

WICKED STABILITY: PROJECT PROGRESS & WORKSTREAM UPDATES

Presenters

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Abstract

It is known that radiation sterilization can result in degradation of certain materials, and of particular concern is molecular changes to the polymers. Because of this, aging studies are typically required for most medical devices and their packaging. However, even though most packaging materials have been well characterized and studied, and there are no known cases where packaging has failed due to shelf life concerns, most medical device companies spend significant time and resources to perform aging studies on their product and packaging. It is known that the presence of antioxidants in a polymer formulation inhibits the degradation that can occur after exposure to radiation. Instead of focusing solely on performing aging studies on every device and packaging combination, we are proposing an alternative approach where device manufacturers could characterize and test their materials for the presence of anti-oxidants as a predictor of material degradation over time. In addition to discussing the science behind this topic, we will also be discussing how we plan to use effective means of collaboration to achieve our goals.

About KiiP

KiiP is one of the collaboration groups formed at the 2019 Kilmer Conference in Dublin that focuses on packaging. Our mission is to collaborate, connect, educate, and promote the value of medical device sterility assurance and its maintenance throughout the value chain for protecting patient safety and improving healthcare outcomes. Among our many activities, the Breaking Bad Biases team (formerly known as Let's Speed Things Up) is studying the material degradation that occurs after radiation sterilization to rethink how we view and perform aging studies.