STAKEHOLDER ENGAGEMENT FOR THE USP CONVENTION – A GIANT LEAP BEYOND THE STAKEHOLDER FORUMS

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GIANT LEAPS

• 50 years since man took first steps on the moon
  “That’s one small step for man, one giant leap for mankind.” Neil Armstrong

• 200 years since a group of physicians concerned about the quality and consistency of medicines published the first USP
GIANT LEAPS START WITH YOUR ENGAGEMENT

• Involve me and I learn
• Learning can facilitate our understanding
• Understanding can help us solve problems
• So please get involved!

*Not really a Benjamin Franklin quote, but it’s apropos!
INDUSTRY PERSPECTIVE ON USP RESOLUTIONS

• Mission/vision of the USP reaches beyond the core business of USP-NF (i.e., Giant Leap)
• USP Convention helps to define specific areas of focus for the next 5 years and beyond
• Industry has a limited voice at the USP Convention, however
  • Industry can contribute Resolutions for consideration
  • Industry can engage with other members of the Convention to help raise awareness of current issues impacting end-users of USP-NF standards
  • Convention members are willing to hear and understand issues to better recommend the focus and direction of USP
IMPACT OF RESOLUTIONS

• USP’s continued engagement with stakeholders
  • Facilitating collaboration with regulators – particular with US-FDA
  • Establishment of Expert Panels with cross-functional members from industry and other areas to provide advisory input to help advance standards with more informed and transparent discussion – Provides experience that may not have been considered previously and at earlier timepoints in the development process

• Foster the continued direction/focus of USP in the areas of
  • Quality Systems, Continuous Improvement and Transparency of USP processes
  • Harmonization and exploring new ways to foster alignment and harmonization with other pharmacopoeias, even expanding beyond PDG/ICH with WHO and other pharmacopoeias

• Historically, many topics driven by industry voices have been instrumental in shining a light and maintaining the focus on the need for support of USP’s core activities (i.e., publication of appropriate standards and supply of the necessary reference standards)
KEY AREAS TO SUPPORT THE QUALITY OF MEDICINES FOR THE 2020-2025 CYCLE

• Enhance and strengthen USP’s Quality Systems
• Continue collaboration with US-FDA
• Continue Harmonization with other pharmacopoeias to foster global harmonization
• Promote greater engagement of stakeholders, especially those directly impacted by USP standards
OPPORTUNITIES FOR ENGAGEMENT

- The USP Convention is a unique experience for industry
- Understand the underpinning of USP governance
- Important for those who actively engage with USP to be familiar with the process
- Even as an Observer, you will have the opportunity to speak openly during the early proceedings
  - Express desired direction of USP and outcome of the Resolutions
  - Ensure that the essence and content of the Resolutions reflects industry needs
- Explore with your companies the need and value of participation at the 2020 USP Convention, particularly since it is the 200th Anniversary of the establishment of USP
- Continue to provide input into submitting Resolutions in the future
When you do nothing you feel overwhelmed and powerless. But when you get involved you feel the sense of hope and accomplishment that comes from knowing you are working to make things better.

— Maya Angelou —
THANK YOU FOR BEING INVOLVED!