

Technical Considerations for Demonstrating Reliability Of Emergency-Use Injectors: A Review Of Draft FDA Guidance For Industry



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INTRODUCTION FDA previously published Guidance for Industry: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products (1) in 2013. This document provided guidance on injector design, materials of construction, performance testing, sterilization, and labelling. FDA has now drafted Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors (2) which provides additional recommendations to demonstrate reliability specifically for these injectors. FDA terminology “Emergency-Use Injectors” refers...

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