USP Open Forum

Improving the Pharma Environmental Footprint

Virtual Meeting:

February 21, 2023 • 9:00–11:00 am EST

USP Open Forum

Improving the Pharma Environmental Footprint

Welcome!

Darcy Gentleman, Ph.D.

Senior Manager,
Stakeholder Engagement

Welcome!

- Agenda
  - Opening remarks and USP focus
  - Panel discussion
  - Interactive discussion
  - Closing thoughts
- Idea generation, sharing knowledge of initiatives
- Help us identify what questions need answers

USP Open Forum

Improving the Pharma Environmental Footprint

Opening Remarks

Jennifer Devine, J.D.

Senior Vice President
Documentary Standards
& Compendial Policy

Our mission

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

Collaborating to achieve our mission

USP Experts & Convention Members

Access to quality medicines

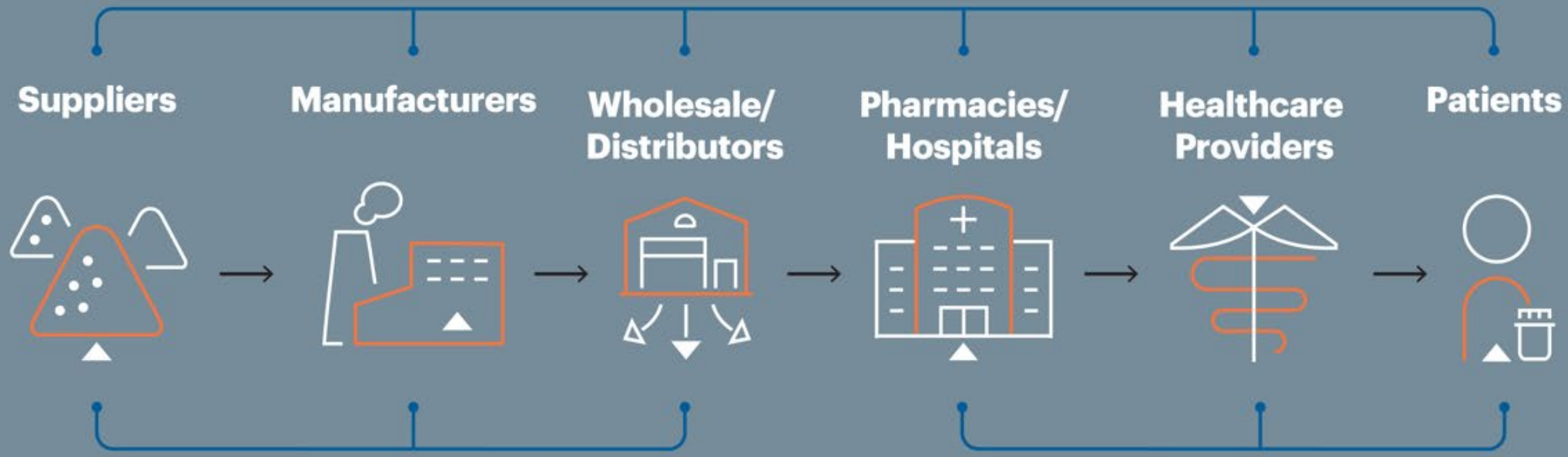
Scientific, healthcare stakeholder communities, including industry & academia

Global regulatory entities and other pharmacopeias

Global impact across the supply chain

USP–NF
9000+ standards

Dietary Supplement Compendium
1200+ standards



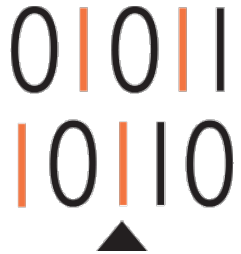
Broadly applicable analytical methods

- 350+ General Chapters
- 3500+ Reference Standards
- 4900+ Monographs
- 550+ Standards for biological products

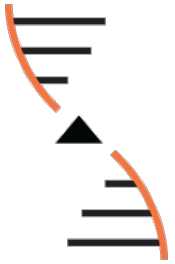
Healthcare Quality and Safety 300+

- Nomenclature
- Compounding
- Model Guidelines
- Labeling

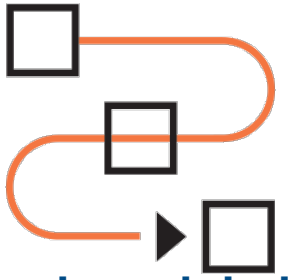
Disruptors shaping our evolution



Digitalization, analytics & informatics



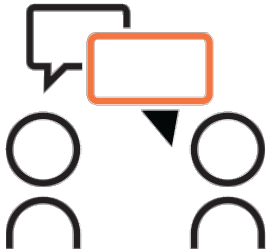
Explosion of new therapies



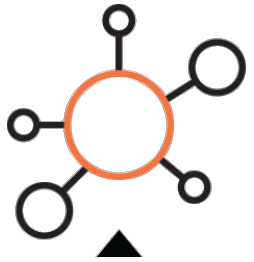
Complex, globalized supply chain

New quality paradigms and technologies

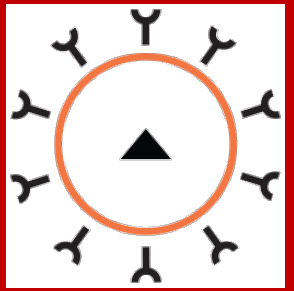
Climate change



New ways of engaging scientists



Medical information & knowledge



Pandemic(s)

Standards, quality, and strategic design

- Quality by design
  - Standards to inform green/sustainable chemistry's "benign by design" paradigm
- Efficiency
  - Public standards for scale and consistency
- Global perspective

Contribute ideas, respect all inputs

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USP's journey in reducing the pharma environmental footprint and future impact possibilities

Speaker:

Gabriel I. Giancaspro Ph.D.

Dist. Scientific Fellow/Compendial Policy Head, USP

USP started this journey three decades ago

USP Convention Resolution

Environmental Concerns (1995)

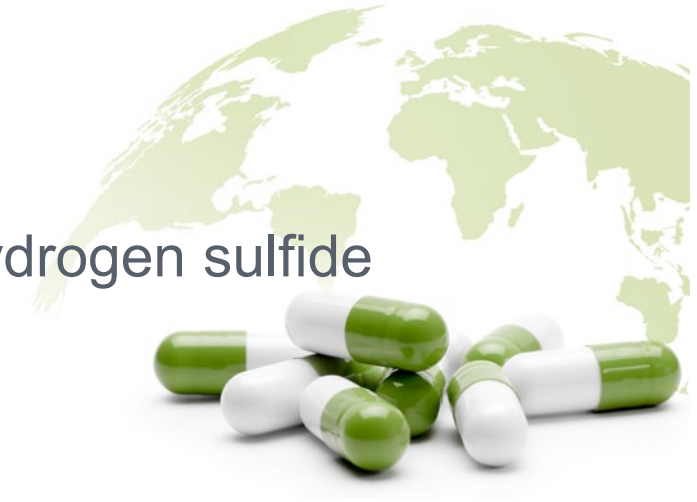
The USP is encouraged to initiate a program to protect the environment by adopting standards and analytical methods for pharmaceuticals, containers, and other articles that reduce the amount of reagents and materials used in pharmaceutical tests and assays that have the potential to cause harm to human health and the environment.

Source: Resolutions Adopted by the USP Convention, 1975 — 2015

Progress report in 2000

1995 Resolution on Environmental Concerns

- Reduction of dissolution medium acid normality
- Stimuli article in 1999 regarding disposal of drugs
- Publication on proper disposal of monograph formulations, given Resource Conservation and Recovery Act
- Elicit help from industry to revise tests using unusually large amounts of hazardous solvents
- Encourage use of lower-volume, higher efficiency separations via a chapter on capillary electrophoresis (CE)
- Reduce/eliminate environmentally objectionable solvents; also hydrogen sulfide
- Eliminate use of cats for testing Depressor Substance test



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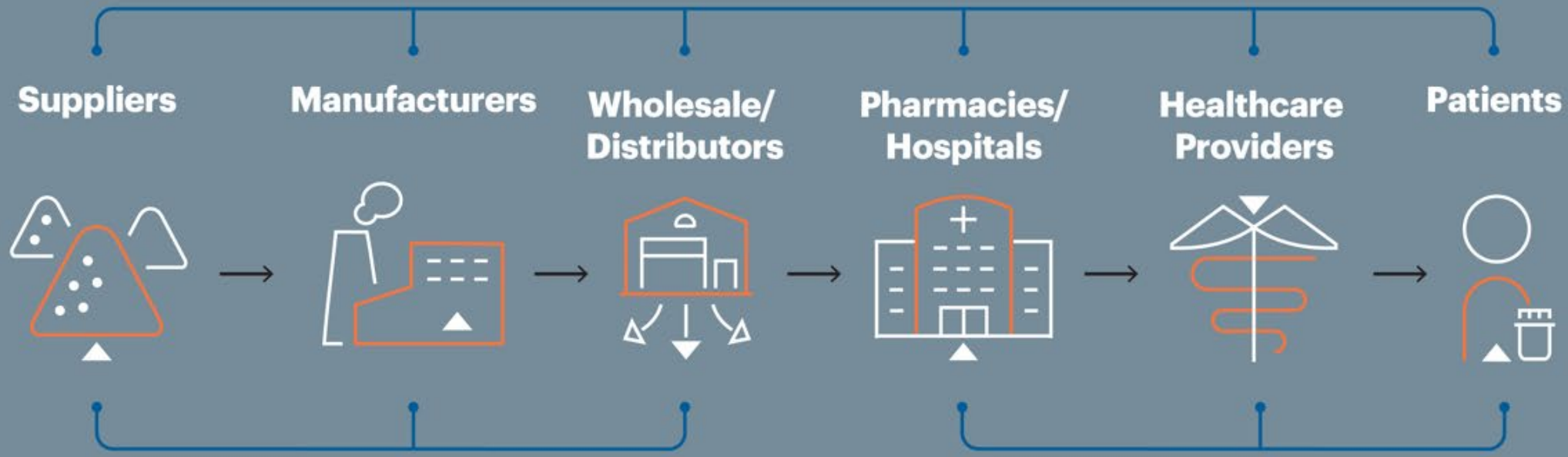

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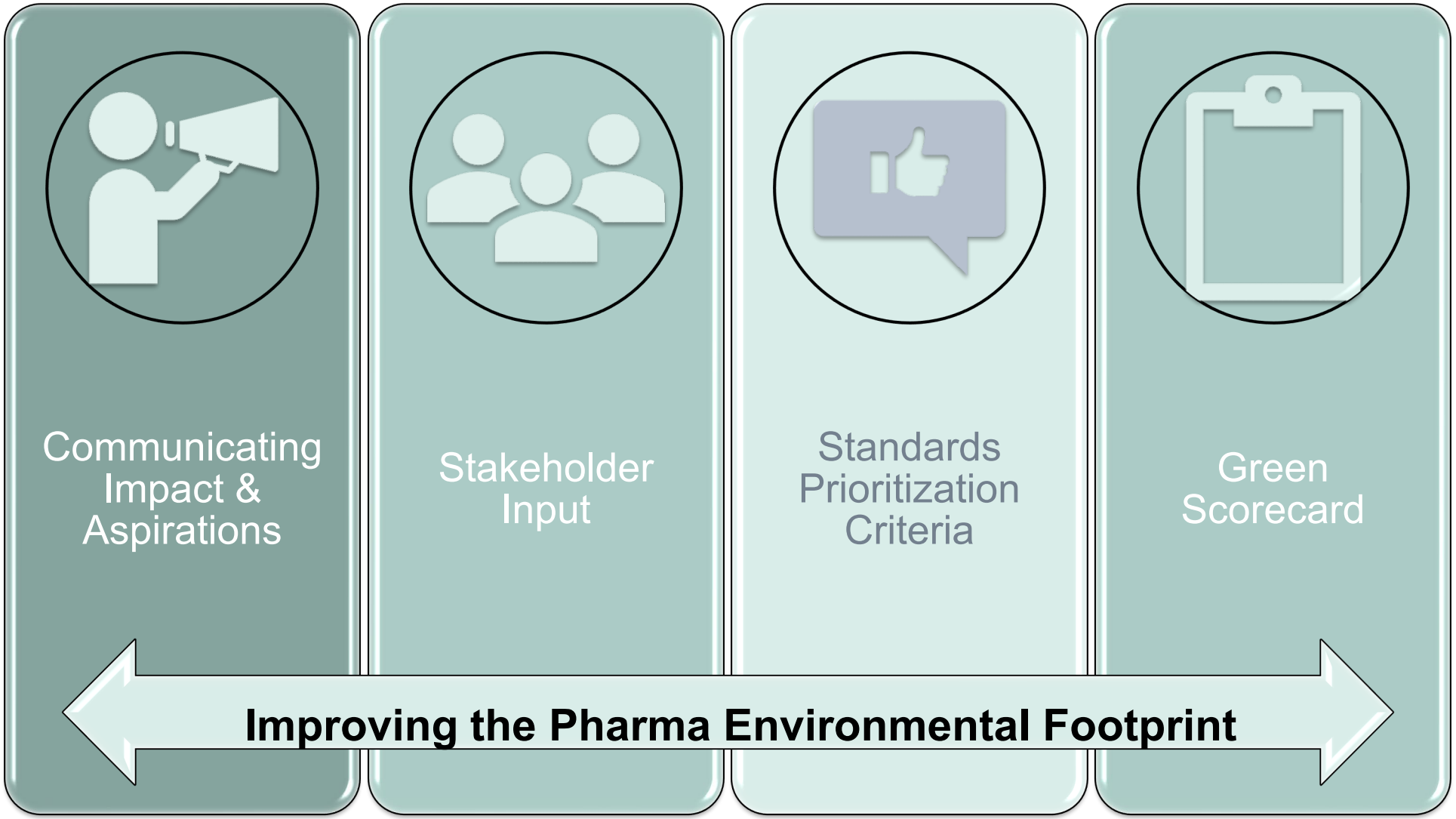
Our journey continues



USP has impacted the pharma environmental footprint mainly through two initiatives

Modernization (official and unofficial)

- Lowering / eliminating / substituting use of hazardous and toxic substances
- Incorporating new methods and technology that are more efficient and less wasteful

Harmonization

- Improving alignment of quality standards with global pharmacopeias
- Moving towards a vision of prospective global convergence in recent times

2015 Resolution

USP Convention Resolution

USP-NF Monograph Modernization (2015)

USP will meet the needs of U.S. Food and Drug Administration (FDA), industry, and other stakeholders for modern monographs within *USP–NF*. USP will work to eliminate the existing backlog of monographs in need of modernization and proactively evaluate and update monographs to maintain their relevance given scientific advances and evolving manufacturing and regulatory approaches. USP will work with industry and FDA to explore new strategies for sharing analytical methods and specifications needed to modernize monographs.

Source: Resolutions Adopted by the USP Convention, 1975 — 2015

Modernization efforts

Lower/eliminate/substitute hazardous substances

- Benzene
  - Avoid (Class 1 solvent)
  - Decrease use in compendia by >80%
- Carbon tetrachloride
  - Class 1 solvent
  - Decrease use in compendia by >96%
- Amoxicillin
  - Strict limits on methylene chloride led supplier to explore enzymatic synthesis
- General Chapter <800>
  - Guidance on environmental quality & control in healthcare settings

Incorporate new methods and technologies to increase efficiency

- Chromatography
  - Column equivalencies
  - GC over LC
  - Reverse phase uses less of toxic solvents
- Explore emerging analytical methods
  - Pharmaceutical continuing manufacturing (PCM)
  - qNMR
  - Biotechnological methods

Pharmacopeial Discussion Group (PDG)

- What environmental or sustainability initiatives do your organizations have underway?
  - What opportunities to connect?
- What more can PDG do together to….
  - **Inventory** the efforts and impact of PDG – and broadcast successes for others to adopt?
  - Bring environmental impact to the table as **criteria** for harmonization?
  - Incorporate green scorecard(s) and modernization priorities to **choose tests**?
  - Encourage **greater industry involvement**?
  - Other?

Encourage smaller volumes

General Notices and Chapter revisions

- Solution preparation
  - Recommend lower volumes with equivalent accuracy
- Chapter <31> Volumetric Apparatus
  - Companion informational <1331> Calibration and Verification of Volumetric Apparatus
  - Including micropipette considerations
- Chapter <41> Balances
  - Companion informational <1251> Weighing on an Analytical Balance
  - Including microbalance considerations

Other ongoing projects

- Evaluation of endotoxin recombinant factor C (rFC) for absence of pyrogen assurance
- Phasing out calomel electrodes (mercury [II] chloride)
- Replacing outdated wet chemistry methods using hazardous reagents
- Eliminating odor/taste aka “organoleptic” tests
- Continuing elimination of toxic solvents
- Analytical quality by design (AQbD) concepts to include reduction in waste generation

2020 Resolutions

- FY2022 Update:
  - "USP conducted studies aimed at optimizing dissolution testing using a reduced volume of dissolution media [to] **reduce the environmental impact of dissolution testing while accelerating the process and expanding test applications** … particle-induced velocimetry studies … along with computational fluid dynamics results, may provide further guidance … **to improve analytical sensitivity while reducing the volume of solvents used**."

Pillars of interest = start of a potential USP framework

Panel discussion

Moderator:

Darcy Gentleman, Ph.D.
Senior Stakeholder Engagement Manager
USP

Lina Bader, Ph.D.
Lead, Equity, Sustainability Policy, and Development
International Pharmaceutical Federation (FIP)

Isamir Martinez, Ph.D.
Scientific Alliances & Business Engagement Manager
Green Chemistry Institute,
American Chemical Society

Jane Weitzel, Ph.D.
Chair,
General Chapters – Measurement and Data Quality USP Expert Committee

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Contact us!

sustainability@usp.org

Thank You

The standard of trust