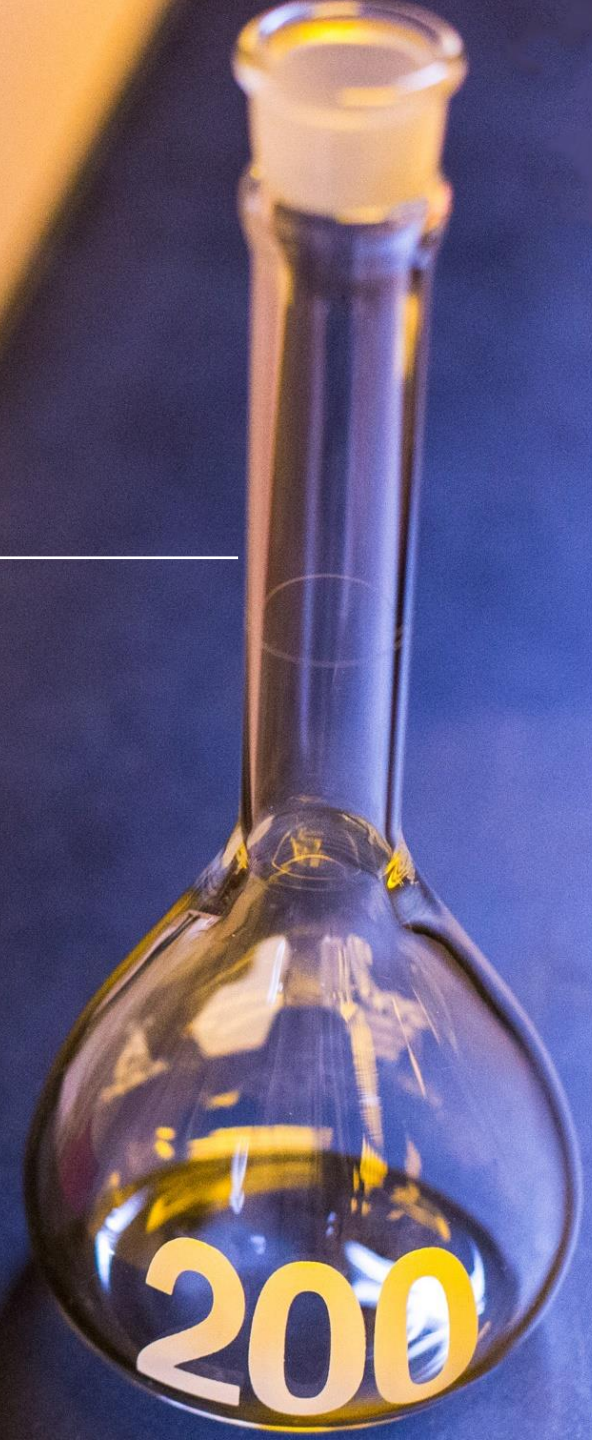


USP Open Forum | Excipients

Goals and Objectives of the Excipients Open Forum

Catherine Sheehan, DRSc., MS.,MS.
Senior Director, Science-Excipients
February 11, 2021



Stakeholder Engagement

Read the PF Stim article and the GA Elemental Impurities Roadmap

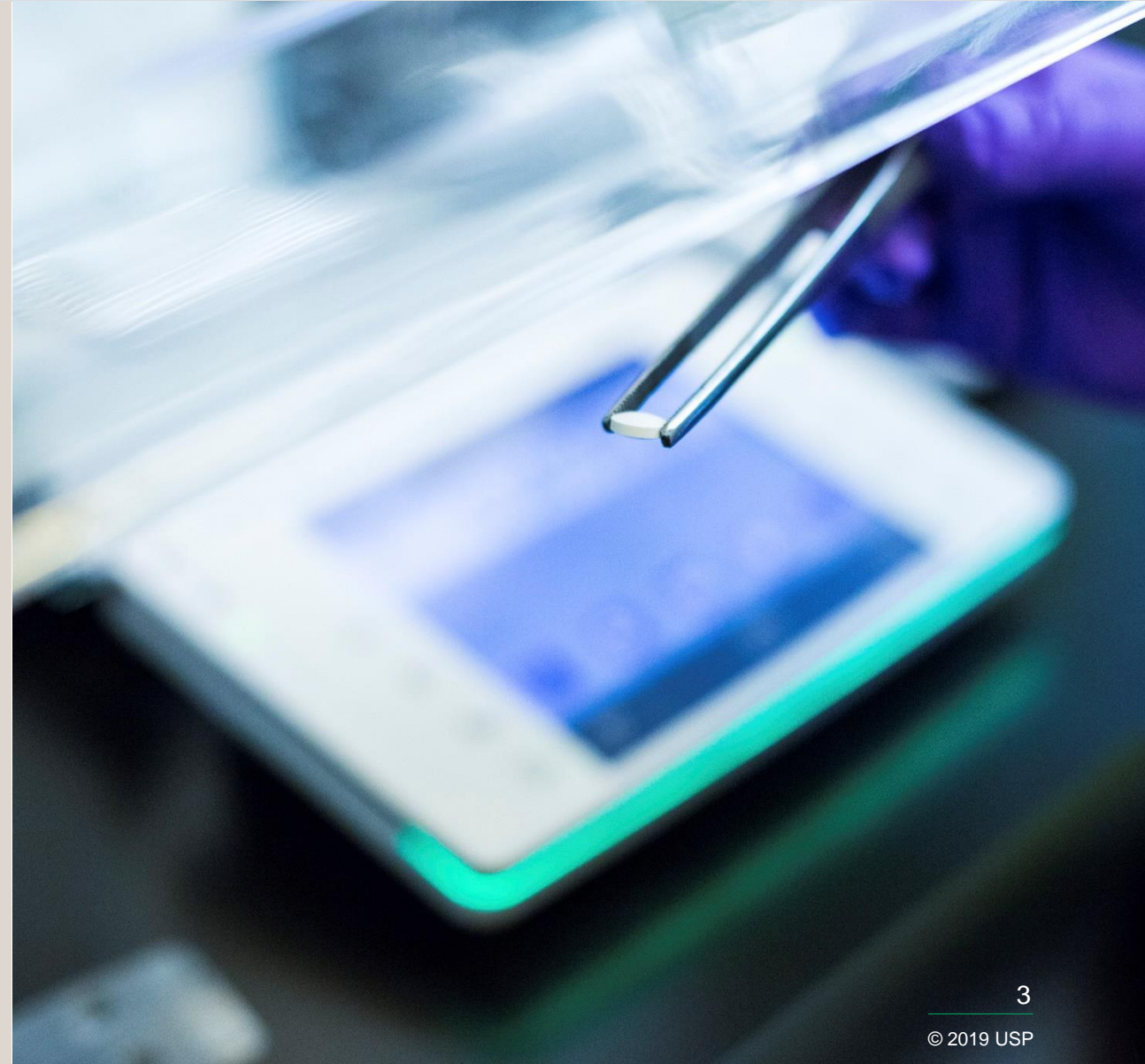
- ▶ Familiarize stakeholders with the general principles and approaches USP has used over the past decade or more for setting excipient Compendial Specifications for Excipient Composition and Organic Impurities.
 - Review of survey responses/Q&A
- ▶ Overview of Excipient Elemental impurities proposed Roadmap for removal and update of element specific chapters and stand-alone tests in excipient monographs
 - Review of the survey responses/Q&A



Stakeholder Engagement

Stakeholder Engagement

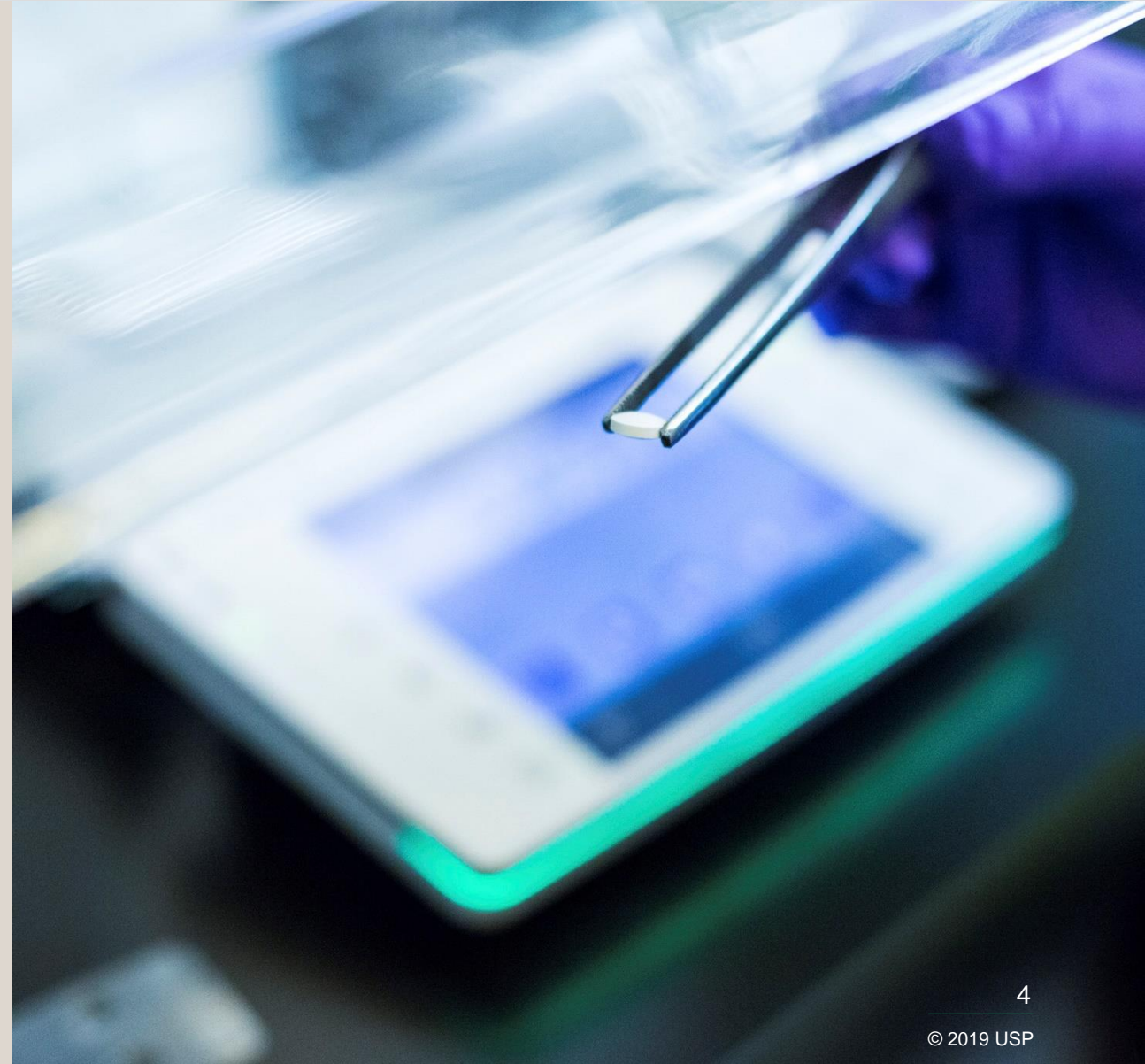
- ▶ Questions submitted at time of registration will take priority and be addressed during the Q&A sessions and the Question & Answer with the Speakers.
- ▶ Questions that are submitted through Q&A on the day will be answered as time permits.
- ▶ Questions not answered because of time constraints will be summarized and included in the Excipient Open Forum Meeting Summary.



Goals and Objectives

Next Steps

- ▶ Your participation in the Open Forum, responses to the surveys and submitted questions are the first steps in addressing your questions and concerns.
- ▶ At the end of the Open Forum, we will provide this information to the Excipient Composition and Impurities Joint Subcommittee to determine next steps: formation of a Project Team and other possible stakeholder engagement activities.



Thank You

