U.S. FOOD & DRUG ADMINISTRATION

Considerations for ISO 11608:2022

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Highlights of 11608 Updates

- **Primary Functions (PF)**
- **Combined Preconditioning Testing**
- **On-body delivery systems (11608-6)**
- Strengthens design controls and risk management requirements
- Human factors

ISO 11608:2022, FDA Recognition

- ISO 11608:2022 is currently recognized
- Transition period for prior versions ends July 9, 2023

Primary Function: Definition

- function or operation of the needle-based injection system, which, if it does not perform to specifications during use, would directly result in a failure to accurately deliver the medicinal product via the correct route and/or directly result in unacceptable harm to the patient

Primary Function

Performance

- Function or operation
- Perform to specification
- During use
- Failure to accurately deliver
- Correct route

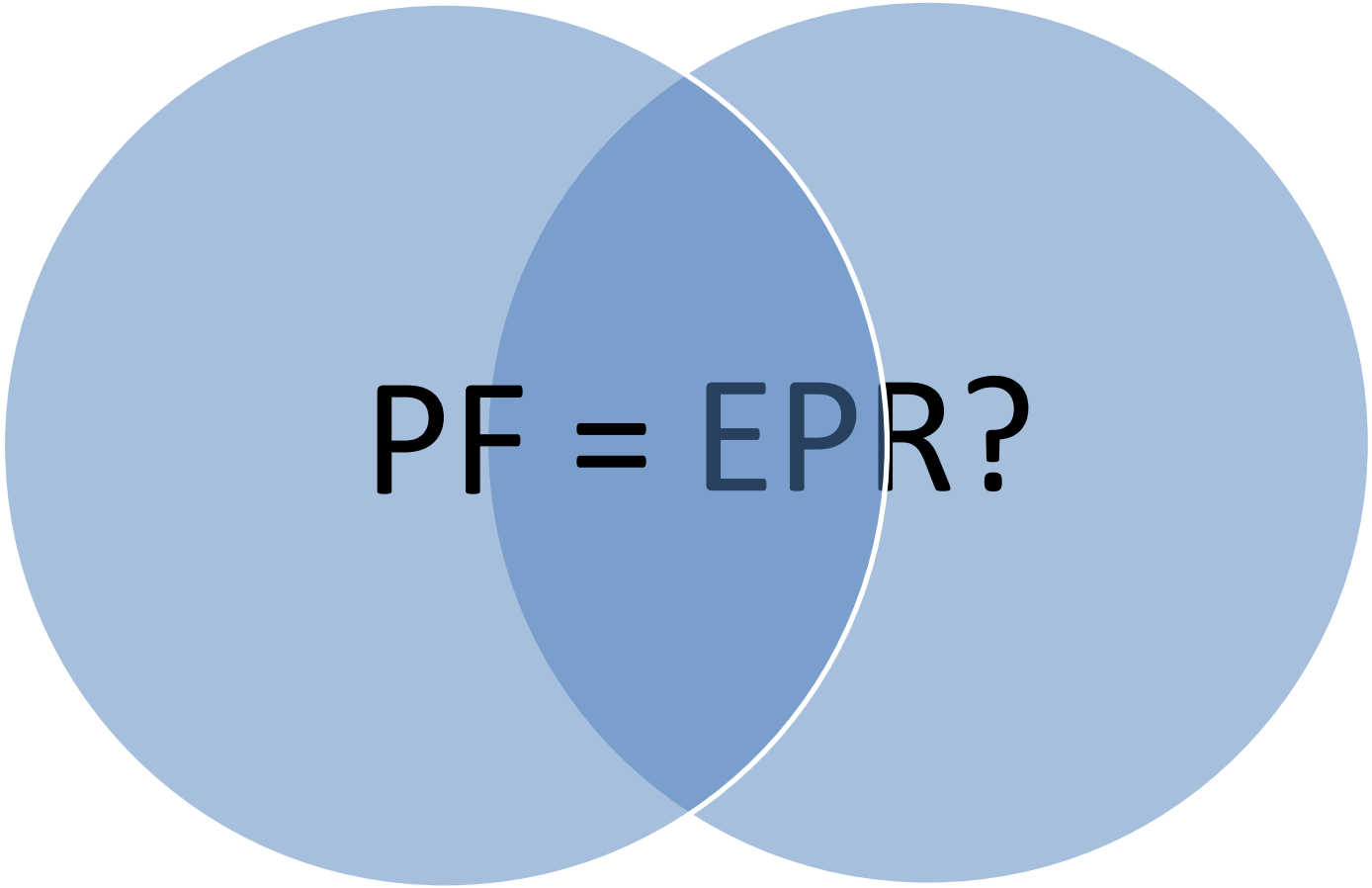
And/or

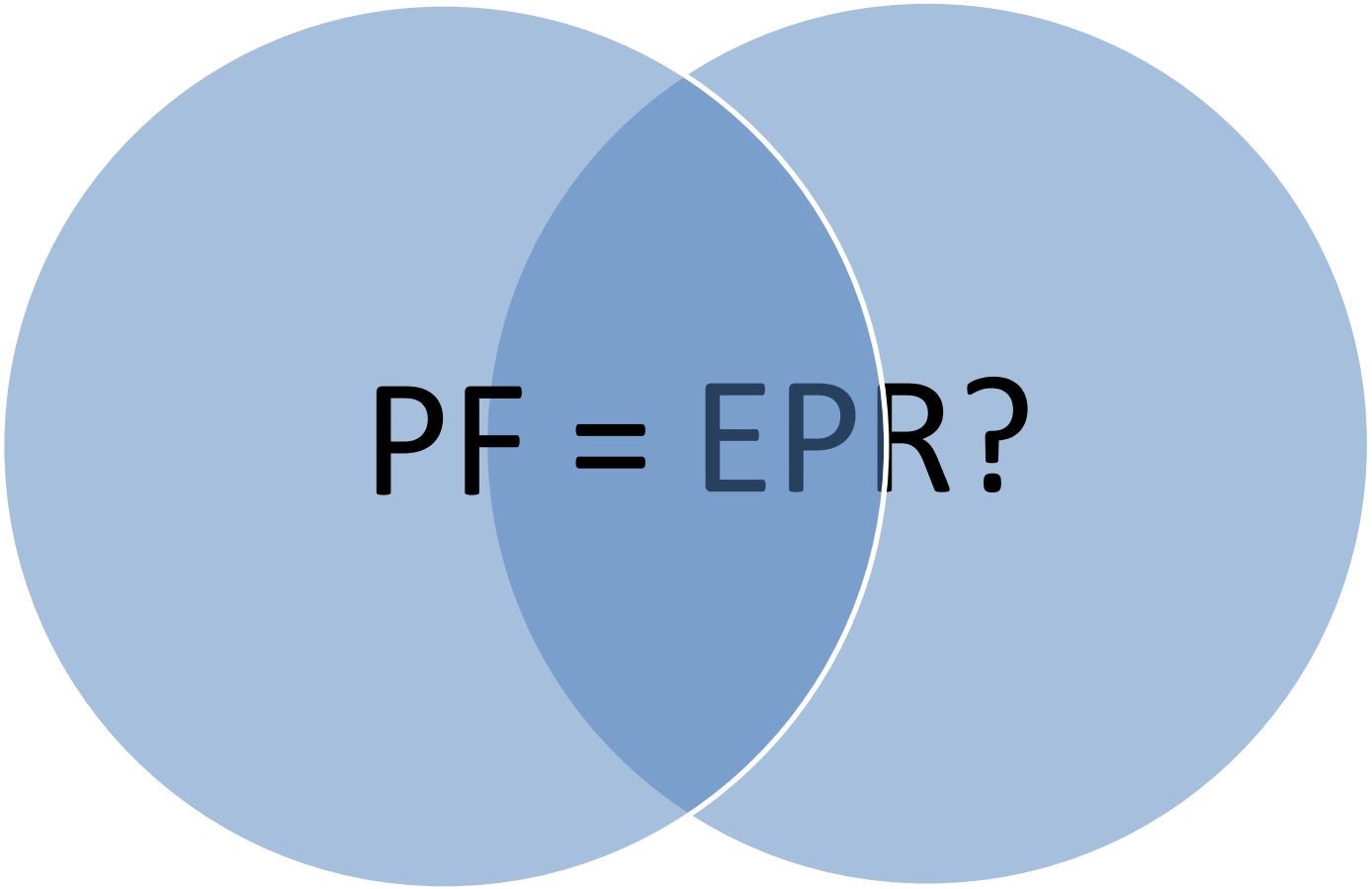
Safety

- Unacceptable harm

Testing Requirements

- Primary functions shall be assessed in accordance with Table 3 conditions and preconditions based on the system designation
- Table 3 – Test Case Matrix
- Annex H (informative), provides example primary functions


PF = EPR?



Examples from 11608

- **Failure of Sterile Barrier**
- **Cap Removal Force**

Combined Preconditioning

- 11608-1 references considerations for combining preconditions prior to performance testing
  - 10.2.3 Life-cycle testing
  - 10.3.7 Transport
  - 10.3.8 Functional stability
  - Annex A.3.1
- 11608-1 – preconditions should be combined if, per risk assessment, high probability of exposure during normal use
- FDA recommends combining preconditions for emergency use products

11608-6, On-body Delivery Systems

- Testing requirements in addition to ISO 11608-1
  - In-use conditions
  - Physical/functional assessment of injection pathway (e.g. needle/cannula)
  - Adhesion
  - Occlusion
  - Dosing Requirements (accuracy, time, profile)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