200 Years of Quality: Building Trust in Medicines and Supplements

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer, USP

Anthony Lakavage, JD
Secretary, USP Convention & Board of Trustees
Sr Vice President, Global External Affairs

Loma Linda University Institute for Health Policy and Leadership
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Agenda

- Who is USP?
- Responding to the challenges surfaced by the COVID-19 pandemic
  - Medicines supply chain resilience
  - Strengthening the supply of trusted, quality COVID-19 vaccines and treatments
- Expanding the quality of dietary supplements
- Facilitated Q & A

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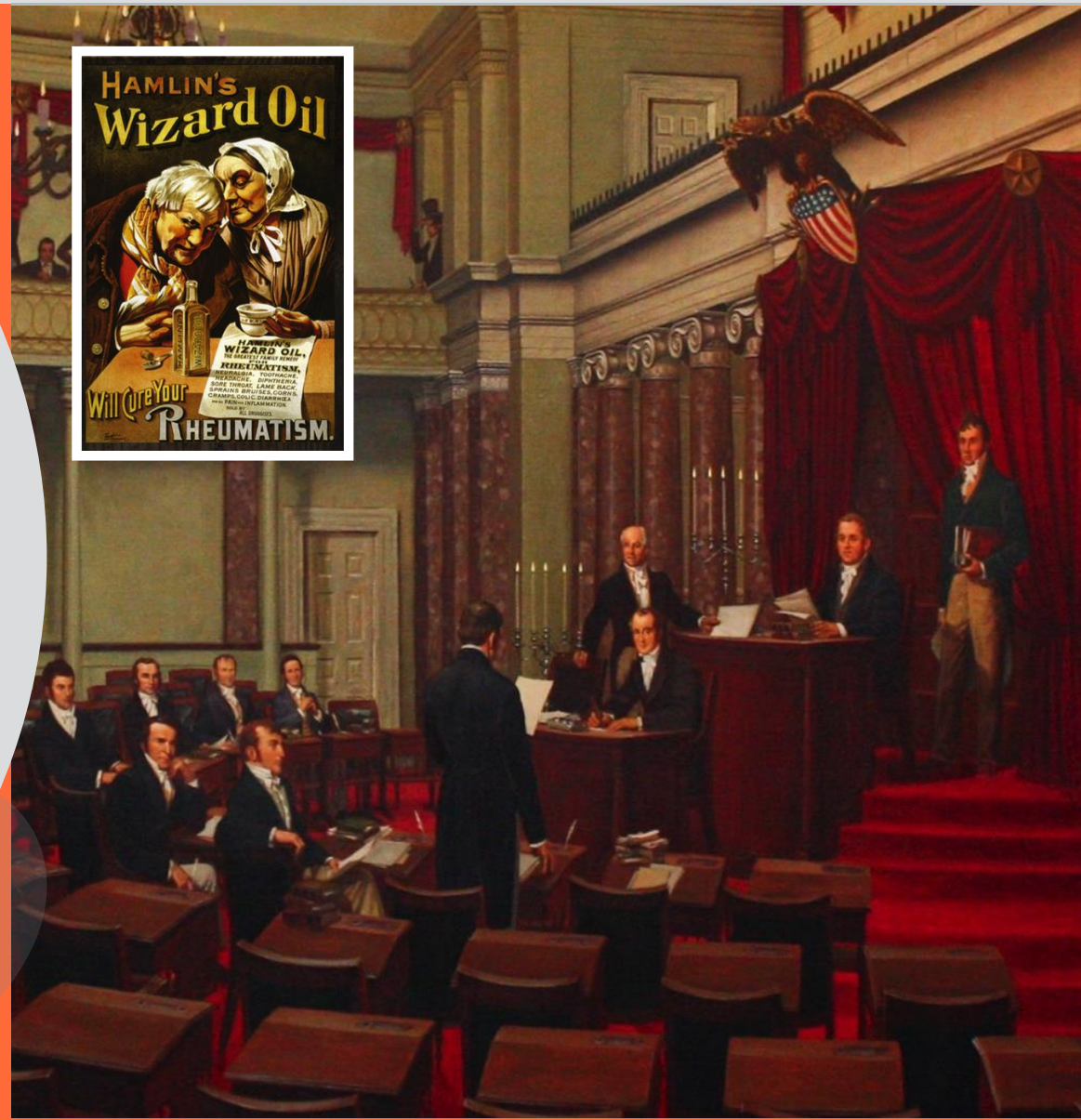
Who is USP?

USP Mission

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

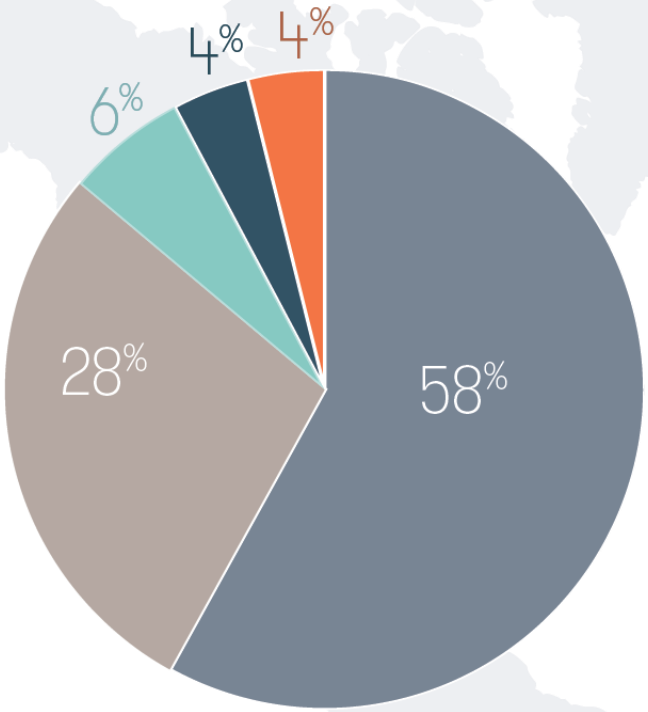


Responding to today's public health challenges through coordinated standards, advocacy, and capability building

- **Standards:** To be a definitive source of standards for the supply of quality medicines
- **Advocacy:** To be the global institutional leader advancing the supply of quality medicines
- **Capability Building:** To be a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients

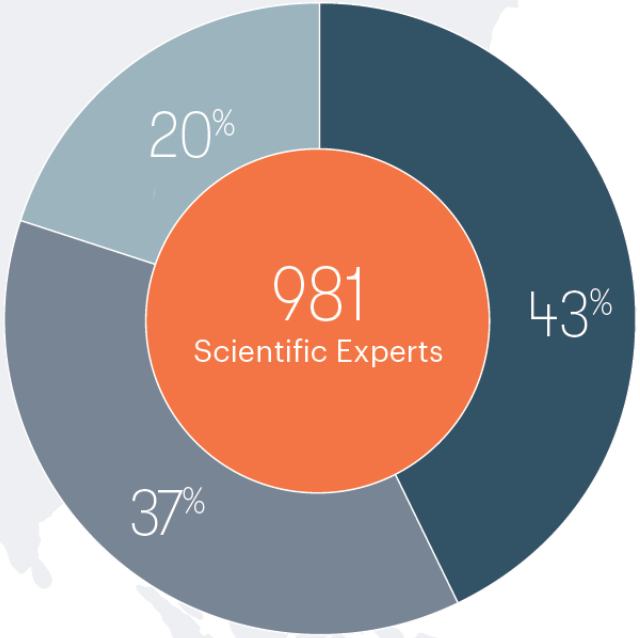
Our people – USP's global staff and volunteers

1200+ Staff



- United States
- India
- China
- Brazil
- Other global sites: Ethiopia, Europe, Ghana, Indonesia, Nigeria, Singapore

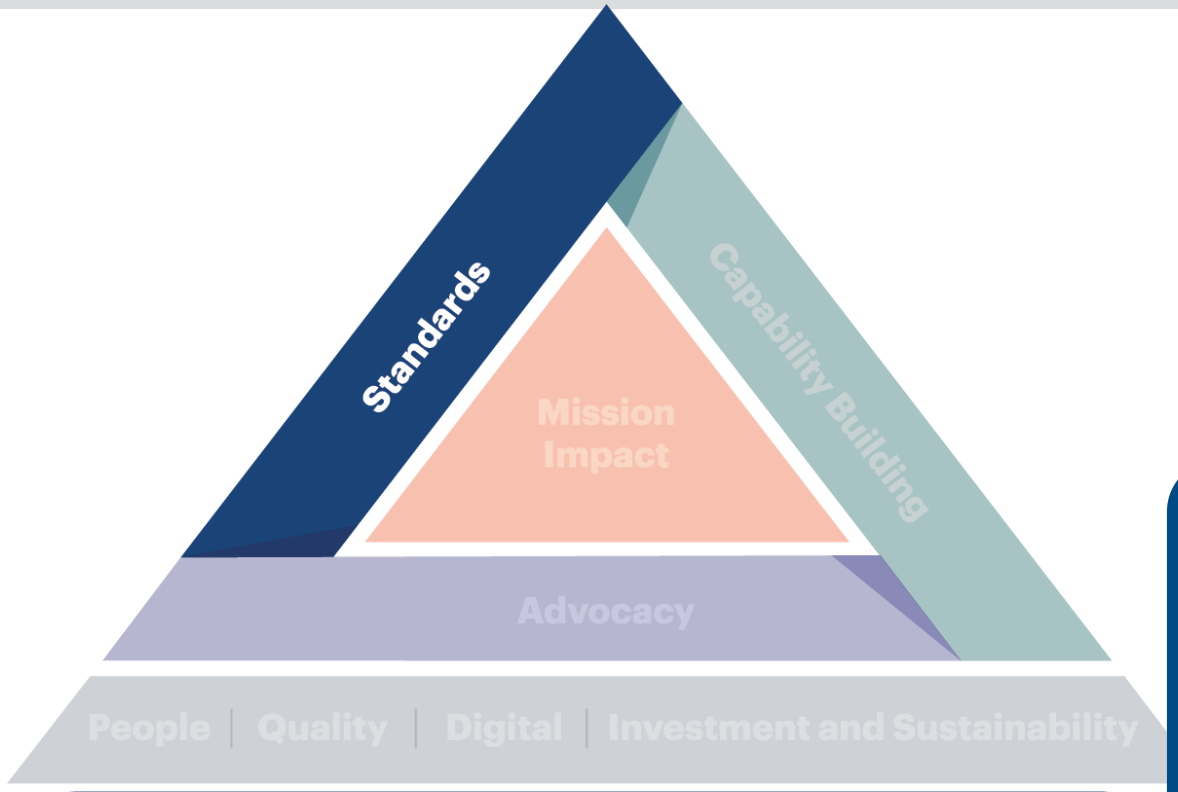
981 Scientific Experts—Volunteers and Government Liaisons



- 428 EC Members
- 362 EP-Only Members
- 191 Government Liaisons

Evolving standards to address quality paradigm shifts

- Leading standardization of new scientific approaches (e.g., risk-based, performance-based, flexible)
- Providing knowledge on more-complicated and emerging modalities
- Facilitating establishing equivalence for evolving analytical and advanced manufacturing technologies
- Ensuring our standards stay relevant and help improve the supply of quality medicines

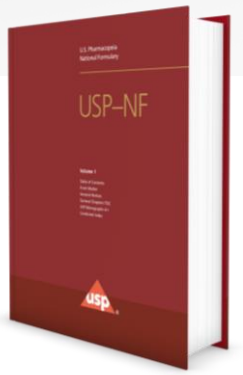


Being a definitive source of standards for the supply of quality medicines

Standards

More than 9,000 USP Standards provide quality benchmarks across the supply chain

- Standards for medicines, excipients, and APIs in *USP-NF*
  - 350 General Chapters
  - 4,900 product-specific monographs
  - 3,500 physical reference standards
- More than 1,200 standards for dietary supplements in the *Dietary Supplements Compendium (DSC)*
- Nearly 1300 standards for Food Ingredients in *Food Chemicals Codex (FCC)*
- More than 500 standards for biologics
- About 300 Healthcare Quality & Safety Standards, including compounding, nomenclature and labeling, safety, etc.

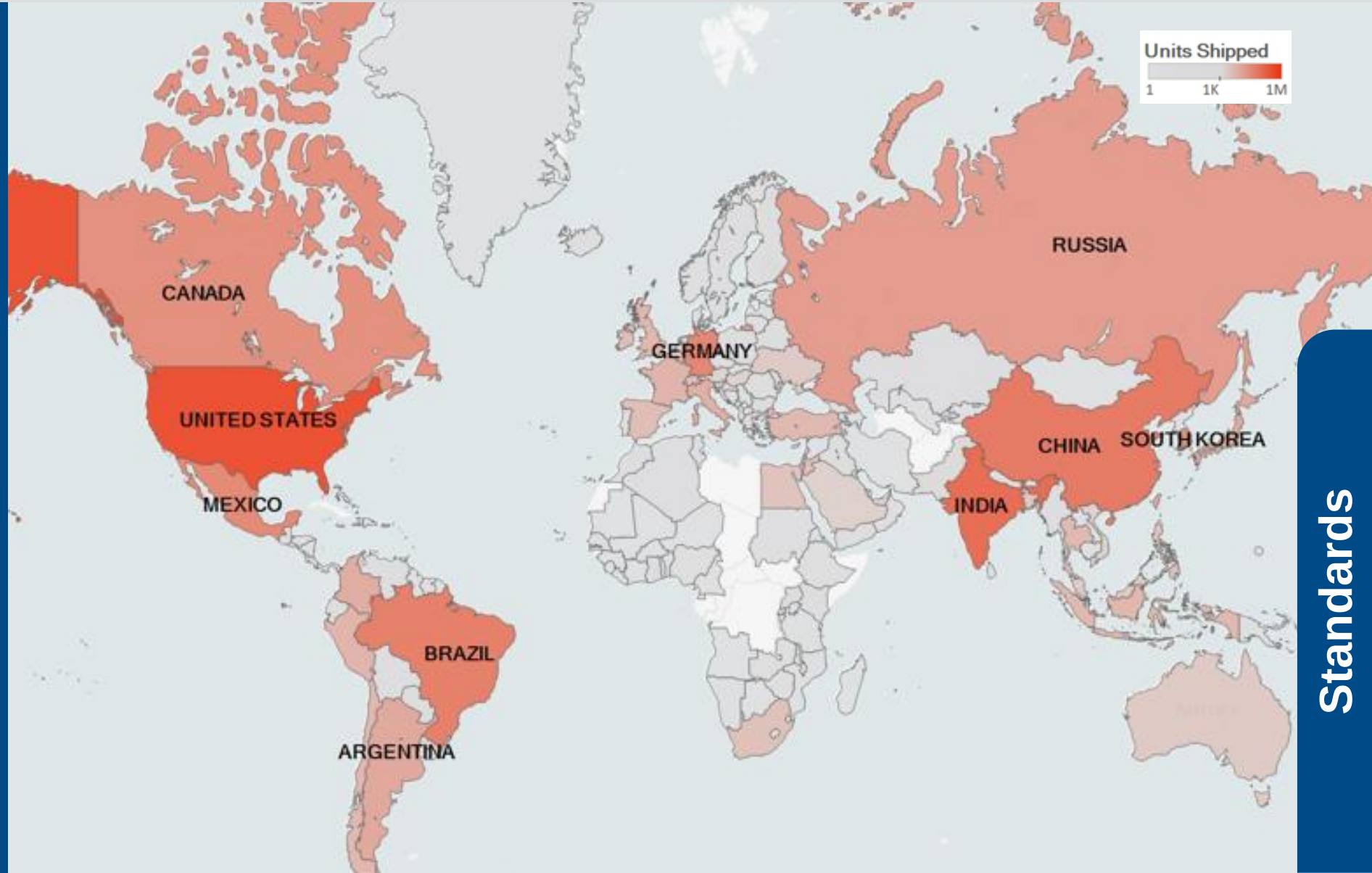


Standards

USP standards are utilized in over 150 countries

USP Reference Standards were shipped to over **22,000** entities in FY19

Units of USP Reference Standards shipped globally (Top 10 countries labeled, 2015-2019)



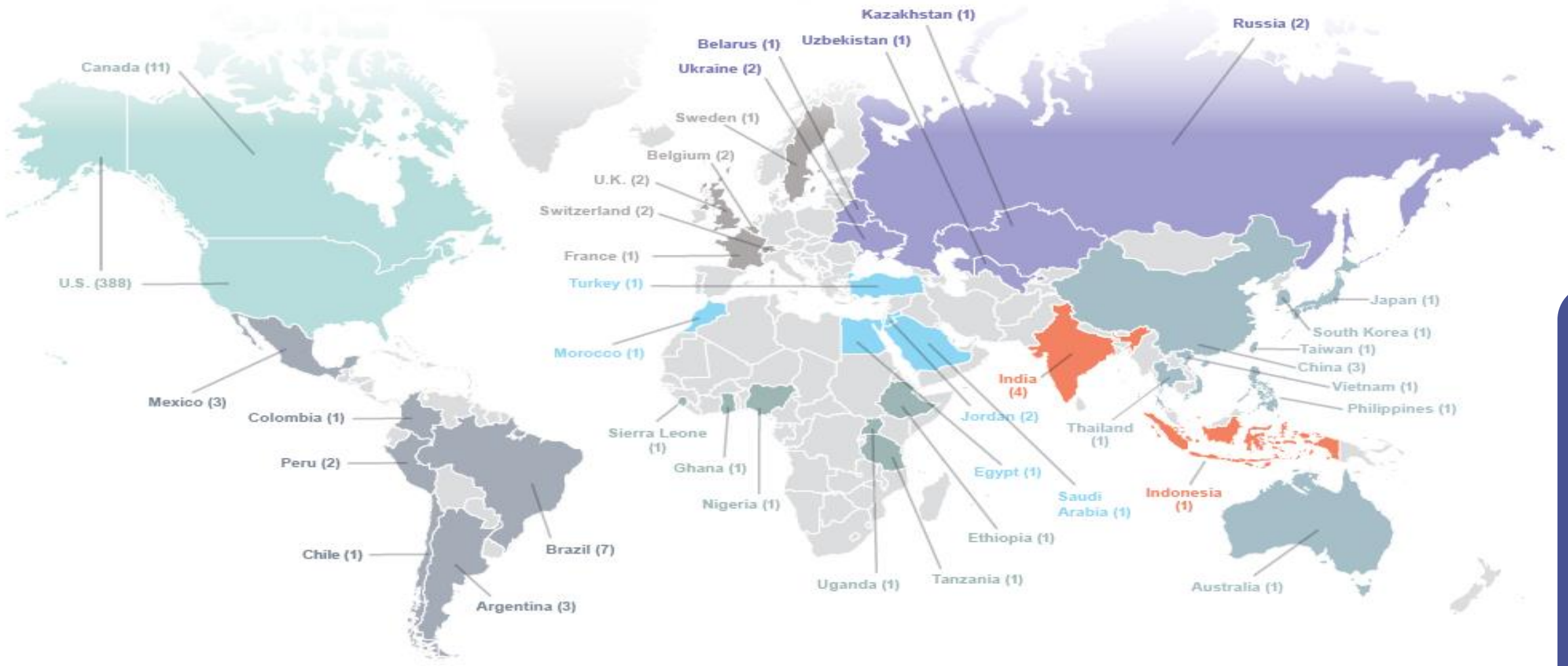
Standards

Advocating for the supply of quality medicines worldwide

- Generating data to inform policy making through the USP Quality Institute (e.g., AMR, excipient quality, and procurement policies)
- Engaging in public dialogues to provide USP's expertise and perspective in the interest of better policy and outcomes
- Collaboration with stakeholders and USP Convention members to help inform and drive change
- Supporting the supply of and public trust in vaccines and treatments to address COVID-19
- Longstanding regulatory engagement with pharmacopeias and governments worldwide

Advocacy

Our global engagement and advocacy is powered by more than 490 USP Convention Organizations



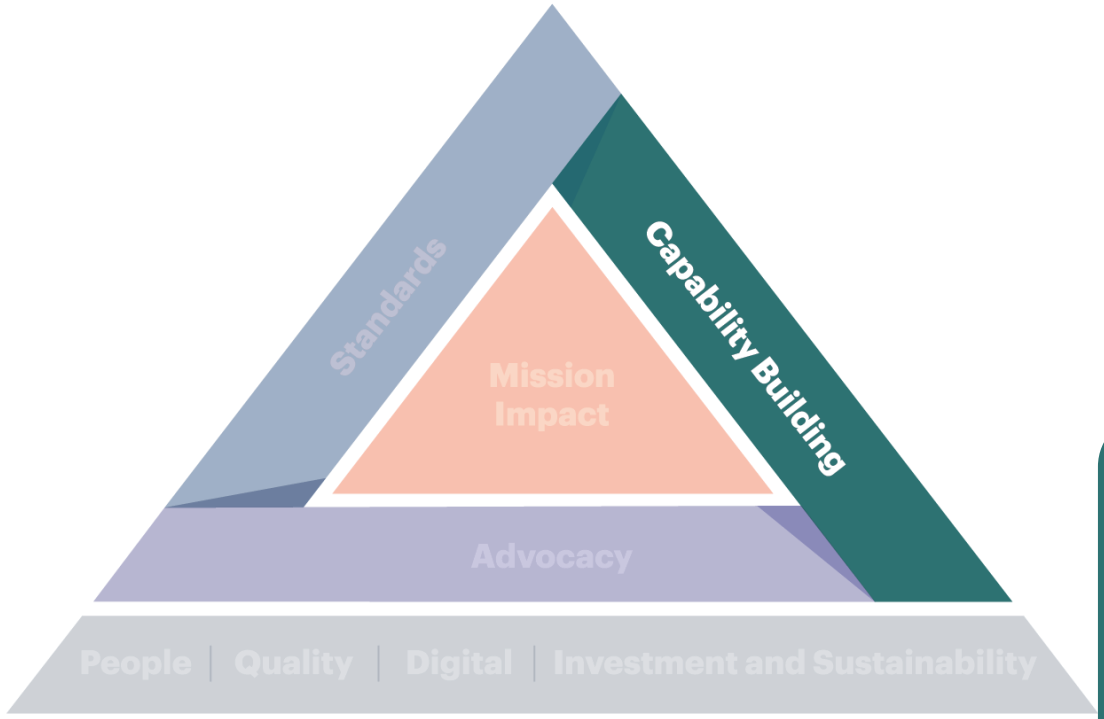
FAST FACTS

490+ Total members | **6** Categories (based on Bylaws) | **40+** Countries represented

Advocacy

Education, training, and verification services to build stakeholder capabilities in advancing medicines quality

- Helping global regulators and manufacturers acquire the required skills, knowledge, tools or enabling environment to advance access to quality medicines and medical products
- Verification services for industry (e.g., dietary supplements, excipients)
- Facilitating the adoption of new manufacturing technologies (e.g., continuous manufacturing)
- Custom tailored standards and tools for analytical research & development (e.g., impurities)
- Donor funded work to support regulatory and industry capability building in LMICs



Being a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients

Capability Building

2 Responding to today's public health challenges

USP's work to address challenges surfaced by the COVID-19 pandemic

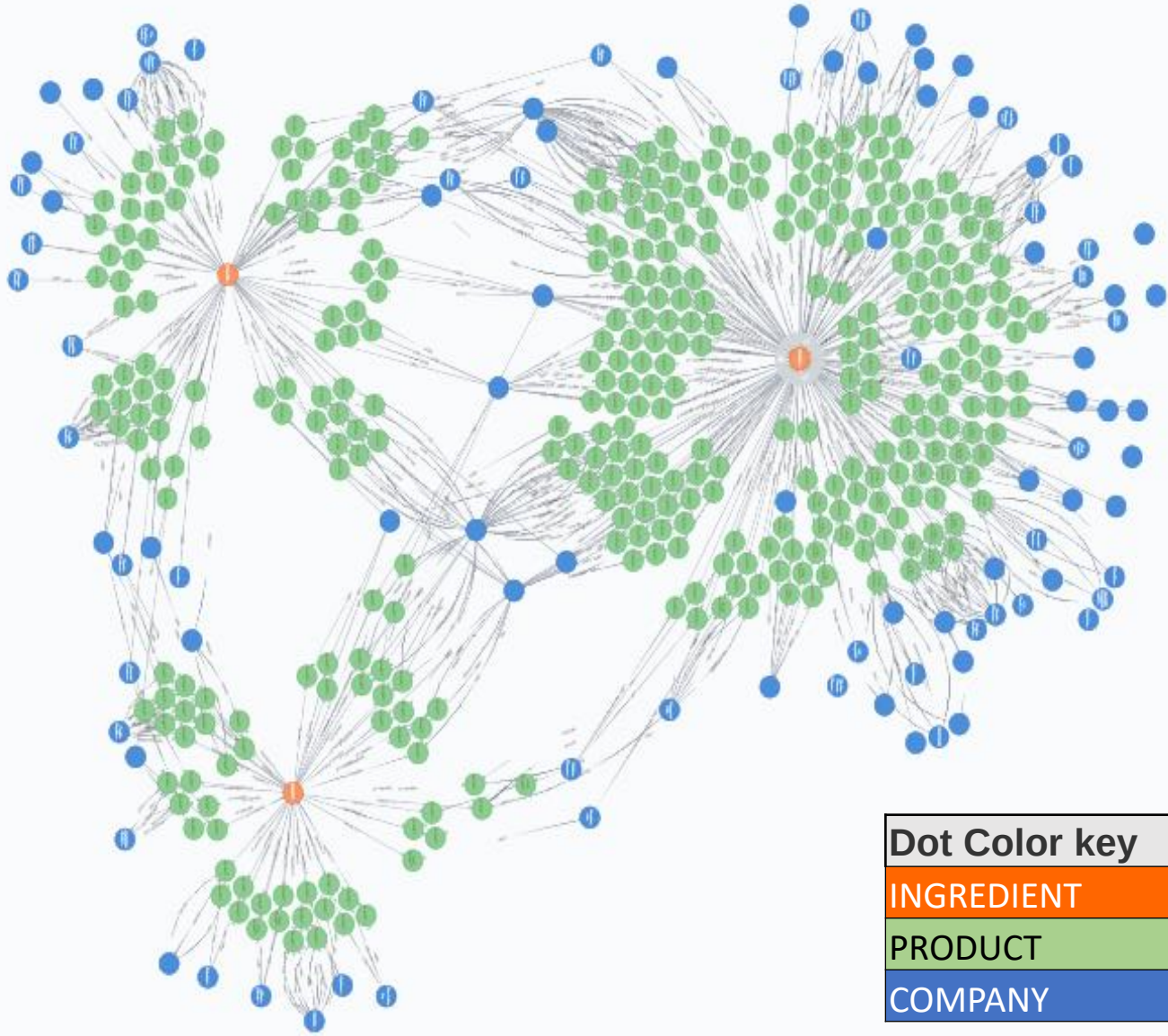
USP has published a white paper identifying key actions to secure a more resilient supply chain

- Foster more, not less, supply chain diversity
- Invest in more manufacturing capacity for critical medicines (e.g., continuous manufacturing)
- **Enable more transparency and data sharing**
- Conduct crisis contingency planning and action
- Strengthen regulatory systems and quality assurance globally

https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/global-policy-supply-chain.pdf

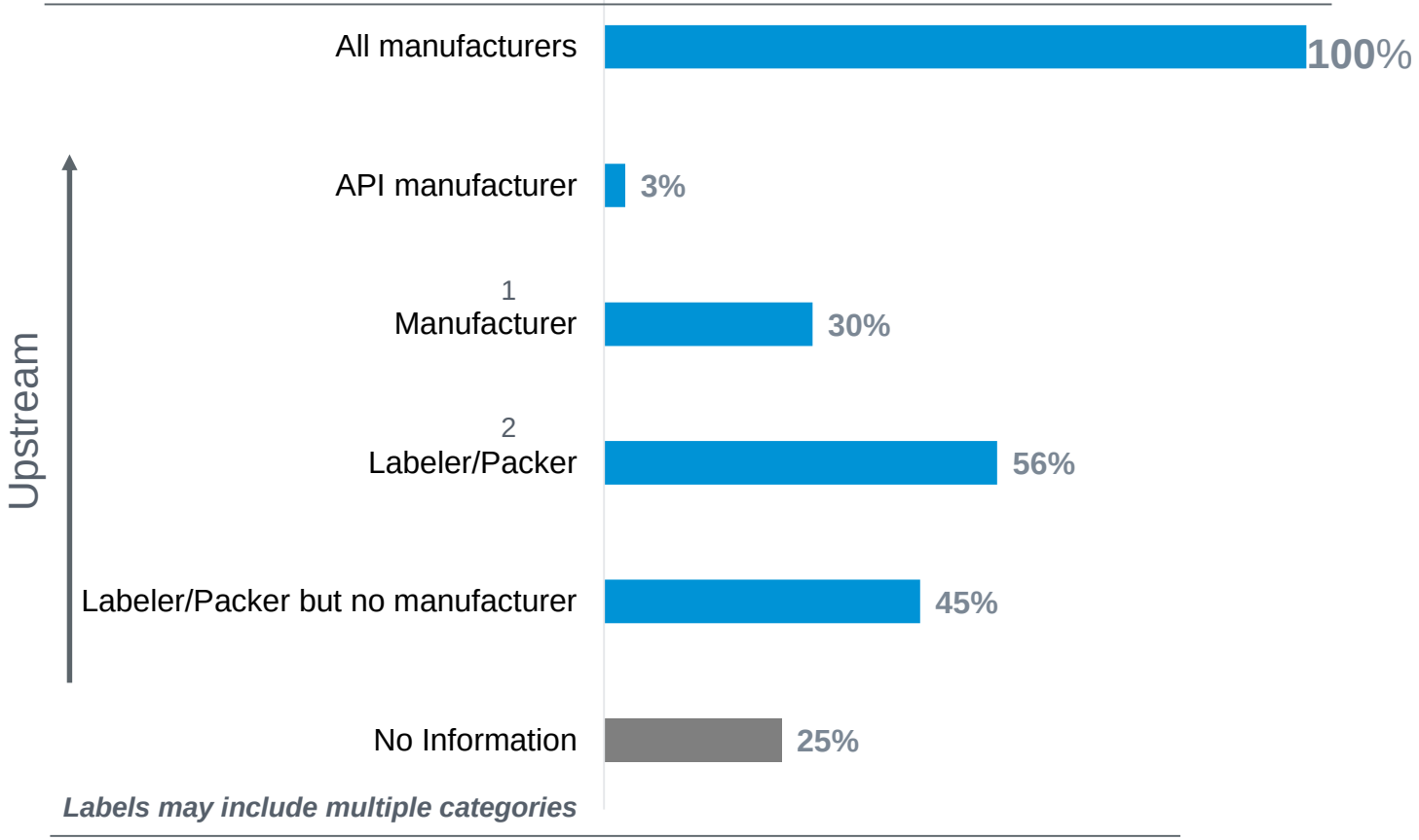
We are generating proactive insights on risk in the upstream supply chain

- We created the USP Medicine Supply Map as an early warning system to identify, characterize and quantify risk in the upstream pharmaceutical supply chain
- Data model links across 10+ datasets and dozens of data elements, including USP's proprietary insights
- "In-the-field" data gathering, including through USP's subject matter expert network
- More than 1 million medicines globally included
- Graph-based data model is capable of tracking quality issues up the supply chain



Example: there is a need for greater upstream supply chain transparency

Information listed on U.S. approved human prescription drug labels (N=40,178)



Source: USP analysis of DailyMed
1 Includes 'Analysis','FDF Manufacturer', 'Manufacturer", Particle size reduction', "Positron Emission Tomography Drug Production', 'Recovery', 'Sterilize', 'Transfill'
2 'Label, Relabel, Pack, Repack''

- While approval information is known, we don't know how many are manufacturing the medicine/API
- All labels specify ANDA filer, an entity responsible for the drug's quality. However, manufacturing is often done by a different entity than the filer
- While manufacturers are required and do report suppliers to U.S. FDA, also sharing supply chain information publicly could help providers proactively safeguard patient health. (e.g., when a safety issue is identified with an API manufacturer, providers will have on-hand information about impacted brands)

Agile approach to support COVID-19 vaccines and treatments

Vision:

1. Improve access to innovative vaccines through reductions in development times and increased scalability

2. Provide a safeguard against poor quality vaccines, ensuring public trust and safety

Building stakeholder capabilities to support development of COVID-19 vaccines and treatments

- Launching the USP Trust Accelerated Program to help speed development of quality COVID-19 treatments and vaccines
- Convening a Vaccine Advisory Group to monitor trends, interpret, refine and prioritize USP's efforts to facilitate global access
- Education and training opportunities from hot topics webinars to industry co-developed courses addressing key vaccine challenges
- Free-of-charge technical assistance to support development and scale-up of potential vaccine candidates
- Convening stakeholders on building and maintaining trust in COVID-19 vaccines. advocating for quality assured vaccines

Expanding the supply of quality dietary supplements

Millions of Americans take dietary supplements

More than **3** out of **4**
Americans take
dietary supplements.[1]

In the past **25 years**, the
dietary supplement industry
grew from

$4 billion with
4,000 products to
$40 billion with
50,000+ products[2]

From 2007-2019,
965 of the products
tested by the FDA were identified to include potentially hazardous substances or hidden ingredients.[3]

1. Council for Responsible Nutrition. (2019). 2019 CRN Consumer Survey on Dietary Supplements. www.crnusa.org/CRNConsumerSurvey
2. Advisory Board. (2019, February 13). FDA says it's cracking down on the $40B dietary supplement industry—but is it just a 'big PR push'? www.advisory.com/daily-briefing/2019/02/13/fda-supplements
3. U.S. Food & Drug Administration. (2019, October 2). Tainted products marketed as dietary supplements. www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder

Overview of dietary supplement regulation in the U.S.

- Dietary Supplements Health Education Act (DSHEA-1994) defines supplements as foods containing dietary ingredients, including:
  - a vitamin; mineral; amino acid
  - an herb or other botanical;
  - a dietary substance for use by man to supplement the diet;
  - a concentrate, metabolite, constituent, and/or extract
- Dietary supplements cannot be marketed for use to treat, mitigate, or cure a disease.
- An exclusion clause prohibits drugs that were the subject of clinical studies before DSHEA to be marketed as dietary supplements
- Dietary supplements do not require pre-market approval, but the FDA must be notified before marketing of “new” dietary ingredients

USP helped form the Dietary Supplements Quality Collaborative (DSQC) to expand the safety and quality of supplements

Steering Committee

AARP Real Possibilities
AMA American Medical Association
CHPA Consumer Healthcare Products Association — Taking healthcare personally.
OAC Obesity Action Coalition
Council for Responsible Nutrition — The Science Behind the Supplements
NSF International
The Pew Charitable Trusts
Pharmavite
USP

Observers

Arthritis Foundation
NACDS
NABP National Association of Boards of Pharmacy
Purdue College of Pharmacy

Members

eat right. Academy of Nutrition and Dietetics
Alliance for Aging Research
ashp pharmacists advancing healthcare
Center Boston Medical — Exceptional care. Without exception.
Boston University
Children's Hospital of Philadelphia
The Gerontological Society of America
LegitScript
NCL National Consumers League
Obesity Society — Research. Education. Action.
UMKC
UL
American Botanical Council Since 1988
APhA American Pharmacists Association

DSQC Advancing the Quality and Safety of Dietary Supplements

DSQC delivers its mission through three pillars

Promote Safety

Advance Transparency

Embrace Quality Practices

There is a greater need to advocate for greater transparency and quality of supplements

- The supplement industry has grown from a few thousand to well over 50,000 products[1]
- 25 years after Congress enacted DSHEA, the greatest weakness is FDA's inability to "see" into the marketplace
- FDA has limited means of knowing
  - What products are in the market
  - Which companies are producing supplements
  - What ingredients they contain

1. Advisory Board. (2019, February 13). FDA says it's cracking down on the $40B dietary supplement industry—but is it just a 'big PR push'? www.advisory.com/daily-briefing/2019/02/13/fda-supplements

USP launched the Dietary Supplement Verification Program to strengthen public trust and help ensure the quality of supplements

The USP Verified Mark on a dietary supplement label indicates that the product:

- Contains the ingredients listed on the label, in the declared potency and amounts.
- Does not contain harmful levels of specified contaminants.
- Will break down and release into the body within a specified amount of time.
- Has been made according to FDA current Good Manufacturing Practices using sanitary and well-controlled procedures.

Data Source: Verification Programs

Public quality standards help strengthen stakeholder trust across the supply chain

Industry

Dietary supplement and ingredient manufactures produce quality products

Practitioner/Patient

Uphold practitioner and patient confidence in the quality of their supplements

Governments

Regulators ensure quality products reach consumers

Facilitated Q & A

Stay Connected

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