NABP
National Association of Boards of Pharmacy

USP COVID-19 Vaccine Handling Toolkit: Operational Considerations to Support Confidence, Trust, and Quality

Thursday, March 25, 2021

www.nabp.pharmacy/webinar

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COVID-19 Vaccine Handling and Operational Best Practices

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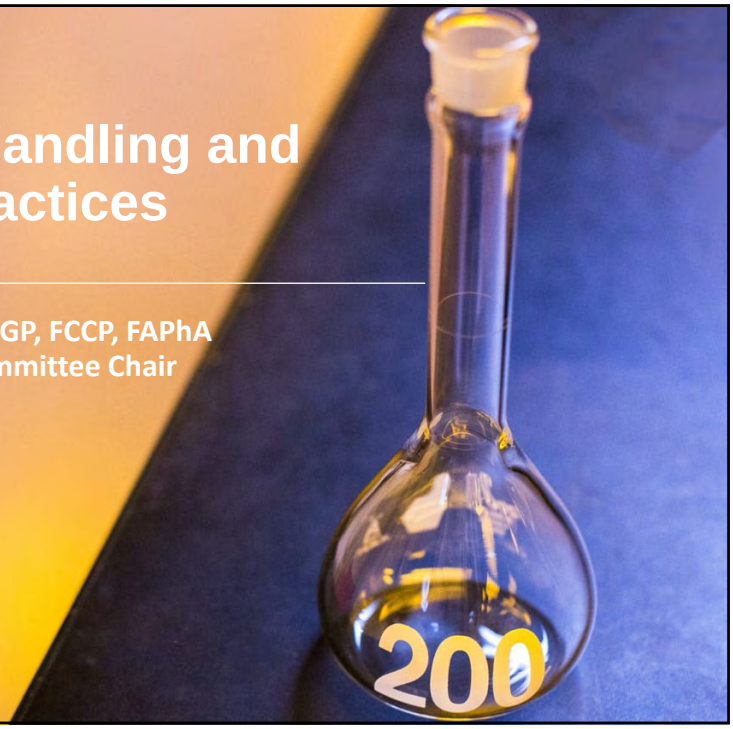
March 2021

200 usp The standard of trust



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Disclosures

- Melody Ryan and Farah Towfic report they have no actual or potential conflicts of interest associated with this presentation.
- Off-label use of medication will be discussed during this presentation.
  - COVID-19 vaccines have emergency use authorization (EUA), which is not Food and Drug Administration approval.

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Learning Objectives

- Describe the USP COVID-19 Vaccine Handling Toolkit
- Explain how to accelerate delivery of COVID-19 vaccines
- Support the safe handling of COVID-19 vaccines while maintaining quality and trust

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Self-Assessment Questions

- The beyond use date for COVID-19 vaccines are best assessed through:
  a. Application of USP<797> to all vaccines
  b. Following manufacturer labeling in the Emergency Use Authorization
  c. None of the above
- The transport of prepared COVID-19 vaccine product may take place under which of the following conditions?
  a. Vaccine in frozen state in vials
  b. Vaccine in refrigerated state in vials
  c. Pre-drawn syringes in refrigerated state
  d. COVID-19 vaccines should not be transported once delivered to provider site
  e. A, B, and C

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Overview

- Who is USP?
- Building trust in COVID-19 vaccines through quality
- USP COVID-19 Vaccine Handling Toolkit
  – Preparation and labeling
  – Storing, handling, and transporting
  – Waste minimization and ancillary supply disposal
- Facilitated Q & A

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Who Is USP?

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USP Mission

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

8

Collaborating to Achieve Our Mission

Partnering with our expert volunteers

Access to quality medicines

Partnering with global regulators, including the United States FDA and WHO

Partnering with stakeholders, including industry, practitioners, and academia

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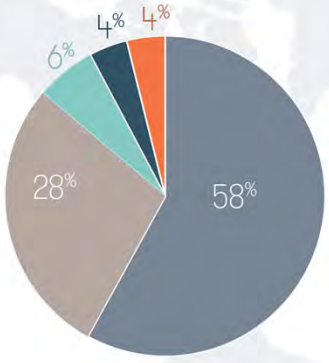
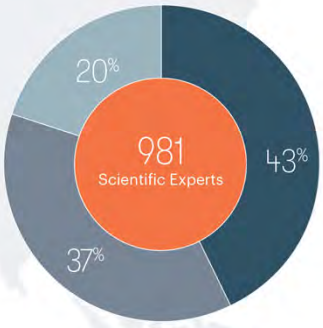
Our People – USP's Global Staff and Volunteers

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

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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

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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

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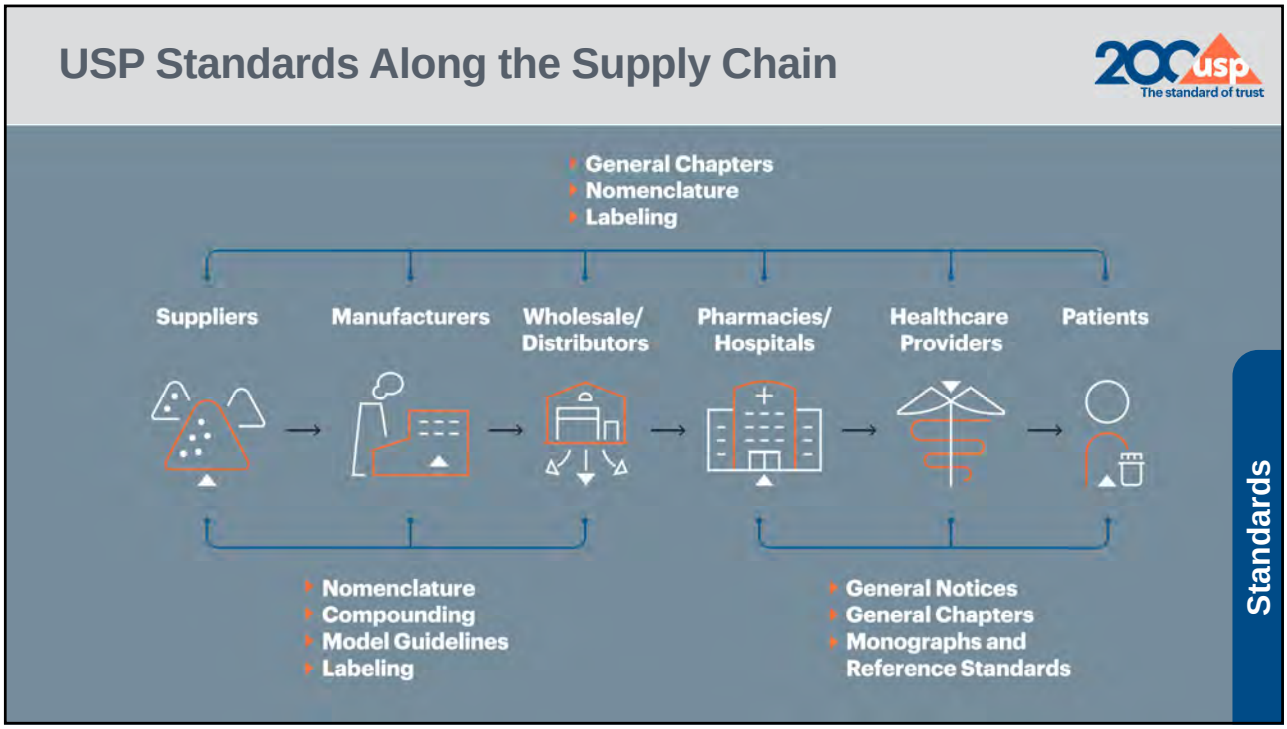
USP Standards Along the Supply Chain
The standard of trust
General Chapters
Nomenclature
Labeling
Suppliers
Manufacturers
Wholesale/ Distributors
Pharmacies/ Hospitals
Healthcare Providers
Patients
Nomenclature
Compounding
Model Guidelines
Labeling
General Notices
General Chapters
Monographs and Reference Standards
Standards

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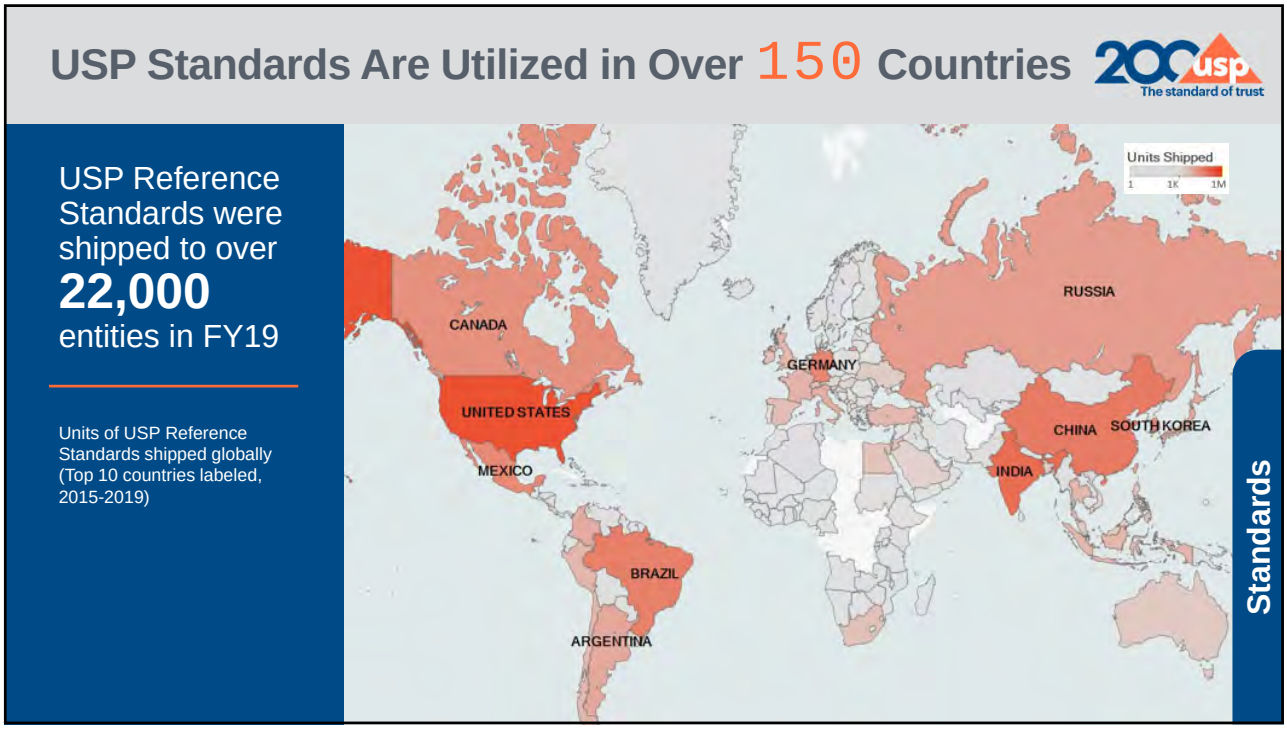
USP Standards Are Utilized in Over 150 Countries
The standard of trust
USP Reference Standards were shipped to over 22,000 entities in FY19
Units of USP Reference Standards shipped globally (Top 10 countries labeled, 2015-2019)
Units Shipped
1
1K
1M
CANADA
UNITED STATES
MEXICO
BRAZIL
ARGENTINA
GERMANY
RUSSIA
INDIA
CHINA
SOUTH KOREA
Standards

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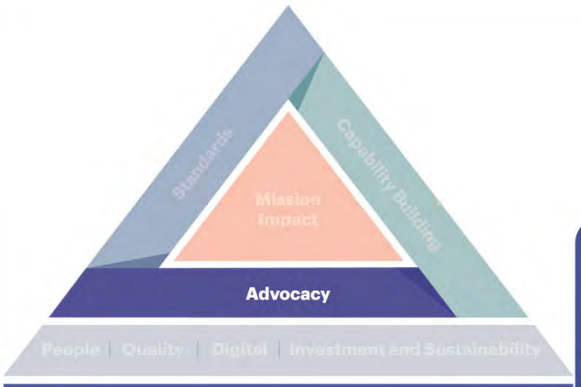
Advocating for the Supply of Quality Medicines Worldwide

- Generating data to inform policy making through the USP Quality Institute (eg, 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



Being the global institutional leader advancing the supply of quality medicines

Advocacy

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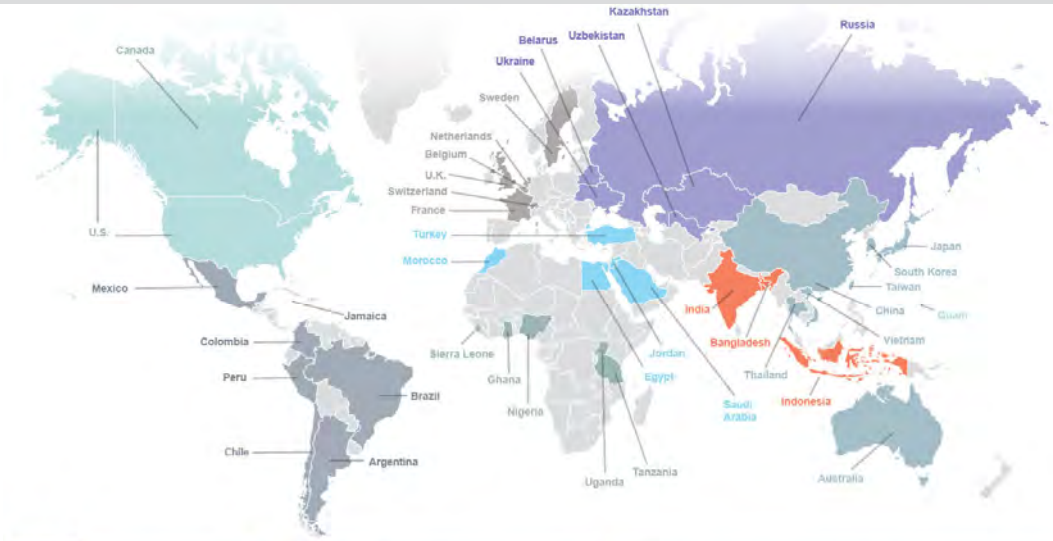
Our Global Engagement and Advocacy Is Powered By More Than 490 USP Convention Organizations



FAST FACTS

490+ Total members | 42 Countries represented

Advocacy

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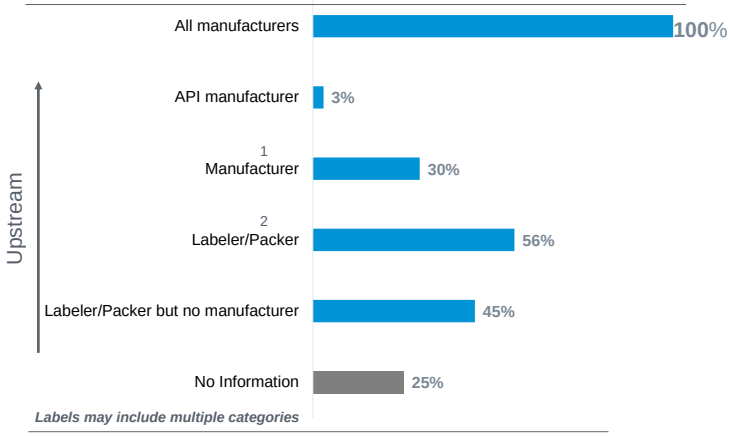
Example: There Is a Need for Greater Upstream Supply Chain Transparency

Information listed on US-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 the 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 US FDA, also sharing supply chain information publicly could help providers proactively safeguard patient health. (eg, when a safety issue is identified with an API manufacturer, providers will have on-hand information about impacted brands.)

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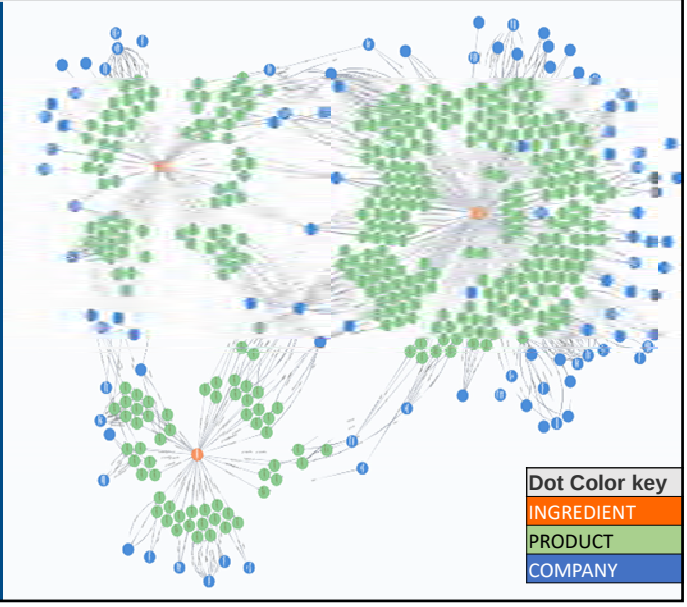
We Are Generating Proactive Insights on Risk in the Upstream Supply Chain

- 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



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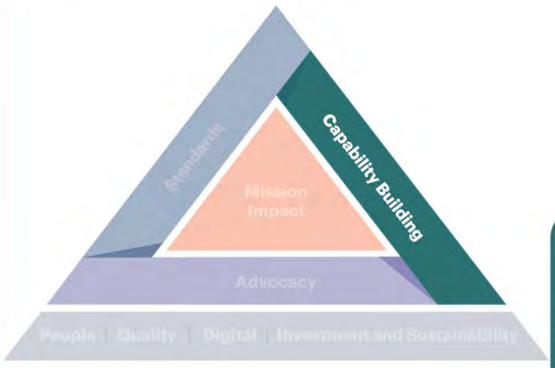
Education, Training, and Verification Services to Build Stakeholder Capabilities in Advancing Medicines Quality

- 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 (eg, dietary supplements, excipients)
- Facilitating the adoption of new manufacturing technologies (eg, continuous manufacturing)
- Custom tailored standards and tools for analytical research & development (eg, 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

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2 Building Trust in COVID-19 Vaccines Through Quality

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COVID-19 Vaccine – Learning About Trust and Confidence

- Reagan-Udall Foundation for the FDA conducted the COVID-19 Vaccine Confident Project in 2020 to identify gaps in trust and patient confidence in vaccines
- Communities interviewed
  - Frontline workers in service, retail, and health care
  - Under-represented communities who experience health disparities and are at increased risk of COVID-19 (eg, Black or African American, Hispanic/Latinx, and Native/Indigenous communities

Source: Reagan-Udall Foundation for the FDA

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Areas of Identified Gaps That Impact Public Trust and Confidence

- Lack of equity and access to vaccines
- Speed of EUA process
- Distrust of government
- Distrust of health care system
- Need for education and communication to bridge the knowledge gap with new vaccine platforms and assurance of quality
- Perceptions of prioritizing economics over science
- Concern the vaccine will not work for certain communities

Source: Reagan-Udall Foundation for the FDA; CDC Equity Task Force

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Addressing Trust in COVID-19 Vaccines

- 83% of individuals rely on health care practitioners as trusted sources of information related to vaccines (eg, pharmacists, physicians, nurses, physician assistants)[1]
- 60% rely on family and friends to deliver information[1]
- Messages that work aim to personalize the message, explain the process, and never shame:
  - Protecting your loved ones
  - Return to normal
  - Acknowledge and address people's fears based on culture (eg, historic injustices such as the Tuskegee Experiment)

Source: 1) Kaiser Family Foundation; Reagan-Udall Foundation for FDA; CDC; APHA

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From the Frontlines: Building Confidence in COVID-19 Vaccines

- Need to address misinformation that is spreading (eg, vaccine ingredient base like polyethylene glycol versus ethylene glycol)
- Example patient interactions

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USP COVID-19 Vaccine Handling Toolkit

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USP Engagement in COVID-19 Vaccine Preparation and Handling

We asked – What are other organizations doing? How can USP help fill gaps using our expertise?

Our focus:

- **Communities** – supporting our convention stakeholders with their work (eg, vaccine platform technology, convention roundtable with US FDA, advocacy to build trust in quality of vaccines)
- **Scientific expertise –** creating operational considerations driven by USP's public quality standards for compounding, microbiology, containers, labeling, distribution, stability, and storage

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USP Created the "COVID-19 Vaccine Handling Toolkit"

- **Content will be evolving**
  - Quickly developed by over 40 independent expert volunteers led by USP's Healthcare Safety and Quality Expert Committee with representation from several other Expert Committees including government representatives from the Centers for Disease Control and Prevention (CDC) and the US Food & Drug Administration (FDA)
  - USP is engaging with manufacturers that are anticipated to enter the marketplace to update our toolkit to launch new versions in tandem with regulatory approval
- **Reaching our stakeholders**
  - USP will push content out through convention membership, government representatives, including CDC website, HQS listserv, and media
  - Initial engagement numbers (version 3 launched 3/12)
    - > 38,000 page views (average time spent = 7:43 minutes)
    - > 15,000 downloads

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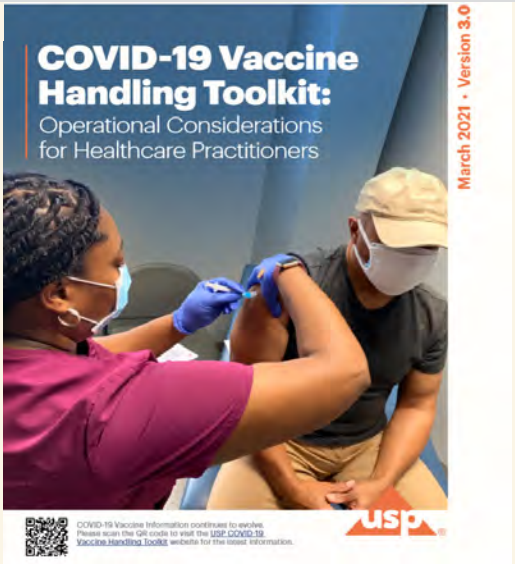
COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners

- Empowers practitioners with critical information that facilitates **operational efficiencies** during the handling of COVID-19 vaccines while preserving quality and safety
- Includes operational strategies in three key areas:
  - Preparation and labeling
  - Storing, handling, and transporting vaccine
  - Waste minimization and ancillary supply disposal



https://www.usp.org/covid-19/vaccine-handling-toolkit

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Preparation and Labeling

- Driving consistency across states in preparation
- Enabling pre-draw of syringes (detailed BUD in syringe)
- Supporting different practitioners preparing and administering vaccines and critical labeling examples
- Operational efficiencies that drive more vaccines in arms at an accelerated rate while ensuring quality, safety, and public trust

Labeling Considerations

When the COVID-19 Vaccines are not being prepared for immediate administration, appropriate labeling considerations should be undertaken. If the vaccines are sent outside the facility in which they were prepared for administration, a designated person must ensure that contact information of the preparation facility is conveyed and available at the site where they will be administered.

Examples of pre-drawn syringe labels

Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension
Date & Time to discard (6 hours after dilution):
Lot no:
Initials of preparer(s):

Moderna COVID-19 Vaccine (100 mcg / 0.5 mL) IM suspension
Date & Time to discard (6 hours after puncture):
Lot no:
Initials of preparer(s):

Janssen Ad26 COVID-19 Vaccine (5×10^{10}vp / 0.5 mL) IM suspension
Date & Time to discard:
(6 hours after vial puncture at 2°C to 8°C (36° to 46°F)
or 2 hours at up to 25°C (77°F))
Lot no:
Initials of preparer(s):

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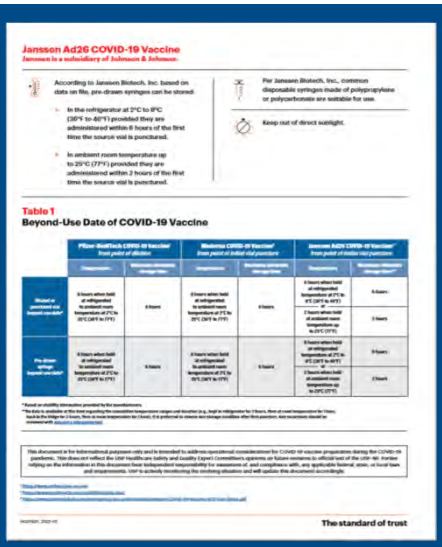
USP COVID-19 Vaccine Fact Sheets

Beyond-Use Date in Vial and Syringe for COVID-19 Vaccines



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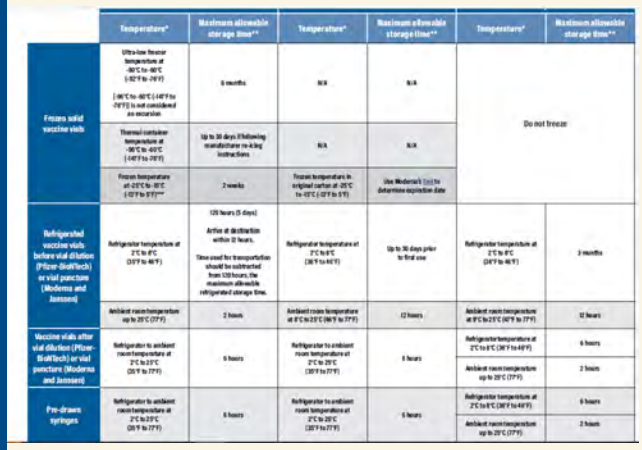
Storing, Handling, and Transporting COVID-19 Vaccines

- Vaccines will need to be transported to mass vaccination clinics, nursing and long-term care facilities, and more
- Vaccines need to reach more than 300 million individuals in the United States and billions of people around the world
- Utilization of mobile clinics, practitioners who have not been involved in vaccination in the past, and other considerations will drive creativity in how vaccines are delivered to the patients who need them most
- As more vaccines enter the marketplace, challenges and disparities in storage, handling, and transport become more pronounced and potential safety concerns



	Temperature*	Maximum allowable storage time**	Temperature*	Maximum allowable storage time**	Temperature*	Maximum allowable storage time**
Frozen solid vaccine vials	Ultra-low freezer temperature at -80°C to -60°C (-112°F to -76°F) [-90°C to -60°C (-130°F to -76°F) is not considered an excursion	6 months	N/A	N/A	Do not freeze	
	Thermal container temperature at -90°C to -60°C (-130°F to -76°F)	Up to 30 days, if following manufacturer re-icing instructions	N/A	N/A		
	Frozen temperature at -25°C to -15°C (-13°F to 5°F)***	2 weeks	Frozen temperature in original carton at -25°C to -15°C (-13°F to 5°F)	Use Moderna's tool to determine expiration date		
Refrigerated vaccine vials before vial dilution (Pfizer-BioNTech) or vial puncture (Moderna and Janssen)	Refrigerator temperature at 2°C to 8°C (36°F to 46°F)	120 hours (5 days) Active at destination within 12 hours. Time used for transportation should be subtracted from 120 hours, the maximum allowable refrigerated storage time.	Refrigerator temperature at 2°C to 8°C (36°F to 46°F)	Up to 30 days prior to first use	Refrigerator temperature at 2°C to 8°C (36°F to 46°F)	3 months
	Ambient room temperature up to 25°C (77°F)	2 hours	Ambient room temperature at 8°C to 25°C (46°F to 77°F)	12 hours	Ambient room temperature at 8°C to 25°C (46°F to 77°F)	12 hours
Vaccine vials after vial dilution (Pfizer-BioNTech) or vial puncture (Moderna and Janssen)	Refrigerator to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	Refrigerator to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	Refrigerator temperature at 2°C to 8°C (36°F to 46°F)	6 hours
					Ambient room temperature up to 25°C (77°F)	2 hours
Pre-drawn syringes	Refrigerator to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	Refrigerator to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	Refrigerator temperature at 2°C to 8°C (36°F to 46°F)	6 hours
					Ambient room temperature up to 25°C (77°F)	2 hours

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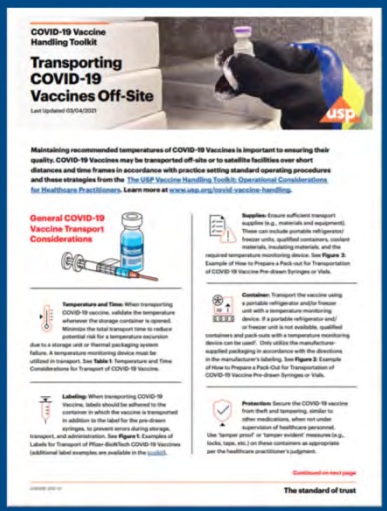
USP COVID-19 Vaccine Fact Sheets

Transporting COVID-19 Vaccines Off-Site



COVID-19 Vaccine Handling Toolkit

Transporting COVID-19 Vaccines Off-Site

Maintaining recommended temperatures of COVID-19 Vaccines is important to ensuring their quality. COVID-19 Vaccines may be transported off-site or to satellite facilities over short distances and time frames in accordance with practice setting standard operating procedures and these strategies from the The USP Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners. Learn more at www.usp.org/covid-vaccine-handling.

General COVID-19 Vaccine Transport Considerations

Supplies: Ensure sufficient transport supplies (e.g., materials and equipment). These can include portable refrigerator/freezer units, qualified containers, coolant materials, insulating materials, and the required temperature monitoring device. See Figure 2. Example of How to Prepare a Pack-out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials.

Temperature and Time: When transporting COVID-19 vaccine, validate the temperature whenever the storage container is opened. Minimize the total transport time to reduce potential risk for a temperature excursion due to a storage unit or thermal packaging system failure. A temperature monitoring device must be utilized in transport. See Table 1. Temperature and Time Considerations for Transport of COVID-19 Vaccine.

Container: Transport the vaccine using a portable refrigerator and/or freezer unit with a temperature monitoring device. If a portable refrigerator and/or freezer unit is not available, qualified containers and pack-outs with a temperature monitoring device can be used. Only utilize the manufacturer-supplied packaging in accordance with the directions in the manufacturer's labeling. See Figure 2. Example of How to Prepare a Pack-Out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials.

Labeling: When transporting COVID-19 Vaccine, labels should be adhered to the container in which the vaccine is transported in addition to the label for the pre-drawn syringes, to prevent errors during storage, transport, and administration. See Figure 1. Examples of Labels for Transport of Pfizer-BioNTech COVID-19 Vaccines (additional label examples are available in the toolkit).

Protection: Secure the COVID-19 vaccine from theft and tampering, similar to other medications, when not under supervision of healthcare personnel. Use "tamper proof" or "tamper evident" measures (e.g., locks, tape, etc.) on these containers as appropriate per the healthcare practitioner's judgment.

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The standard of trust

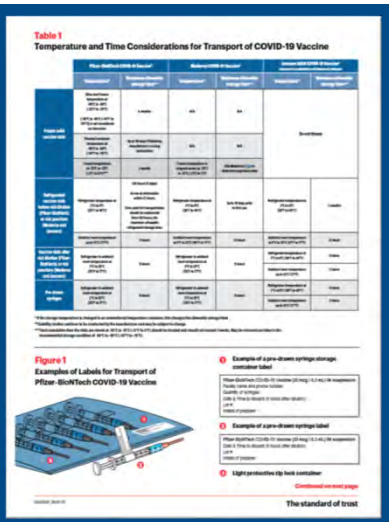

Table 1
Temperature and Time Considerations for Transport of COVID-19 Vaccine

Figure 1
Examples of Labels for Transport of Pfizer-BioNTech COVID-19 Vaccine

Example of a pre-drawn syringe storage container label

Example of a pre-drawn syringe label

Light protective zip lock container

Continued on next page

The standard of trust

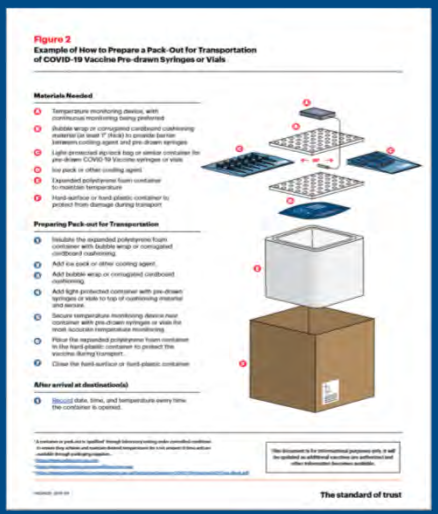

Figure 2
Example of How to Prepare a Pack-Out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials

Materials Needed

- Temperature monitoring device, with continuous monitoring being preferred
- Bubble wrap or corrugated cardboard cushioning material (at least 1" thick) to provide barrier between cooling agent and pre-drawn syringes
- Light protected zip-lock bag or similar container for pre-drawn COVID-19 Vaccine syringes or vials
- Ice pack or other cooling agent
- Expanded polystyrene foam container to maintain temperature
- Hard-surface or hard-plastic container to protect from damage during transport

Preparing Pack-out for Transportation

- Insulate the expanded polystyrene foam container with bubble wrap or corrugated cardboard cushioning
- Add ice pack or other cooling agent
- Add bubble wrap or corrugated cardboard cushioning
- Add light protected container with pre-drawn syringes or vials to top of cushioning material and secure
- Secure temperature monitoring device near container with pre-drawn syringes or vials for most accurate temperature monitoring
- Place the expanded polystyrene foam container in the hard-plastic container to protect the vaccine during transport.
- Close the hard-surface or hard-plastic container

After arrival at destination(s)

- Record date, time, and temperature every time the container is opened.

The standard of trust

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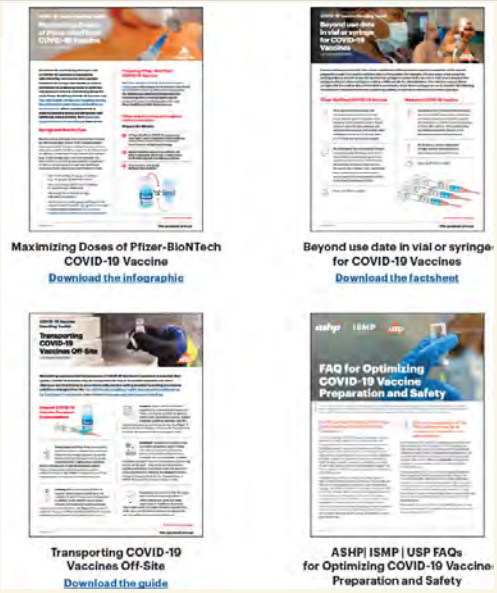
Waste Minimization and Ancillary Supply Disposal

Goal: Support settings in preventing vaccine waste and addressing gaps for vaccine administrators in proper disposal of ancillary supplies

- Special considerations to optimize vial pressure to maximize number of doses per vial become critical
- Correct needle and syringe combination
- Vial septum rotation during needle insertion
- Disposal of unfamiliar ancillary supplies such as dry ice
- Ensuring safe disposal of empty vials to prevent diversion



Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine
Download the infographic

Beyond use date in vial or syringe for COVID-19 Vaccines
Download the factsheet

Transporting COVID-19 Vaccines Off-Site
Download the guide

ASHP| ISMP | USP FAQs for Optimizing COVID-19 Vaccine Preparation and Safety

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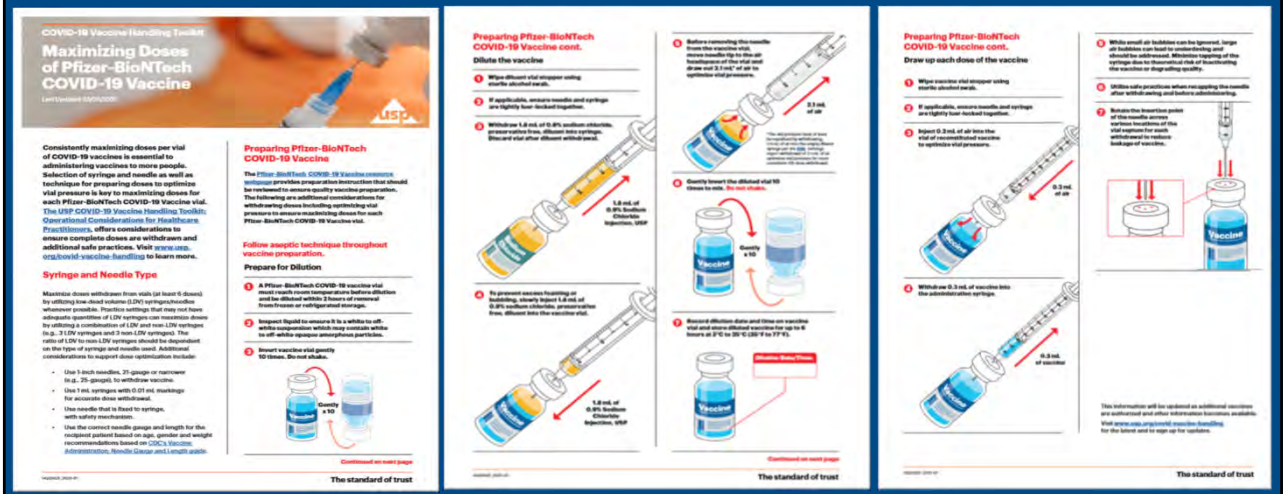
Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine



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Self-Assessment Questions

- The beyond use date for COVID-19 vaccines are best assessed through:
  a. Application of USP<797> to all vaccines
  b. Following manufacturer labeling in the Emergency Use Authorization
  c. None of the above
- The transport of prepared COVID-19 vaccine product may take place under which of the following conditions?
  a. Vaccine in frozen state in vials
  b. Vaccine in refrigerated state in vials
  c. Pre-drawn syringes in refrigerated state
  d. COVID-19 vaccines should not be transported once delivered to provider site
  e. A, B, and C

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4 Facilitated Q & A

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3. Enter the session code provided on the next slide
4. Complete the course and speaker evaluations
5. Select the appropriate credit (pharmacist or pharmacy technician)
6. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
7. Click the claim button

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