

SPEED UP BIOPHARMA DEVICES' RELEASE TO MARKET

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It is a challenge in the biopharma industry to attain appropriate qualification protocols for devices. The manufacturers necessitate device storage that lasts for an extended period of time.

Single-use devices may need storage for up to 6 years before their functional lifetime actually starts. In other words, every product completes its unique journey before it can be functionally used by the customer.

At this point, the manufacturer needs to provide a quality certificate that guarantees the device's safety and robustness during its life cycle. Likewise, package material aging information is needed to ensure package integrity, satisfy FDA validation requirements, and provide evidence of sterility and fitness for use over a product's life cycle. To decrease the time necessary for testing prior to commercialization, or in other words to speed up product's market release; manufacturers perform accelerated-aging studies on the product/ package combination. These studies are performed at elevated temperatures, so to simulate the realistic life span of the product. Life span of every product is unique in line with its application requirements and consists of sections such as storage of components, assembly and irradiation, storage of the irradiated product and finally application. Polymers are similar to living organisms and their properties are time, temperature and stress dependent, making the job of simulating the life cycle very complicated and difficult.

As Sartorius Stedim Biotech, we are taking this challenge and adapt our aging methodology to each polymers. Our method will be shared to show how we can speed product introduction to market.

Biography

Dr. Nazli Gulsine Ozdemir has received her PhD from Kingston University London, UK at the age of 28 and following her graduation she worked as a postdoctoral researcher at University of Bristol, UK. Currently she works as a materials specialist, at Sartorius Stedim Biotech in the United Kingdom. She has published 10 papers as first author in reputable journals. She has also given speeches in many polymer engineering and materials science conferences across the globe.

Nelly Montenay has received a degree in Engineering from the ITECH Lyon Engineering School. She is specialized in polymers science and plastic transformation. She is Platform Manager for Single Use Systems in Sartorius Stedim Biotech Research and Development Group, with 14 years of experience in polymer science, film development and product qualification testing.