ABSTRACTS FOR INVITED TALKS AT CONFERENCES THIS FALL

For additional information or to speak with a subject matter expert in any of the areas described below please contact Jim Veale, President, Lighthouse at jveale@lighthouseinstruments.com

2014 ISPE Annual Meeting

Oct12-15, 2014 Caesars Palace ♦ Las Vegas, Nevada USA

Dr. Jim Veale, President Lighthouse, will give an invited talk in the Manufacturing Technology Session entitled "Benchmarking Study of Container Closure Integrity for Sterile Products"

Abstract:

Should pharmaceutical manufacturers implement 100% leak detection into sterile fill and finish operations? Container closure integrity (CCI) is critical to maintaining parenteral product stability and sterility. Defects in packaging components or out of control manufacturing processes result in CCI failures which in turn put product and ultimately patients at risk. Fully automated leak detection systems for monitoring CCI are now available that record data and provide insight into the number and type of package defects in individual batches. Lighthouse has analyzed batch CCI data from over 15 million vials manufactured by 4 large pharmaceutical companies, 2 from Europe and 2 from the USA. The data includes both liquid and lyophilized product manufactured over several years. The analysis shows that on average 0.6% of product show some type of container closure defect.

PDA 9th Annual Global Conference on Pharmaceutical Microbiology

Oct 20-22, 2014 Bethesda, MD

Dr. Tony Cundell, Consulting Microbiologist, will give an invited talk entitled "Innovative Technology: Use of Online Headspace Analysis for Media Fill Inspection"

Abstract:

To validate an aseptic filling process, in excess than 10,000 vials are filled with soybean-casein digest broth, stoppered and sealed. The vials are inspected for damage and incubated between 20-35°C for at least 14 days. After incubation, the vials are inspected for microbial contamination in the form of turbidity, pellicle formation, submerged floccular growth or precipitation. The contents of the so-called turbid vials are microscopically examined and subcultured to confirm the presence of microorganisms and the microbial isolates identified to the species level. As visual inspection is a time consuming and probabilistic process its replacement with a rapid, on-line, objective physicochemical inspection process would be most welcomed by the pharmaceutical industry and their regulators.

Any microorganisms growing in the broth will consume oxygen and produce carbon dioxide changing the composition of the headspace in the vials. This change can be non-destructively detected using laser headspace analysis of oxygen and carbon dioxide. Data are presented on the change in headspace gas composition during microbial growth of compendial and sentinel organisms, i.e. slow growers and low CO_2 producers. The effect of inoculum size, incubation temperature, growth characteristic in liquid culture, and headspace volume and container type on the time to detection was explored. Details on the business case for the capital purchase of automated online inspection systems is presented as well as details of the laser technology behind this rapid and non-destructive measurement method.

The presentation will illustrate in a case history the potential cost savings and increased filling capacity that would be achieved this media fill inspection technology.

Lyophilization Forum 2014
Oct 20 - Oct 21, 2014 Philadelphia, PA
Dr. Derek Duncan, Director Product Development, will give an invited talk entitled “Rapid Moisture Monitoring and 100% Container Closure Inspection of Lyophilized Vials”

Abstract
Laser-based headspace analysis has proven to be useful in freeze drying activities, from the development of lyo cycles and the validation of freeze dryers to final quality inspection of freeze dried product. Data from industry case studies are presented in this paper, which demonstrates the wide utility of this analytical technique for freeze drying activities. Quantifying the amount of water vapor in the headspace of freeze-dried vials with an optical method enables rapid non-destructive moisture analysis. Experiments have demonstrated that the amount of headspace water vapor directly correlates to the lyo cake moisture content. Stability studies have shown that the degradation of the active pharmaceutical ingredient correlates to the initial water vapor concentration present in the freeze-dried vial. These results indicate that rapid water vapor determination with an optical method could replace the slow destructive traditional methods for moisture analysis of freeze-dried products. This paper presents data from industry case studies involving lyo chamber moisture mapping, freeze drying cycle optimization, and 100% moisture inspection of commercial freeze-dried products