

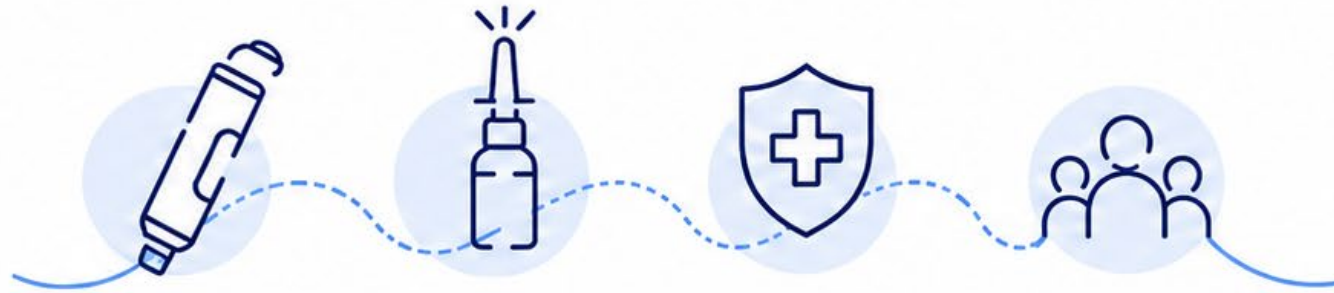
Generic Autoinjectors & Intranasal Rescue Devices: Real-World Emergency Use Considerations

Regulatory science considerations for emergency-use generic combination products



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Emergency Use Is a Distinct Use Context



Time Pressure

- Rapid administration
- Little time to recover from error



Stress & Cognitive Burden

- Panic, urgency, and reduced working memory



Variable Environments

- Noise, lighting, gloves, weather, and movement



Diverse Users

- Laypersons, first responders, caregivers, and military users

Equivalence Dimensions for Emergency-Use Products



Functional Equivalence

Can the device perform the intended action?



Perceptual Equivalence

Does the user recognize and interpret the product as expected?



Cognitive Equivalence

Does the device support the same understanding and use sequence under stress?



Critical Task Alignment

Are essential tasks recognized and completed in the same way?



Examples: Autoinjectors — orientation, activation, and feedback cues | Intranasal rescue devices — positioning, handling, and sequence



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Potential Consequences of Interface or Sequence Differences

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**Delayed
administration**



**Incorrect
operation**



**Use confusion
relative to the RLD**



**Clinically meaningful
use-related risk**

*Examples may include autoinjector orientation, activation, or feedback cues,
and intranasal device positioning, handling, or re-dosing sequence.*



**Even seemingly minor differences in interface, cues, or
sequence may alter user behavior under emergency conditions.**

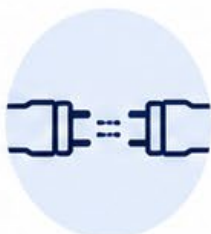
Where Additional Regulatory Science May Be Needed

Targeted research needs to strengthen emergency-use generic combination products



Better definition of emergency-use equivalence expectations

Specify what equivalence means under time pressure, stress, and variable conditions.



Clearer bridging approaches for interface differences

Develop practical approaches to evaluate and justify interface differences across products.



Stronger critical task comparison methods

Establish robust, reproducible methods that align critical tasks across devices and contexts.



More explicit human factors expectations for ANDAs

Articulate clear human factors requirements relevant to abbreviated submissions.

Comparative Equivalence Modeling (CEM)



Task convergence



Cognitive equivalence



Perceptual cue similarity



Risk alignment



Under emergency-use conditions, seemingly minor interface differences may introduce meaningful safety risk.

Closing Takeaways for Emergency-Use Equivalence

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Predictable Performance

Emergency-use devices must behave predictably – even when people do not.



Risk Alignment

For emergency-use products, what matters is risk alignment, not procedural mimicry.



Meaningful Equivalence

Equivalence should be demonstrated at the level of cognition, perception, risk, and critical task performance.



The future of comparative human factors is comparative reasoning grounded in cognitive equivalence, perceptual convergence, risk alignment, and environment-specific user burden.