Comparative-use study of brand-name vs. generic drug-delivery medical devices

Project Overview

Drug-delivery devices such as syringes are often manufactured in both brand-name and generic versions, which are expected to be comparable in their use. While minor design differences may exist, these are typically assumed to not impact use.

However, a comparative study is required to assess whether such differences lead to use errors beyond an acceptable safety threshold—in which case the generic version cannot be deemed equivalent in use to the brand-name device.

Scope of the Challenge

Evaluate whether design differences between brand-name and generic devices introduce critical task errors that exceed a pre-established safety margin, potentially compromising device comparability.

Research Approach

Conducted a comparative-use study with representative end users, testing both device types in controlled, simulated-use scenarios. Assessments were designed to capture performance on critical tasks necessary to safely interact with the product. .

Results

Analysis of use errors and non-safety-related feedback revealed clear differences in how users performed critical tasks across the two devices, highlighting areas where error rates exceeded acceptable thresholds

Findings provided **key insights into device comparability**, directly informing regulatory decisions and impacting the generic device's eligibility for market introduction as a therapeutically equivalent alternative