

PHARMACEUTICAL

IPP Container Closure Integrity Testing (CCIT) Seminar

A detailed look into regulatory guidelines and best practices.

Thursday March 10, 2022 IPP, Saxon Business Park, Hanbury Rd, Stoke Prior, Bromsgrove B60 4AD

AGENDA

10.00-10.30:	Meet and Greet
10.30-12.00:	'CCIT Method Selection through the Product Lifecycle' presented by Brandon Zuralow (CSO at CS Analytical)
	Presentation goal: Impart an understanding that CCI method selection is dependent on product, package, study goals, and lifecycle stage.
	Key points:
	1. Not all CCI methods are suitable for every use-case.
	2. Comprehensive lifecycle approach is best for reducing risk and increasing knowledge of your package system. Typical stages for CCI would include package development, manufacturing/assembly validation, distribution, and stability.
	3. Multiple CCI technologies may be used based on the specific product, package, and lifecycle stage to be evaluated.
12.00-01.00:	Lunch & Networking
1.00-3.00pm:	Demonstration of CCIT technologies with Tyler Harris (GTS Applications Engineer) at
	PTI - Packaging Technologies & Inspection
	This will give our guests the chance to have a detailed look at the inner workings of PTI's VeriPac Vacuum Decay and MicroCurrent HVLD E-Scan 655 testing machines.
3.00pm:	Q&A opportunities with guest speakers and IPP

OUR SPEAKERS



Brandon Zuralow Chief Scientific Officer, CS Analytical

Dedicating his entire 10+ year career to the niche of compendial container testing and container closure integrity. Prior to joining CS Analytical, Brandon worked with life-science clients to develop and implement comprehensive container testing strategies directly supporting FDA filings through Containsure, his consulting firm founded in 2018. Prior to this, he gained 8 years of cGMP experience at Whitehouse Laboratories applying compendial chapters such as USP <381>, <660>, <661> and their EP counterparts; as well being instrumental in the creation of the world's first comprehensive cGMP, FDA-registered contract CCI laboratory, working with methods now found in USP <1207>.

Brandon is a contributor to industry guidance documents and textbook chapters, USP Expert Advisor, and a speaker on the topic of compendial container testing and CCI at client sites, training seminars, and conferences in the US, Europe, and Asia. Brandon holds a B.S. in Biology from The College of New Jersey with coursework completed toward an M.B.A from Rutgers University.

Tyler Harris Applications Engineer, PTI



Tyler is a 2018 graduate of Virginia Tech with a B.S. in Packaging Systems and Design. His background and expertise are in packaging, mechanical design, and quality engineering. He joined PTI in October of 2020 as an Applications Engineer assisting Sales and Engineering teams in feasibility study work, service, and sales support. Tyler has practical hands-on experience with all PTI sensory technology platforms including Vacuum Decay, MicroCurrent HVLD, Airborne Ultrasound and Force Decay.

ABOUT CS ANALYTICAL LABORATORY

The world's only cGMP, FDA-registered contract laboratory exclusively designed and dedicated to container testing for the pharmaceutical, biotechnology, and medical device industries, the CS Analytical Team includes world-leading experts and thought-leaders on FDA and EU regulatory

expectations and USP and EP primary package testing requirements inclusive of container closure integrity (CCI) testing (CCIT). Test services include CCI method development, validation, and analysis, USP/EP/JP physical and physicochemical testing, and Comprehensive and Complementary services for all common or unique primary packaging components and systems inclusive of glass, plastic, elastomeric, and more. CS Analytical is the single source to ensure a regulated industry product-package system meets strict, complex, and ever-changing regulatory requirements.

ABOUT PTI - PACKAGING TECHNOLOGIES & INSPECTION

Headquartered in Hawthorne, New York, a Westchester County community close to New York City. PTI is a collective of scientists, engineers and packaging practitioners focused on improving the entire package quality experience throughout the packaging lifecycle. PTI has engineered and developed seven different inspection technology platforms to assure container closure integrity. Each technology is grounded in the belief that without a reliable test method there is no test method. PTI's technology offerings focus on container closure integrity, providing a deterministic measure of package performance that critical applications require. The solutions are widely used to improve a variety of packaging design and material challenges, providing package performance data in the development phase through to in-production on-line package inspection.

ABOUT INDUSTRIAL PRODUCTION PROCESSES (IPP) LTD

With over 40 years' experience, IPP (IPT Ltd trading as IPP in Ireland and formerly APP in the UK) is a technical distributor of manufacturing equipment to the electronics, pharmaceutical and medical device sectors across Ireland and the UK. With a strong presence representing package equipment and instrumentation, our team of service and sales engineers is committed to meeting the technical requirements of our clients in a timely and effective manner.



To register for this event please contact: **Steven Gruar** UK Sales Manager, Life Sciences, IPP <u>sgruar@ippgroupItd.com</u> +44 7341 885483



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