Do you know at what stopper height your product is at risk of losing closure?

COMPLY WITH EU GMP ANNEX 1 SECTION 8.28



Lighthouse Instruments offers a Container Closure Integrity (CCI) study that demonstrates at what stopper height displacement the risk of losing CCI becomes problematic. Partner with Lighthouse to make science-based, data-driven decisions to effectively qualify your automated inspection platform.

Section 8.28 of the new EU GMP Annex 1 states:

"Where capping of aseptically filled sterile product is conducted as a clean process with grade A air supply protection, vials with missing or displaced stoppers should be rejected prior to capping. Appropriately qualified, automated methods for stopper height detection should be in place."

Ensure compliance with Section 8.28 of the EU GMP Annex 1 by reaching out to us today!

Contact us at CCITExperts@lighthouseinstruments.com



