Welcome

Empowering a healthy tomorrow

USP stakeholder engagement through standards development

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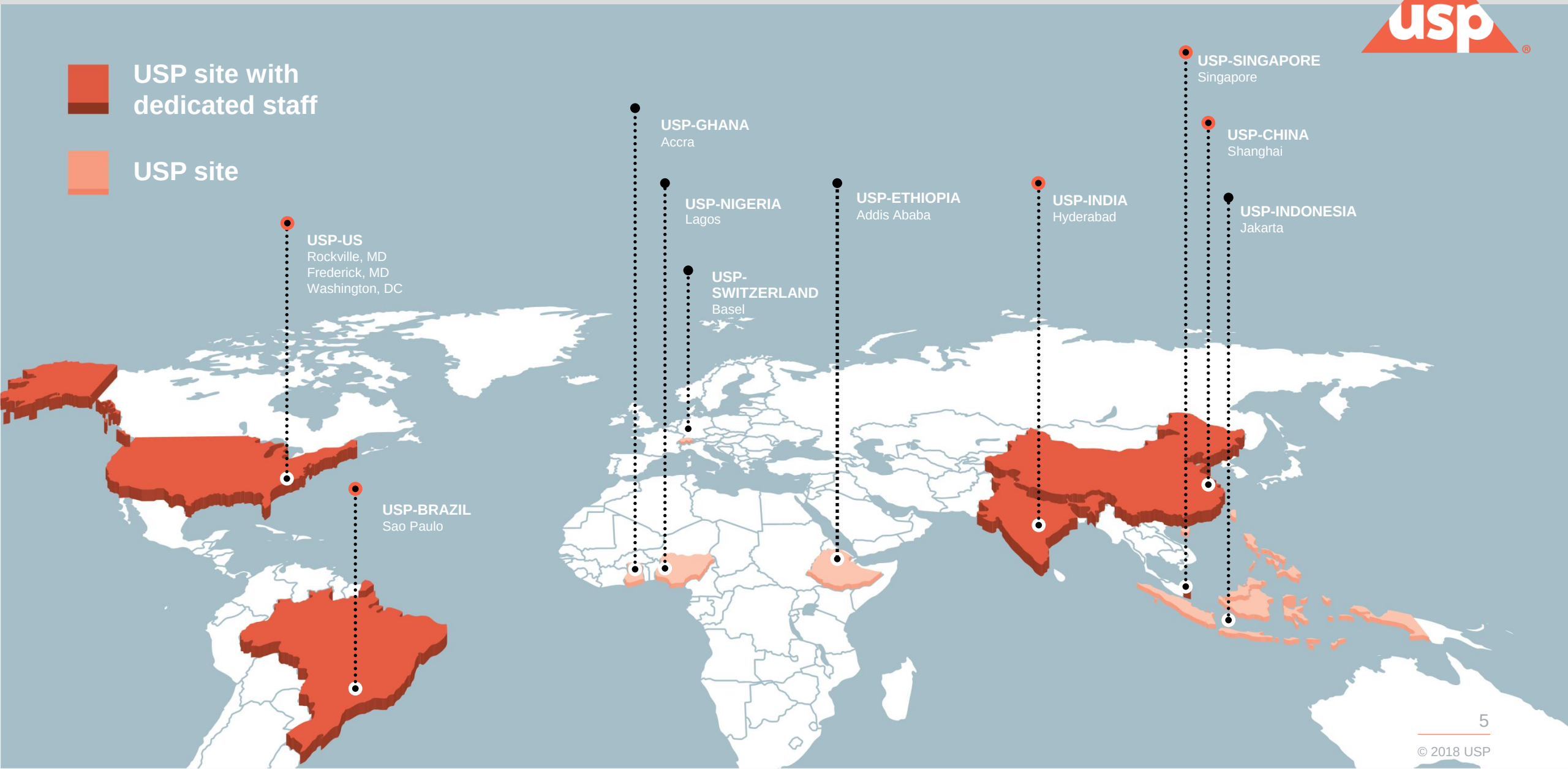
Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods


200
years building quality foundations for a healthier world
3,700+
reference standards
are available in 140 countries
50,000
people have attended trainings
on the effective use of USP standards since 2000
2
billion people
around the world have access to quality medicines, dietary supplements and food as a result of our standards, advocacy and education

We work globally



For quality standards to be impactful, they must be…

Aligned with
Public health and patient safety priorities

Developed by
Independent experts

Adapted & Improved
For technology and evolution of healthcare

Practical for
- Users of the standard
- Enforcers of the standard

Measured by
Public health impact indicators

Informed by
Real world implications for patients and practitioners

FDA-USP-Industry – developing standards

Stakeholders

USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.

- Healthcare Practitioners
- Patients
- Academicians
- Healthcare Industry
- Regulatory Authorities
- Manufacturers

USP Process

1. Public Health Need
- Need identified by any stakeholder or USP
- Need evaluated for possible standard development

2. Draft Standard
- Best practices and scientific information collected

3. Public Comment Period
- Draft standard published for stakeholder input

4. Review & Approval
- Comments evaluated and addressed
<or>
- Comments evaluated and further revision and comment needed

Revision Continues

Approved

5. Publication
- Final standard published with official date at least 6 months after publication

USP Expert Committee

USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.

- Healthcare Practitioners
- Academicians
- Healthcare Industry
- Regulatory Authorities (Non-voting Liaisons)
- Manufacturers

Stakeholder Implementation

Regulatory Authorities, State Practice Boards, Healthcare Industry, Healthcare Practitioners and other stakeholders utilize USP Healthcare Quality & Safety standards within their specific authority to help ensure public health.

Industry partners help drive quality

In 2016, more than **150 companies**

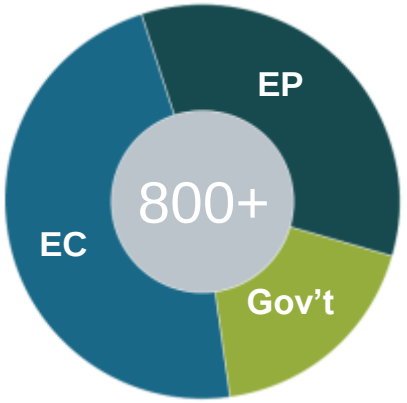
provided monographs and bulk materials to contribute to USP's standards development process that positively impacts global public health

800

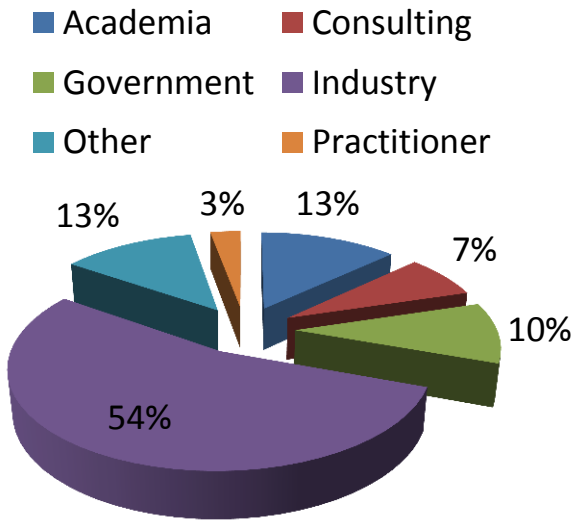
external experts

from industry, governments, nonprofits and academia

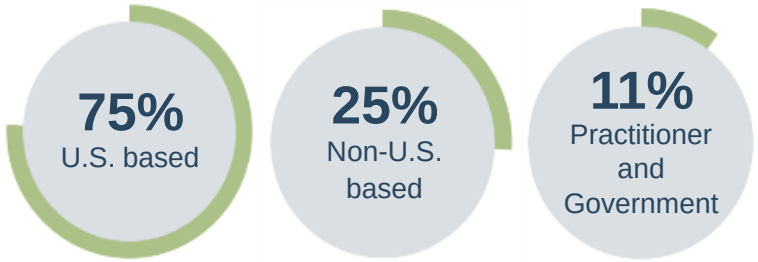
Independent scientific expertise behind our standards



Over 800 Scientific Experts: volunteers & government liaisons



Expert Committee Members by the numbers



Independent scientific expertise behind our standards

- Leaders in their respective fields in industry, academia, healthcare, regulatory affairs
- Together they contribute to standards development through Expert Committees and Expert Panels
- Government Liaisons also contribute to the process
- 100+ FDA staff participate as government liaisons, representing FDA opinions and viewpoints at public USP meetings (as opposed to USP volunteers, who represent their own opinions rather than their employers')

2020–2025

call for candidates

Join us on the Journey

Collaborate with highly dedicated leaders from science, medicine, healthcare practitioners, industry and academia to help us establish standards that make it possible for 2 billion people around the world to have access to quality medicines, dietary supplements and foods.

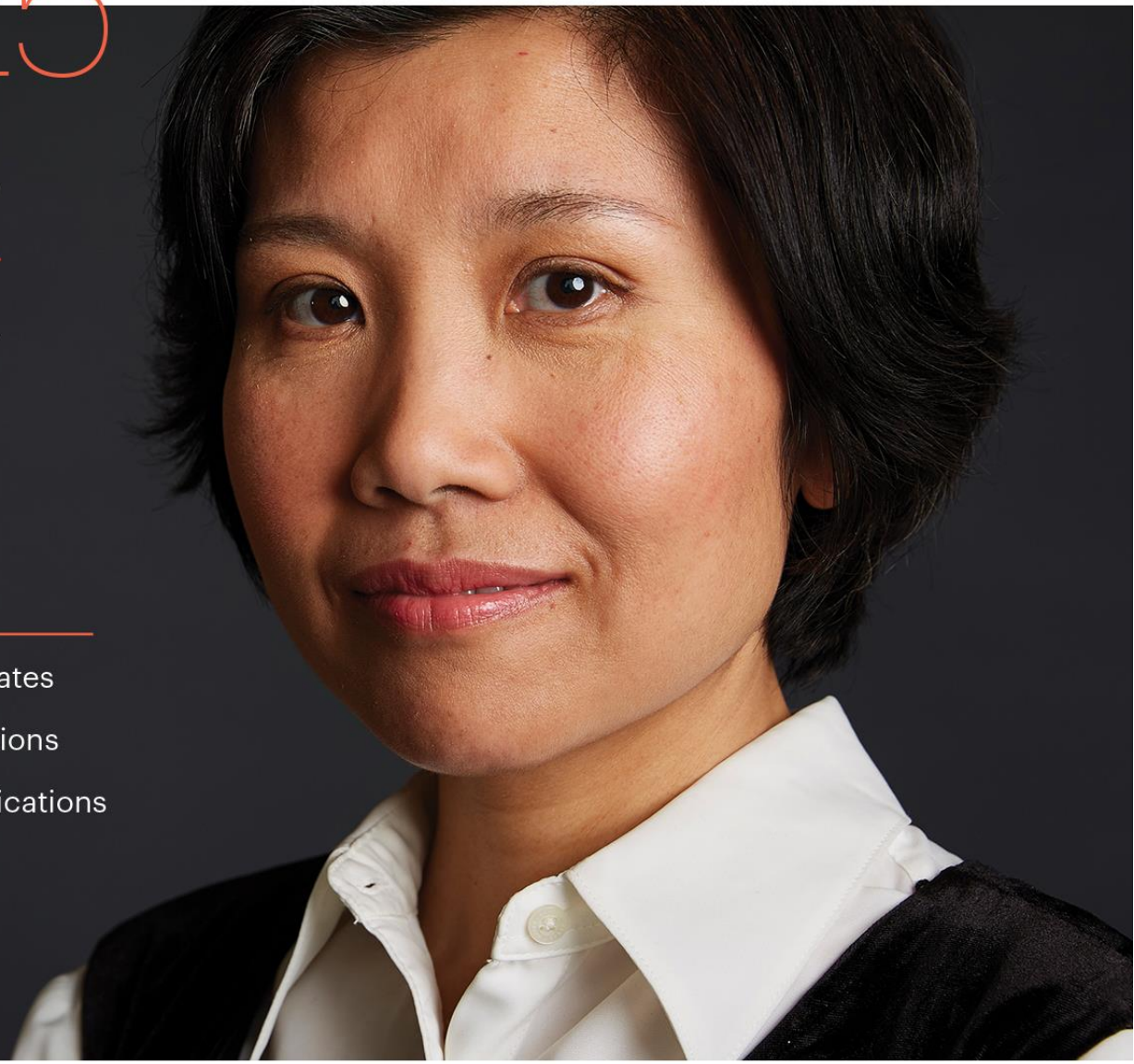
Important dates:

Jul 2018: USP launched the 2020-2025 Call for Candidates

Jan 2020: Deadline for Expert Committee chair applications

May 2020: Deadline for Expert Committee member applications

Jul 2020: 2020–2025 Council of Experts and Expert Committees begin their work



usp®

For additional information visit **callforcandidates.usp.org** or contact **USPVolunteers@usp.org.**

Engage, partner and advocate for quality

Partnerships drive quality

Partners in science

academics, practitioners

Partners in industry

R&D companies and generic manufacturers

Partners in government

regulatory and health authorities

Advocating for quality

- Increasing engagement with Congress has been a top priority
  - Opportunities for standards to contribute to policy
  - Minimize risks to public health and USP
- Created US advocacy function
- Established a local office in downtown, Washington, DC
- Robust and frequent engagement with the Hill and stakeholder groups.

FDA relationship

Resolution I –

Collaboration with the U.S. Food and Drug Administration

USP will increase communication and collaboration with the U.S. Food and Drug Administration (FDA) to promote alignment with FDA's regulatory and scientific policies from the inception of the standards planning and development process. USP will work with FDA, industry, and other stakeholders throughout the process to increase understanding of the regulatory impact of such proposals.

We have…

- Developed US regulatory affairs central function
- Built a systematic regulatory intelligence program
- Created internal coordination mechanisms
- Expanded Engagement – share perspectives, seek alignment, support FDA objectives
  - Regular meetings, advisory Committees, public meetings, written Improved partnership key FDA staff; meetings and outreach to key leaders and centers

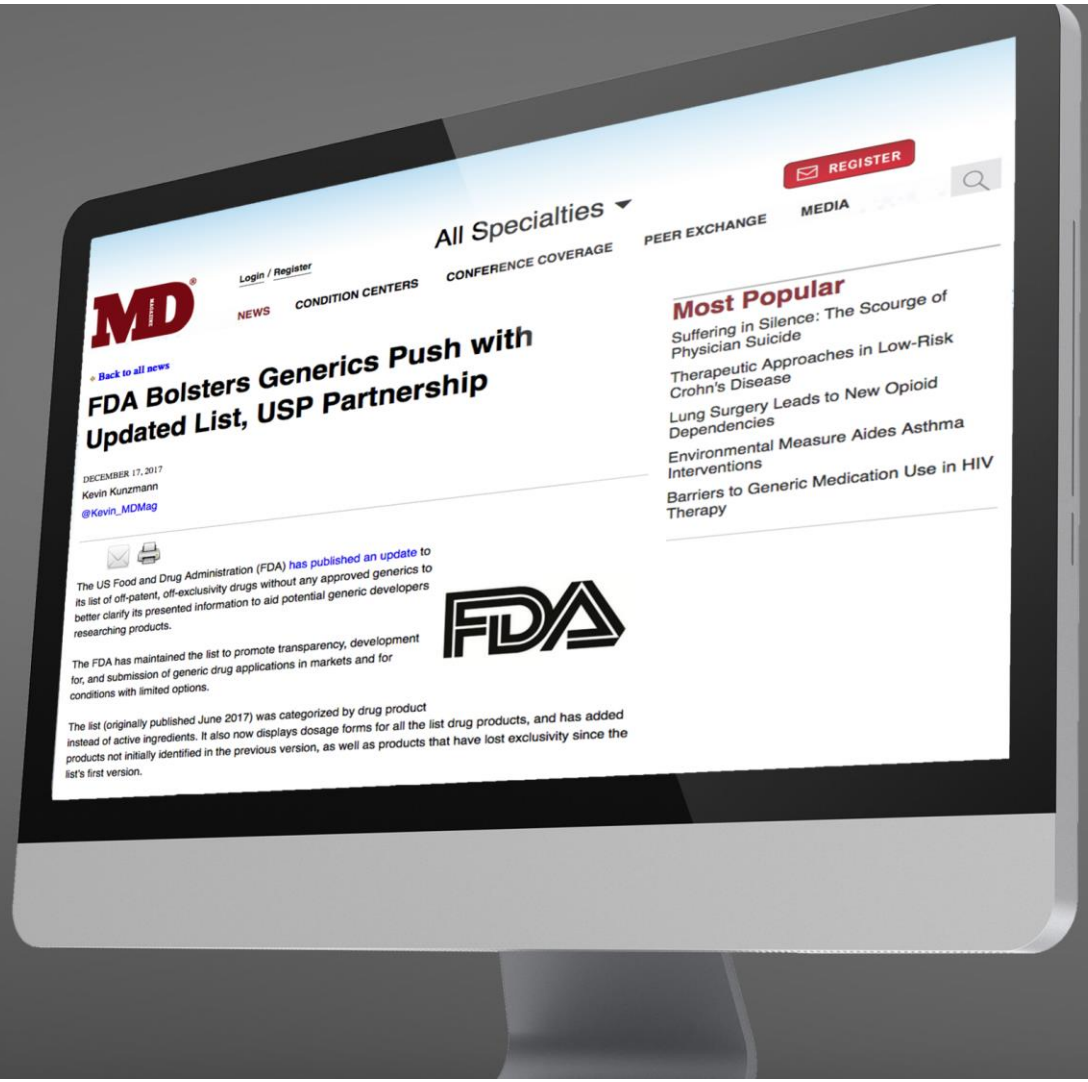
FDA-USP partnership

USP and FDA Work Together to Protect Public Health

- Five **FDA** centers and the Office of the Commissioner have established **delegates at USP's Convention**, the top leadership body of our organization.
- **USP** staff maintain **executive-level contacts with FDA leadership** and **routine contacts with FDA's Compendial Operations and Standards Branch** through quarterly meetings.
- **More than 100 FDA staff** participate as government liaisons **in USP's Expert Committees and Expert Panels**, the bodies that develop and revise USP's documentary and physical standards.
- **FDA enforces USP standards** for drug substances, drug products, and excipients **under the FD&C Act**.
- **USP and FDA** engage **in Cooperative Research and Development Agreements**.
- FDA staff participates in **USP workshops and Stakeholder forums**.

Advancing priorities

As part of the update, the FDA will now work with the US Pharmacopeial Convention (USP) to maximize the utility of the potential generics list, by allowing the nonprofit organization to use the list as a reference to determine drugs to advance the development of generic medicines for.



Access to generics

Exploring ways to advance generic action plan:

- Aligning priorities through dialogue/meeting with:
  - FDA leadership
  - Industry leadership
- Mapping USP's monograph work to FDA's biannual list
- Next steps:
  - Understanding facets of the "list"
  - Engaging in discussion(s) with stakeholders
  - Advancing processes that will support regulatory predictability and quality

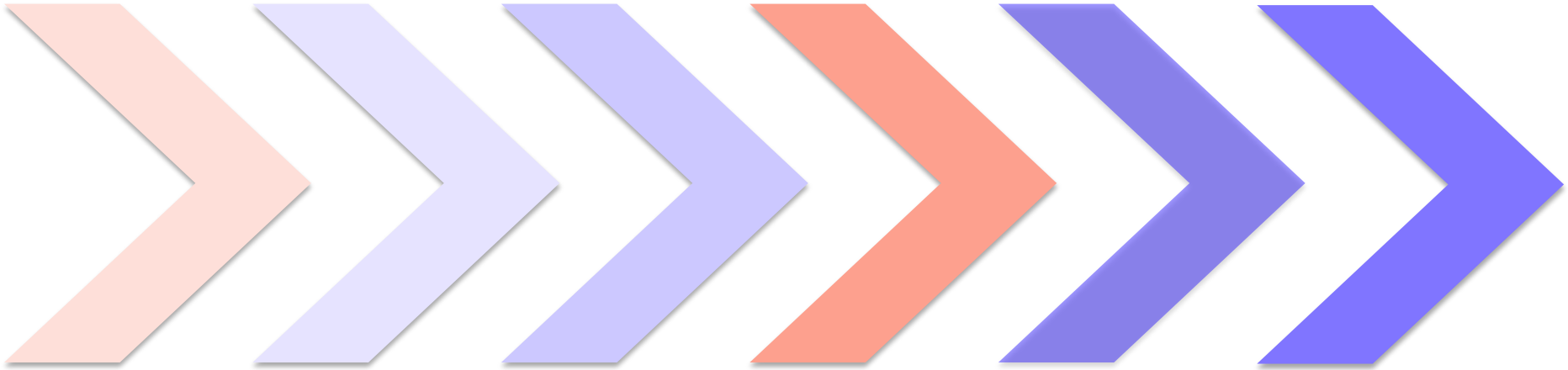
Standards to address

Prescription Opioids Abuse

USP's work on US opioids abuse epidemic

The approach . . .

- Early input from stakeholders
- Brainstorm on impactful solutions with HQS Expert Committee
- Engagement and buy-in from the community in the standards setting process



Assess current USP standards in opioids area.

Landscape federal and state actions and priorities

Expert Comm and USP staff brainstorm on potential areas for standards

Discussion forum with 20 govt agencies and **top stakeholders to validate ideas** and blue sky for more ideas

Formal full day **USP Roundtable** with 60 stakeholder groups **to gather specific feedback on 4 proposals**

HQS Expert Development of concepts with continued out reach to Stakeho

USP and OTC reform

Discuss options and develop a roadmap forward

In support, USP is working to:

- Advance quality of OTC monograph products
- Identify roles of public standards and what needs they fulfill
- Explore innovations in monographs and their process
- Remain aware and mindful emerging reform

Achieving in Up-To-Date

Lack of access to critical information for monograph development

Critical Resources Information Sharing Priorities (CRISP)

- Concerted effort to describe the issue, explore options, and maximize resources
- Accomplishments:
  - Ongoing FDA engagement
  - Defining and understanding the problem through data analysis, legal analysis, and outlining USP processes
  - Options developed: establish data supported best practices, process enhancements, and legal theories

Achieving in Up-To-Date

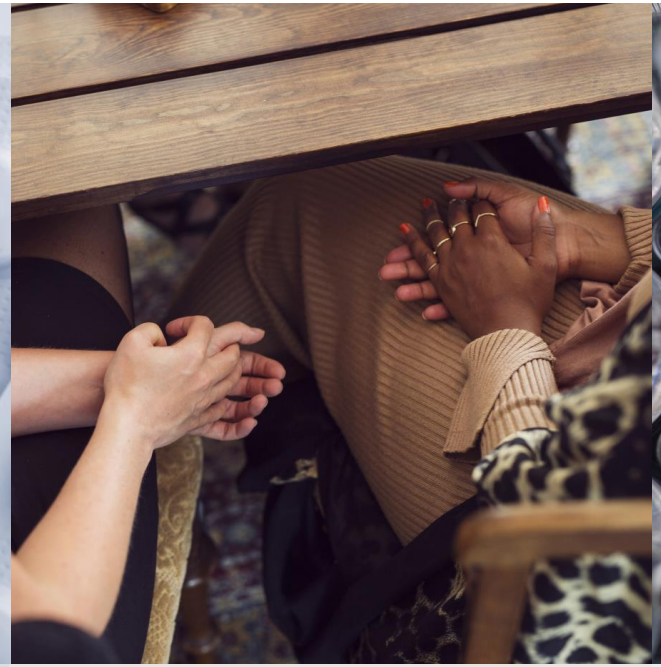
Engagement to address challenges:

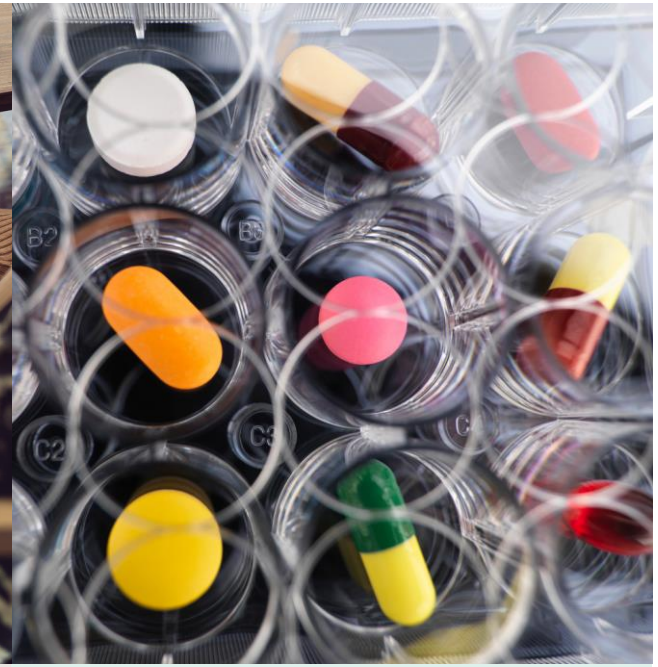
- Identifying and addressing issues around sources of information used to develop impurities-limits
- USP process for outreach to manufacturers of proposed monographs
- Developing, with stakeholders, a strategy to get more clarity/specifity in PF comments
- Pending process as a facilitating mechanism

Pending Process

- Current process became effective in June 1, 2015
- Developed in close consultation with FDA
- Utilizes *Pharmacopeial Forum (PF)* to solicit public comment when needed
- Incorporates development of new monographs associated with applications under FDA review into the regular USP-NF process
- Process documented in Pending Monograph Guideline

Working together to advance health through quality





Advancing quality
[What we do]

Working with partners
[How we do it]

Building a healthier world
[Our impact]

Questions

Empowering a healthy tomorrow

Thank You

Empowering a healthy tomorrow