

USP Open Forum | January 27 & 28, 2021

Manufacturing Alcohol to Combat a Public Health Emergency:

Insights on Regulatory and
Quality Requirements



USP Overview

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January 27, 2021





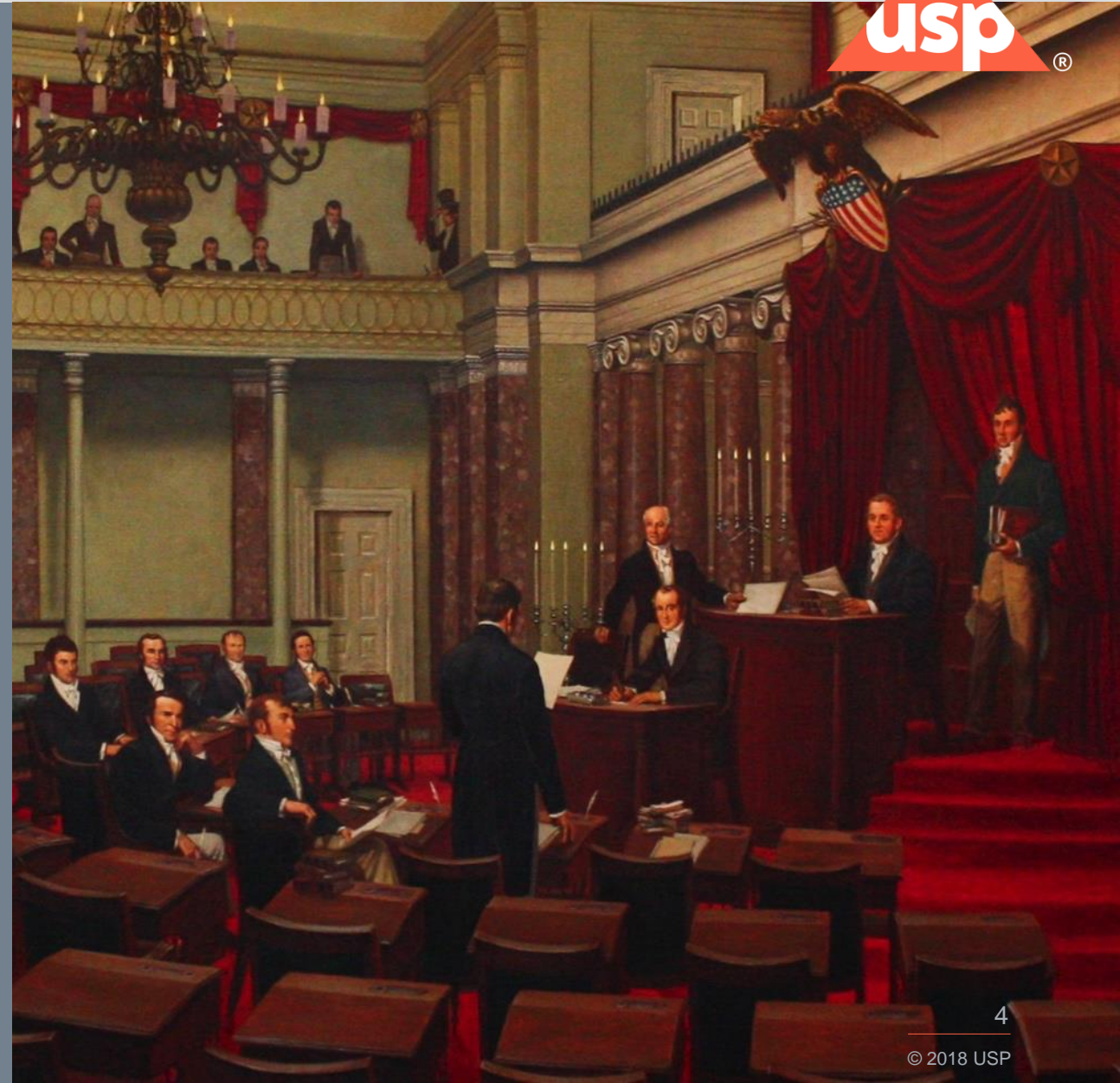
Mission

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



Need for standards

- ▶ 11 Founding members with a vision
- ▶ Legal recognition
- ▶ Official compendium



Role of USP Drug Quality Standards and Law

USP's standards have been recognized in U.S. law under the Federal Food, Drug, and Cosmetic Act (FDCA) since 1938

Under the relevant FDCA provisions:

- ▶ A drug with a name recognized in the *USP–NF* must comply with the **identity/identification** requirements of its monograph, or be deemed adulterated, misbranded, or both
- ▶ A drug must also comply with compendial standards for **strength, quality, and purity** unless labeled to show all respects in which the drug differs



USP and the FDA Have a Shared History and Mission



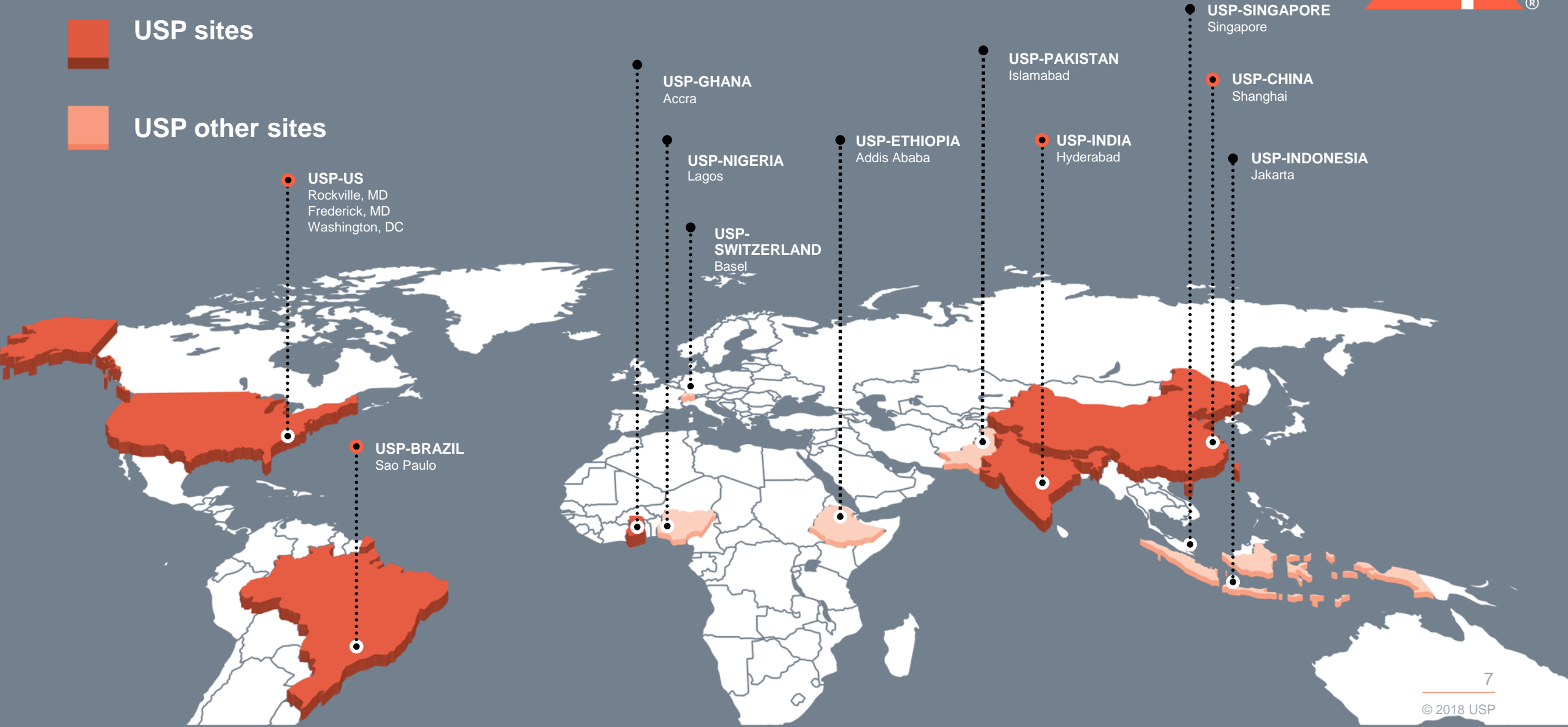
- ▶ For more than a century we have shared a close relationship and collaborative history with the FDA
- ▶ Together we have worked to protect the public health and promote the quality and safety of medicines, supplements, and foods
- ▶ Our work compliments that of the FDA and other government agencies at home and abroad, through our drug and biologic standards, dietary supplement standards, food ingredient standards, verification programs, and other activities around the globe

We work globally



 **USP sites**

 **USP other sites**





Setting the Standard

How we work



USP Monograph Development Process



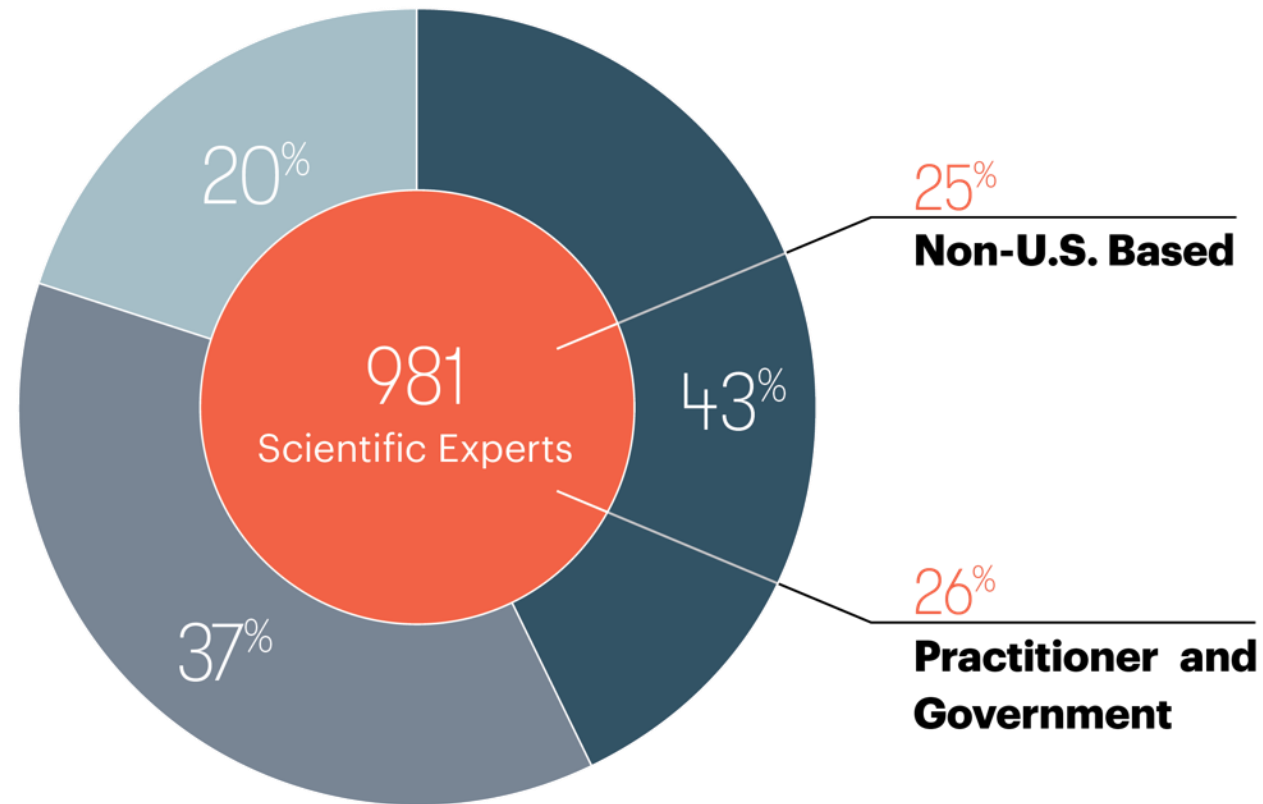
* Monograph candidates have to meet USP's criteria for inclusion in either FCC or USP-NF (criteria include approved legal status, no known safety concerns, commercially available ingredient, clear identification and description, among others).

USP staff and volunteer experts partner to develop standards



981 Scientific Experts— Volunteers and Government Liaisons

- 428 Expert Committee Members
- 362 Expert Panels-Only Members
- 191 Government Liaisons



2020-2025 standards development



2020-2025 Council of Experts – Expert Committees

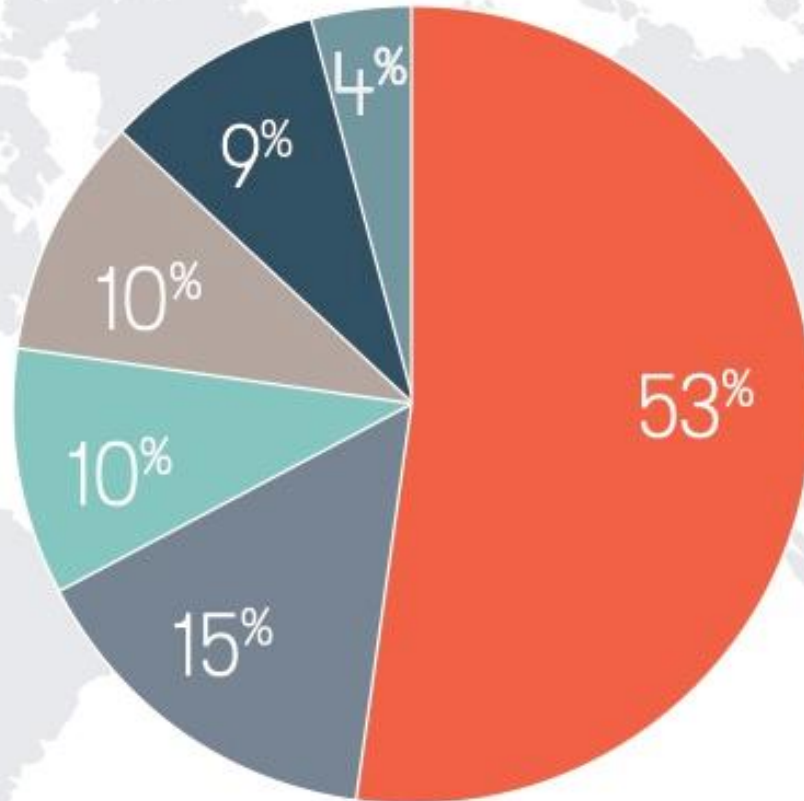
Chemical Medicines	Biologics	Excipients	Dietary Supplements & Herbal Medicines, Food Ingredients	Healthcare Quality & Safety	General Chapters
1 Antibiotic, antiviral, & antimicrobial	1 Peptides & insulins	1 Simple: Carbohydrates, minerals & salts	1 Food ingredients	1 Nomenclature & labeling	1 Packaging & distribution
2 Cardiovascular, cough, cold & analgesics	2 Therapeutic proteins	2 Complex: Polymers, oils, fats, waxes, plants & clays	2 Non-botanical dietary supplements	2 Healthcare quality	2 Microbiology
3 Gastrointestinal, renal, endocrine, ophthalmic, oncology, dermatology & animal health	3 Advanced therapies (cell, gene, tissues, & genome-editing)*	3 Excipient test methods*	3 Botanical dietary supplements & herbal medicines	3 Compounding	3 Dosage forms
4 Nonradioactive imaging agents, aerosols, radiopharmaceuticals, psychiatric, & psychoactive	4 Antibiotics using microbial assays		4 Admission, evaluation & labeling*	4 Healthcare information & technology*	4 Chemical analysis
5 Pulmonary & steroids	5 Complex products & vaccines				5 Physical analysis
6 Over-the-counter (OTC) methods & approaches					6 Statistics
					7 Measurement and Data Quality*

* Represents a new Expert Committee

Global staff presence



1200+ Staff



- Laboratory/Science
- Administration
- Global Information Services
- Development, Mrkt & Program Ops
- Global Public Health
- External Affairs

US 69% | India 17% | China 6% | Brazil 4%
Other global sites 4% (Ethiopia, Europe, Ghana, Indonesia, Nigeria, Pakistan, Singapore)

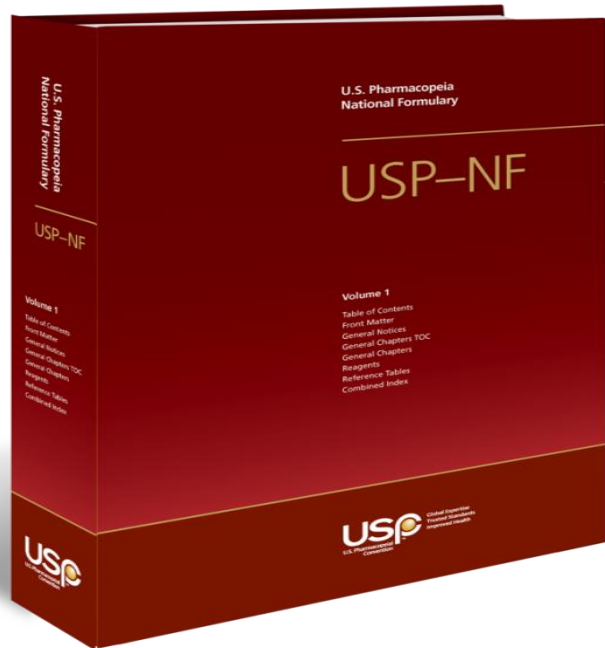
3,600+

reference standards

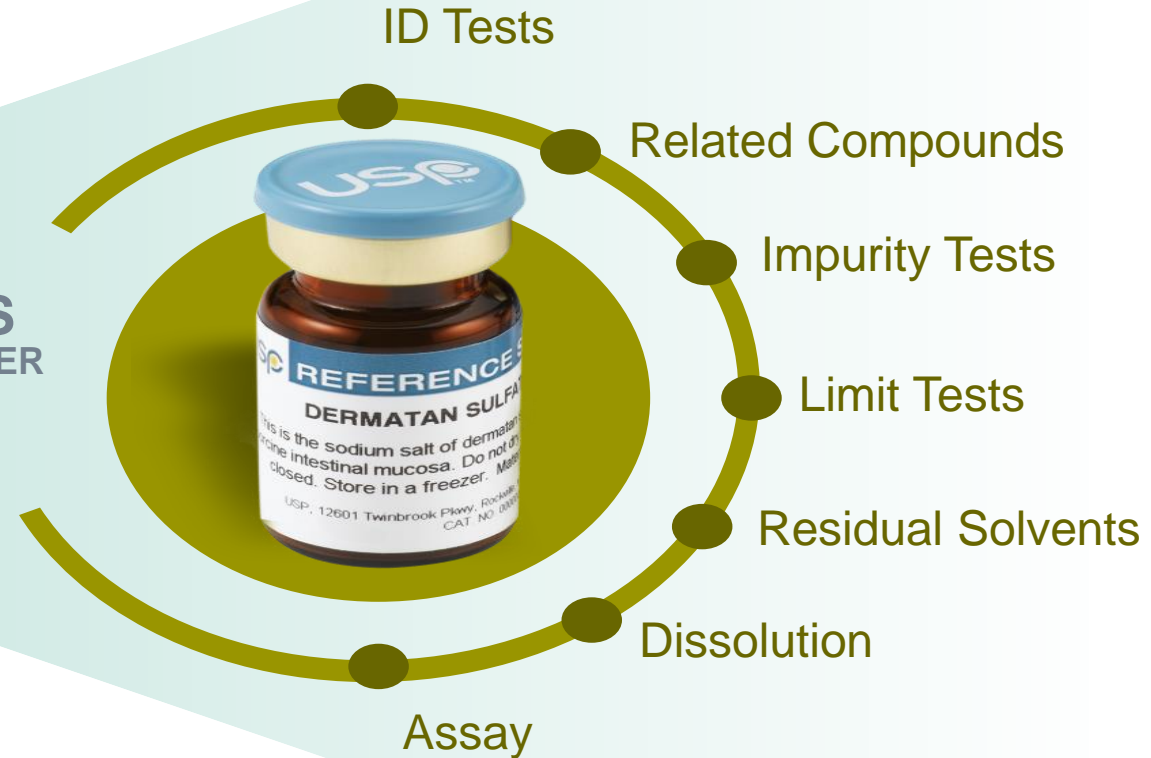
are available for prescription and OTC drugs, biologics, excipients, dietary supplements and foods



USP Reference Standard



**ENABLES
MANUFACTURER
TESTING**



Impact

Substandard Medicines

- ▶ Substandard medicines are a global health threat
- ▶ USP works at the policy level to raise awareness, build evidence, and garner support for helping ensure that quality medicines reach patients around the world
- ▶ Compliance with USP standards help assure that patients receive quality medicines



Falsified Medicines

- ▶ Counterfeiters intentionally sell falsified or fake medicines – a global issue, particularly acute in low- and middle-income countries
- ▶ In 1 year, 122,000 children in sub-Saharan Africa were projected to die from counterfeit anti-malarials¹
- ▶ We work with local regulators around the world to develop the capacity to detect and remove falsified and substandard medicines from the market



1. Renschler JP, et al. Estimated under-five deaths associated with poor-quality antimalarials in sub-Saharan Africa. *Am J Trop Med Hyg.* 2015;92(Suppl 6):119-126.

Adulteration

- ▶ Complex global supply chains have made excipients and other raw materials vulnerable to adulteration
- ▶ Our standards, which constantly evolve through public input, help detect adulteration and allow for a rapid response in times of crisis



Thank You



Empowering a healthy tomorrow