

## Improving the Pharma Environmental Footprint Tuesday, February 21, 2023

### EVENT SUMMARY

#### **A challenging problem**

Across the pharmaceutical sector, there is burgeoning interest in improving the pharmaceutical environmental footprint. As in many other industrial sectors, pharmaceutical companies are scrutinizing their own operations, looking for ways to minimize waste and conserve energy in their facilities. Some firms are using “Green Scorecards” as a tool to track their progress on limiting their own environmental footprint.

In the pharmaceutical industry, areas that have attracted particular attention include energy, emissions, water, and hazardous waste, which encompasses harmful chemicals such as solvents, reagents, biohazards, and radioactive substances. To advance progress in these critical areas, U.S. Pharmacopeia (USP) convened a public, virtual Open Forum about improving the pharmaceutical environmental footprint on February 21, 2023. USP is an independent, scientific, nonprofit organization with a mission to improve global health through public quality standards and related programs.

As a standard-setting body, USP has a specific role to play in the efforts to improve the pharma environmental footprint. When USP develops or revises a documentary standard, such as a product-specific monograph or a method guidance general chapter, the effect spans the entire supply chain and is multiplied through many users including suppliers, manufacturers, distributors, pharmacies, and healthcare providers. Since USP’s public quality standards are used in 22,000 locations in 150 countries, revisions often have a broad impact.

#### **Progress through public quality standards**

USP’s scientific standards are developed by committees of independent Expert Volunteers through a rigorous process that seeks out and considers input from numerous stakeholders including government agencies, industry, regulators, patient advocacy groups, academia, other pharmacopeias, and the public. Additionally, the founding governing body – the USP Convention – passes Resolutions every five years to articulate strategic priorities. The end result of this collaborative process consists of USP monographs and general chapters, which help companies achieve efficiency, consistency, and quality in the manufacture and testing of drugs, dietary supplements, and foods.

In 1995, the problem of pharmaceutical waste products was recognized in a USP Resolution to protect both the environment and human health. USP scientists developed

standards and analytical methods to reduce or eliminate the use of reagents and other potentially harmful materials used in pharmaceutical quality tests. USP also published General Chapter <467>, *Residual Solvents*, which classifies solvents by risk level and describes control strategies, limits, and analytical methods. USP has continued its commitment to advance progress in this area, as have other pharmacopeias, which have decreased the use of some higher-risk solvents such as benzene, carbon tetrachloride, and methylene chloride. This includes the use of alternative solvents that are less hazardous to human health and the environment.

### **USP Open Forum engages stakeholders**

One hundred stakeholders from various perspectives—associations, industry, academia, and government—attended the USP event, where they shared ideas and helped identify key questions that need to be addressed and answered. USP leadership set the stage by providing a brief overview of the environmentally conscious work USP has accomplished to date. Attendees were challenged to consider principles of Design Thinking, such as how Analytical Quality by Design, known to the pharmaceutical industry, fits together with the concept of Benign by Design, often associated with green/sustainable chemistry.

A panel from the International Pharmaceutical Federation (FIP), American Chemical Society Green Chemistry Institute (ACS GCI), and USP Expert Committee on Measurement and Data Quality provided important perspectives to spark attendees' ideas for an interactive session (see panelist details below). Many attendees participated actively during an online discussion session.

### **Open discussion platform: Attendee ideas**

USP asked all attendees to provide ideas, comments, and questions in a live discussion platform on improving the pharma environmental footprint. Participation was brisk. Attendees submitted approximately 40 ideas in this brief exercise, with the ideas falling into five categories plus "other."

- The number of ideas submitted varied between the categories. The categories were then ranked from "most ideas" to "least ideas" as follows: Other (predominantly regarding harmonization); Biodiversity Conservation; Waste; Energy & Emissions; Water Stewardship; and Lab Employee Health & Safety.

### **Q&A with the panelists**

As noted above, a moderated panel shared their perspectives on sustainability as it pertains to the pharmaceutical industry. The panelists were Dr. Lina Bader of the International Pharmaceutical Federation (FIP), Dr. Isamir Martinez of the Green Chemistry Institute at the American Chemical Society, and Jane Weitzel, Member of the USP Council of Experts and Chair, General Chapters – Measurement and Data Quality Expert Committee; Dr. Darcy Gentleman of USP moderated the panel. Question frames, with answers from the panelists, appear below.

- How can drug quality and patient safety be maintained while also reducing the harmful environmental impact of methods used to make and test drugs?
  - Patient safety must be maintained, and all drugs should be safe and efficacious. Fortunately, this focus on quality and safety does not preclude improvements in lab procedures. Modifications can be developed and implemented to reduce toxic waste products and lessen environmental damage.
  
- How can the pharma community transition to “green chemistry” and focus more on sustainability?
  - Everyone in the supply chain needs to start applying green/sustainable chemistry principles. Labs can choose safer reagents and can conserve water. Companies should assess how they can replace some of their long-standing, ingrained processes with greener approaches. Innovative technologies are needed to significantly reduce or eliminate damage to the environment; some promising examples include flow chemistry and the use of new membranes for separation.
  - Many pharma companies are recognizing the value of collaborating with each other as they transition to green chemistry. The environmental footprint is large and can seem daunting without shared support.
  - Innovation does not always mean the discovery of something new, like a novel molecule or device. Instead, developing a new way of doing established things is also innovation. Old tools can be used in novel ways. To improve the environmental footprint, companies should identify the parts of a process that may be most amenable to modification and/or provide the greatest contribution to reducing the footprint.
  
- How can the pharmacy profession contribute to sustainability efforts?
  - Pharmacy students need training and education about sustainability and the mitigation of climate change. All types of pharmacy professionals – early-career pharmacists, seasoned pharmacists, and pharmacy technicians – have a role to play in promoting sustainability. For example, pharmacists can provide drug disposal education to consumers and patients.
  
- When industrial sectors consider sustainability, some focus at the macro level, for example, nation-level emissions and systems approaches, while others pilot at the micro level and then scale up after completing demonstration projects. Which approach has shown more promise in pharmaceuticals?
  - Both micro- and macro-level efforts are needed. Smaller companies are learning how to work on sustainability while larger companies are ahead. Other companies are starting this journey. Ideally, companies can learn from

each other.

- What can USP do to guide and support stakeholders, such as smaller companies, in their efforts to improve the environmental footprint?
  - It would be very helpful if USP could assist companies with convincing analytical chemists, and scientists in general, to try new methods. Changing minds is very difficult.
  - Many companies want to do something to contribute to sustainability efforts, but they don't know what to do. USP could provide workshops, training, resources, and other educational opportunities to assist these companies.

For further information, or to share comments and questions, contact USP at [sustainability@usp.org](mailto:sustainability@usp.org)