COMBINATION PRODUCTS SUMMIT

FT. WORTH, TX • NOVEMBER 28–30, 2023

Evolution of Essential Performance Requirements

Moderator: Rumi Young

Panel Members: Ashley Boam, Sarah Mollo, Alan Stevens, Matthew Ondeck, Subhi Saadeh

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

Inspiring Collaboration. Leading Innovation. Making a difference.

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Evolution of EPRs

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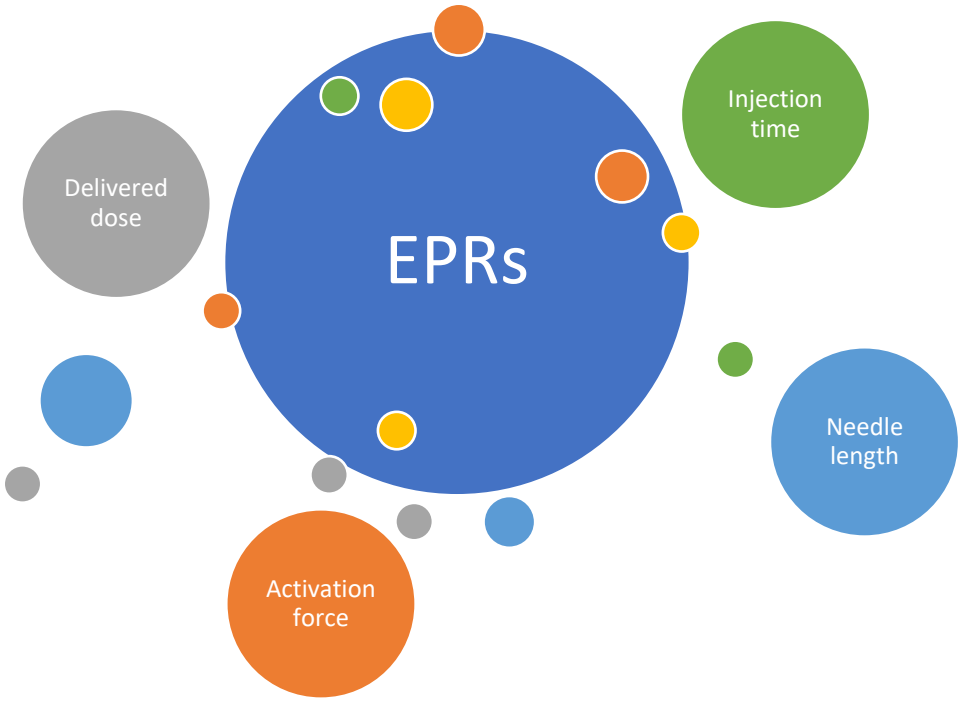
Panel Members

Essential Performance Requirements (EPR) Background

- EPRs have been noted in FDA **drug-led** combination product in submissions and interactions since ~2017
  - NDA, BLA, ANDAs, etc.,
- No ***formal*** definition on EPRs
- FDA has shared that a guidance is being drafted and undergoing the clearance process



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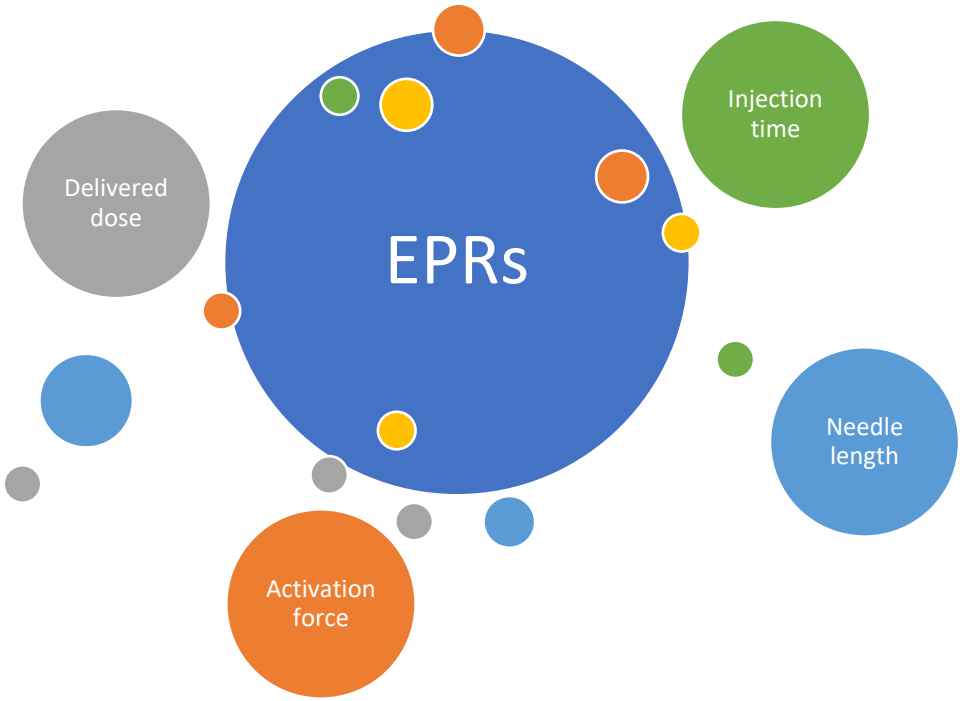
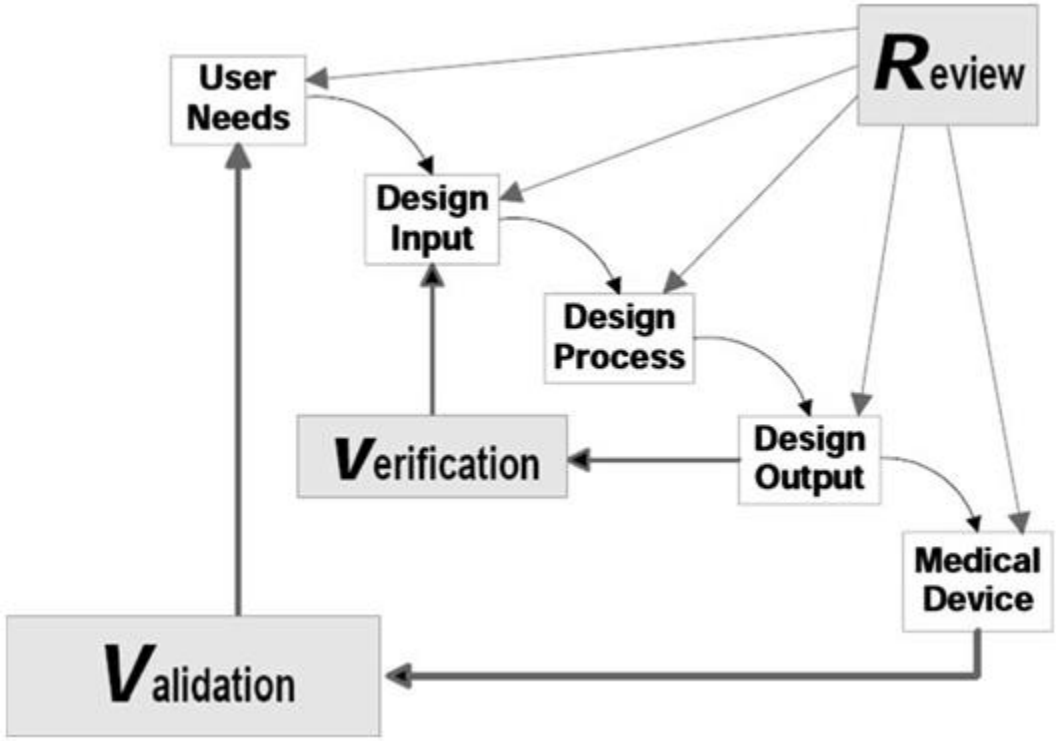


Why do I need EPRs? Are they required?

Essential Performance Requirements – What do We Know

- Design Verification
- Clinical Validation
- Manufacturing control strategy
- EPRs compared when:
  - **bridging** between different device formats
  - **bridging** between an originator and generic/biosimilar products
  - Assessing **post-market** changes



Essential Performance Requirements - Terms

Primary Function

11608-1 (2022)

Primary functions include functions or operations where, if they failed to operate or perform according to specifications, would impact the dose from being delivered accurately via the correct route and/or create unacceptable harm to the patient

Critical Quality Attribute

Q8(R2) (Nov 2009)

Is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality. CQAs are generally associated with the drug substance, excipients, intermediates (in-process materials), and drug product

Established Condition

ICH Q12 (May 2021)

Legally binding information considered necessary to assure product quality

Panel Discussion