

# Policy Update: How to Get Where We Want to Go

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# Current Overarching Focus

- Enabling policy coordination/direction
- Improving coordination, strengthening relationships, training
- Breaking down silos



# Guidance/rulemaking updates

Publications pending with OCP

- Human factors guidance
- CGMPs guidance
- Postmarket safety rule
- Postmarket changes guidance
- Product classification guidance

Some other efforts

- Cross-labeled combination products
- Medical apps and clinical decision-making support
- Generics

# Working together

- Hearing from you
- Understanding & trust
- Getting the word out
- OCP, a resource, open door



# Final thoughts

- 80/20, 90/10, when and how to publish
- Clarity and predictability v. flexibility and uncertainty
- We have to get there together

# For additional information

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