COVID-19, USP’s Impact:
Overview of USP’s Response

Christine Yu, Manager, Research & Innovation,
USP’s 3-part response to the COVID-19 pandemic

1. Ensuring safety and security of staff
2. Adapting our operations
3. Delivering on our public health mission
Goal: Reduced challenges to the supply of new and existing quality medical products required for, and impacted by, the Covid-19 pandemic

- Maintain and strengthen production of quality medical products required for, and impacted by, the Covid19 pandemic
- Maintain and strengthen support to regulators and public health stakeholders to ensure quality medical products in response to the Covid19 pandemic
- Increase prioritization of supply chain resiliency and quality of medical products on balance with current public health challenges
Addressing shortage risks in a three-prong approach

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Ensure Rapid Revisions and EC Continuity

- **Rapid Response Revisions**: Expedited timelines for monograph revisions to prevent supply disruptions.
- **Rapid Response Notices** on the uspnf.com, under Notices
  - Centralizing information on uspnf.com for compendial users
- **Continuity of meetings and ballots**
  - Contingency planning around quorum in the event of more widespread illness.
  - Support for Virtual Meetings
Supporting Drug and Vaccine Development for COVID-19

Contact: Fouad Atouf, Ph.D. Vice President, Global Biologics; Email: fa@usp.org

- USP offers technical assistance during product development and manufacturing, including but not limited to the following areas:
  - Best practices that are broadly applicable to manufacturing and testing strategies to ensure alignment with global regulatory guidelines
  - Qualification of excipients and raw materials to be used in manufacturing
  - Development, qualification, and validation of physicochemical tests and biological procedures that support characterization and release of (bio)pharmaceuticals
  - Approaches to analytical methods can meet compendial and regulatory expectations.

- Connect service providers that have passed USP’s quality audit program to companies in need of additional analytical services
Thank You