

## A Letter to the FDA on Technical Considerations For Demonstrating Reliability Of Emergency-Use Injectors Submitted Under a BLA, NDA or ANDA



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By

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Members of the Editorial Advisory Board of the Journal of Validation Technology (JVT) and Journal of GXP Compliance (JGXP) thank the Food and Drug Administration (FDA) for the opportunity to submit comments on the Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA. We agree with FDA's assessment that expectations for demonstrating the reliability of emergency-use products should be clarified. The draft guidance provides valuable information as to the elements and approaches that might be used. These are vital devices; we...

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