FDA Guidances Related to Combination Products

Compliance Policy for Combination Product Postmarketing Safety Reporting	Postmarketing Safety Reporting for Combination Products	How to Prepare a Pre-Request for Designation (Pre-RFD)	Classification of Products as Drugs and Devices and Additional Product Classification Issues	Current Good Manufacturing Practice Requirements for Combination Products
Addresses how to comply with the final rule on post-marketing safety reporting requirements (PMSR) for combination products.	Addresses specific means by which applicants may comply with the final rule on PMSR requirements for combination products.	Assists sponsors in obtaining a preliminary assessment from FDA through the Pre-Request for Designation (PreRFD) Process and helps a sponsor understand the type of information to provide in a PreRFD.	Focuses on cases in which a product may be classified as a drug or device and addresses additional issues relating to product classification, including how to obtain classification determinations from FDA for medical products.	Explains the final rule on CGMP requirements for combination products (final rule as codified in 21 CFR part 4) that FDA issued in January of 2013.
Released: April 2018	Released: April 2018	Released: March 2018	Released: September 2017	Released: September 2017

Additional Updates

The abbreviated 510(k) program has been expanded to outline how sponsors can win clearance for devices after showing they meet certain performance levels, rather than through direct comparisons with predicate products.

The *Multiple Function Device Products* draft guidance describes FDA's current approach to regulating digital health tools and medical devices that include both medical device functions and non-medical device functions.

Hear directly from FDA as they examine recent and ongoing changes in the regulatory ecosystem for combination product development and approval at DIA's *Combination Products Conference*.

To learn more, visit DIAglobal.org/Combo18