help identify organizational strengths and weaknesses, and will help prioritize efforts. These nine areas include policy, data management, frequency, basis for specifications, calculation consistency, response, organization skill set and execution, risk-based approach, and commercialization.

Fifteen pharmaceutical and biotech companies responded to a survey inquiring about their level of maturity in each of those nine critical areas as they are today and as they intend to be three years from now. Executives who are thinking about putting in place such programs in their organizations are likely to find this information quite useful.

"The pharmaceutical industry must continuously seek out new ways to improve their manufacturing processes and their reliability," said Dr. Cini. "Process capability indices have been used extensively in other process industries. It is a valuable concept and tool that our industry should embrace. By the same token, it is important to adapt this tool to some of the unique features and challenges that we face, in particular the way we set specifications."

Parts [one through four](#) of the article can be seen in the January-February on-line issue of Pharmaceutical Engineering, with a separate [conclusion](#) published on March 1.

About Tunnell Consulting and Turesol Staffing Solutions

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.

Turesol provides those same clients with a broad range of staffing solutions from temporary staffing, long term contracts, temp-to-perm conversion, permanent placements and functional outsourcing.

To learn more, visit us online at <http://www.tunnellconsulting.com> and at <https://www.turesol.com/>.

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