Summit on Challenges and Solutions in Quality & Safety of Homeopathic Drug Products

June 27-28, 2019 | Hilton Baltimore Inner Harbor

Quality Track: Workshop 2
1:00–2:30 p.m.

Process Validation: What Is It for Homeopathic Products?
Co-presented by Eric Baier, Senior Vice President, Regulatory and Technical Affairs, and Karl John Schlottig, Director, Process Validation, both at Hyland's Inc., A division of Standard Homeopathic Co.

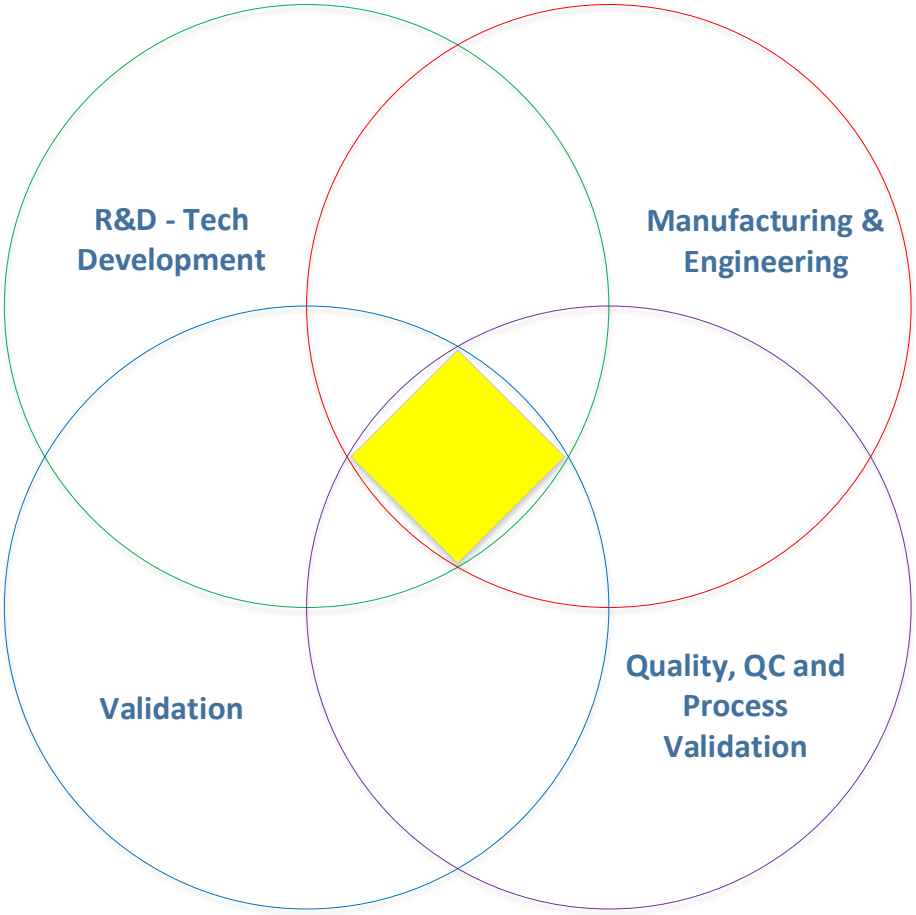
The typical process validation approaches changed with FDA's 2011 *Guidance for Industry: Process Validation: General Principles and Practices*. This workshop will highlight the key differences between this guidance and what was previously practiced. After a survey of the requirements, many of the unique challenges and considerations for homeopathic manufacturers will be discussed, including what you must know before you begin to develop a successful process validation program. This will include the pros and cons of different approaches to demonstrating the effectiveness and consistency of your processes to auditors.

What You Will Learn:

- Process validation defined (old versus 2011)
- Process knowledge needed
- How do I get what I need?
- Trade offs

About the Presenters
Eric Baier is the Senior Vice President of Regulatory and Technical Affairs at Hyland's. He has 25 years of experience in pharmaceutical manufacturing, validation, quality and technical roles. After working in injectables and biotech, Eric joined Hyland's in 1997 as Production Manager and has served as Plant Manager as well as Technical Director. He became the head of Quality at Hyland's in 2012. As a member of the Homeopathic Pharmacopoeia Convention of the United States, Eric services on several committees. He holds a degree in Chemistry and an MBA from Washington University in St. Louis.

Karl John Schlottig is the Senior Vice President of Regulatory and Technical Affairs at Hyland's. For more than 20 years, he has held senior management positions in manufacturing, validation, quality at pharmaceutical and biotech companies such as Alpha Therapeutics, Alza, Baxter, and Genentech. His is skilled in global regulatory compliance; new manufacturing facility design, construction, commissioning and validation; and sterile product processing. From design through licensing, John was the lead person on a new automated sterile bulk manufacturing facility for Shire that was named the 2017 Facility of the Year by the International Society for Pharmaceutical Engineering (ISPE). Through international studies and vast experience, his expertise also includes herbal medicine, covering herb identification and use, cultivation, collection, and medicine preparation, including homeopathy drug products. John graduated from Colorado School of Mines.


R&D - Tech Development
Manufacturing & Engineering
Validation
Quality, QC and Process Validation