2017 Excipients SF Updates

- Up to Date
  - Atypical actives: originally suggested formation of a USP Expert Panel; other options that could be quicker to create a final recommendation to the Expert Committee
    - Consider stakeholder engagement through either Roundtable discussions, Project Team, Working group or Focus group as a quicker way of addressing this topic. We will look for volunteers at this meeting and based on input we will determine the timeline to begin/complete the activity.
  - Working towards addressing the high-priority issues of excipient composition/impurities and excipient nomenclature.
  - Stim article and survey Launched in July 2018, survey completed and report to be generated within the next couple of weeks that will be shared with the Excipients Joint Subcommittee and then with the Excipients Expert Committees.
  - Results will be discussed as part of the USP response to stim article comments.
2017 Excipients SF Updates

- Outreach - USP to Continue to Engage Stakeholders
  - Participate in opportunities for stakeholder involvement
    - USP continues to target critical meetings to attend such as the American Association of Pharmaceutical Scientists (AAPS), American Chemical Society (ACS), Controlled Release Society (CRS) Excipient World to present slides, posters, and publications promoting the importance of excipient quality.
  - Strengthen its communication and collaboration among stakeholders
    - USP continues to participate in ongoing activities being conducted by the Excipient Program Unit (PUT) consisting of both excipients Science and excipients Strategic Marketing and Program Operations team. (e.g., road shows, etc.)
Questions

Empowering a healthy tomorrow
Thank You

Empowering a healthy tomorrow