PURPOSE

Present the perspective of the pharmaceutical industry

- Information shared is not reflective of any one pharmaceutical company or a particular industry group

Provide industry viewpoints with respect to USP-NF Online Updates

- What went right
- Future opportunities
WHAT WENT RIGHT: INITIATING ONLINE PLATFORM UPDATE

Interviews with end-users

Gathering significant amounts of data on how the online book was used as well as future wishes/constraints

Industry Advisory Group creation

Open & frequent two-way communication
WHAT WENT RIGHT: CONTINUING IN THE RIGHT DIRECTION

- Rolling out → without initial price increase
- Reaching out to industry advisory group frequently / and hosting regular webinar’s to receive feedback/announce updates with that group etc.
- Wide e-mail communication to all users
- Listening to pain points being experienced
- Willingness to redesign aspects and following thru on improvements
- Clear communication of designated USP individuals to contact
ACCOLADES

Thank you!
FUTURE OPPORTUNITIES: UNDERSTANDING USER CULTURE

- Regulated Industry: Error free culture mindset
- 100% Quality Oversight (Review) and Continuous Improvement

Will the parachute open?

- Online USP-NF issues can stop or delay testing
FUTURE OPPORTUNITIES: WHAT'S IMPORTANT TO INDUSTRY

- Open & frequent two-way communication
  - In particular with effective dates and changes (no undocumented changes, regardless if thought to be minor in nature)

- Enhanced development transparency
  - Rationale for decision making during standard development
  - Publish all PF comments (even when multiple revisions occur)
Looking forward to continued collaboration, for example:

• Industry advisory board created to support the PILIP (Public Input Lifecycle and Impact Project) in the manner that was done for online changes
• Working groups for high impact General Chapter changes
Thank you