



Join us on **June 21st, 2018 at 2:00PM EST** to learn more about regulatory shifts and the technological drivers for package integrity.

REGISTER BY June 20th to receive log-in information. A suggested donation of \$10 or more to benefit the Education Fund for IoPP - New England is appreciated. Donations may be made via PayPal or check.

Package Integrity: Regulatory Shifts and the Technological Driver by Oliver Stauffer

Packaging regulatory oversight by the FDA has increased with the emergence of combination class II devices, infant product regulations, and general advancement of quality standards surrounding high risk products. Most recently the USP 1207 was rewritten to establish requirements and expectations with regard to testing sterile barrier packaging. The FDA uses the USP 1207 as a guide to relevant methodologies that can be deployed for package integrity testing. The FDA uses the same bar of risk based assessment and suggested methodologies listed in the USP 1207 in regulating a wide range of high risk packaging applications. The discussion will encompass package integrity testing, USP 1207, and regulatory shifts to come. This presentation will offer both in-depth scientific review of unique Container Closure Integrity (CCI) applications comparing various methods and technologies as well as deliver explicit techniques to successfully deploy CCI methods. The presentation will draw on active experiences and will reveal broader strategies for validating and deploying CCI test systems to assure success. A series of defining questions provides both a technically sound pathway for CCI and fulfills on a holistic approach to product quality and safety.

Biography of PTI CEO Oliver Stauffer



Oliver Stauffer received his Bachelors of Science degree from the University of Michigan and completed his MBA at Georgetown University. He began his career in analytical and R & D laboratories, with a focus on sensory technologies, physio-chemical measurement and test method development specific to package testing. Stauffer joined PTI in 2005 as a member of the research and development team working on non-destructive testing of high-risk pharmaceutical packaging. In 2006, he joined the sales team as Systems. He held the position of International Business Development Manager for PTI through 2010, followed by COO through 2015, focusing on global quality solutions for package inspection that provide the highest level of measurement accuracy and reliability. During his time with PTI he has developed several technology platforms, measurement methodologies, and technology patents. In 2016, he was appointed as CEO.