Standards, toolkits and guidance to advance regulator priorities

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USP Overview

- Founded in 1820
- Global non-profit organization
- Mission to advance public health through standards and related programs
- Main laboratories in US and India, with offices in 8 countries
- Standards set by 800+ scientists and experts and 100+ FDA liaisons
- Governed by a Convention comprised of 500 organizations from the health and science community.
- The USP South Asia Chapter includes 8 members. Prof. Suresh Bhojraj serves as Chair.

Highlighting 4 Priority Challenges

1. Nitrosamine impurities
2. Medicine Supply Chain Resilience
3. COVID-19 vaccine development and delivery
4. Quality of COVID-19 treatments

The tools we develop and deploy

- Public quality standards
- Toolkits and guidance
- Technical support
- Best practice sharing
- Technical support

Priority Challenge 1
Addressing Nitrosamine impurities

Challenge

Nitrosamine impurities have been identified in pharmaceutical products at levels that exceed regulatory acceptance.

USP Contribution

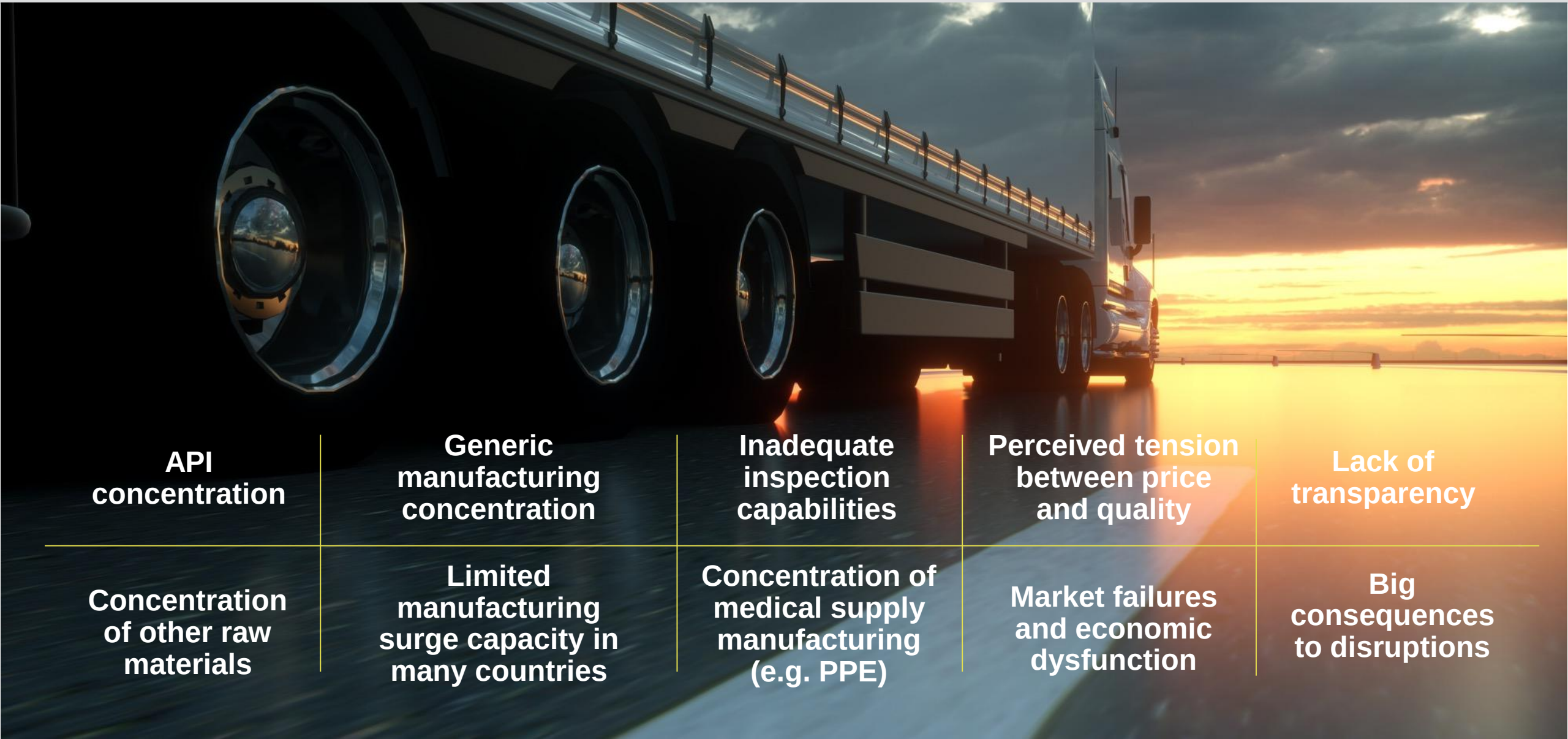
Tools for testing, assessing risk and understanding potential sources related to nitrosamine impurities.

- General Chapter <1469>
- Suite of six reference standards
- Information and training for global regulators

Collaborators

- Indian Pharmacopoeia Commission (IPC)
- Central Drugs Standard Control Organisation (CDSCO)
- ANVISA (Brazil)
- European Pharmacopoeia

Priority Challenge 2
Resilience of the medicines supply chain



API concentration	Generic manufacturing concentration	Inadequate inspection capabilities	Perceived tension between price and quality	Lack of transparency
Concentration of other raw materials	Limited manufacturing surge capacity in many countries	Concentration of medical supply manufacturing (e.g. PPE)	Market failures and economic dysfunction	Big consequences to disruptions

Identifying and mitigating risks upstream, before they result in a crisis downstream

Stakeholder input and policy dialogue

Best practice and policy dialogue

- Increasing transparency in the medicines supply chain
- Key elements to building a more resilient supply chain

Convening stakeholders

- COVID Connect

Convening regulators around best practice
APEC Center of Excellence on Supply Chain Security

- Led and sponsored by the US FDA
  - Based FDA's Supply Chain Security Toolkit
  - Best practice in supply chain security in 10 areas
- USP has collaborated with 21 regulators to train and implement tool kit curriculums
  - Good manufacturing process
  - Good distribution process
  - Internet sales
  - Pharmacy practices
  - Detection/Screening technologies

Priority 3
COVID-19 Vaccines

Challenges and solutions

(I) Help others build and maintain trust in COVID-19 Vaccines

- Partner with established organizations including the **WHO** and **US CDC**

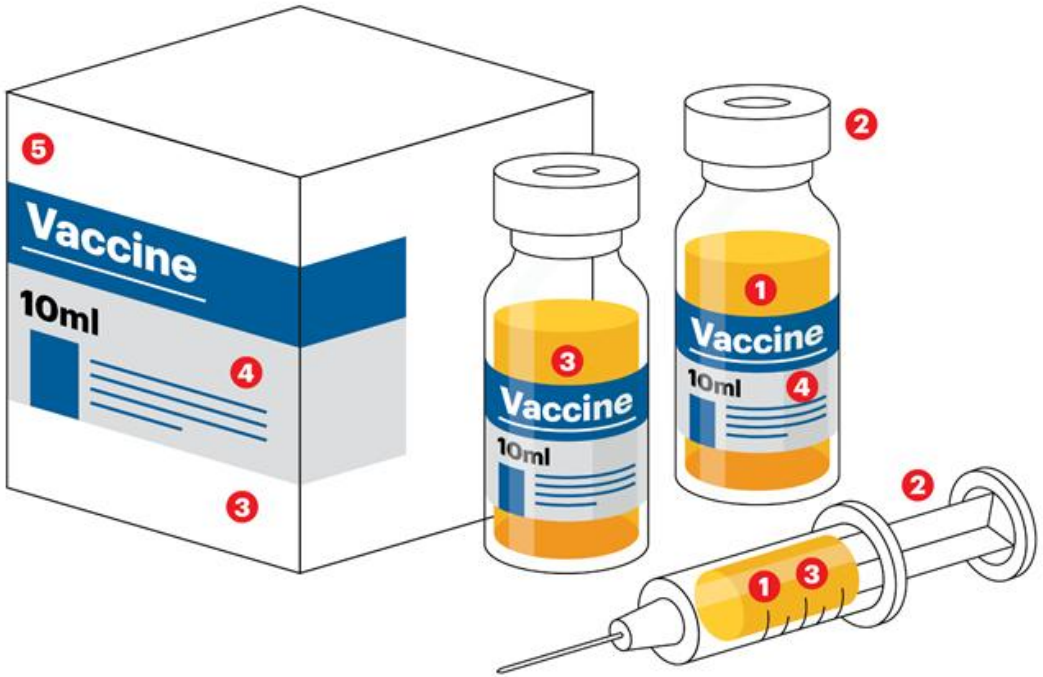
(II) Address Risks of Substandard or Falsified Medicines

- Make standards available that support vaccine quality
- **Develop toolkits for global regulators for quality attributes**
- Develop standards and resources to support cold chain practices
- **Training and toolkits for healthcare practitioners for administration**

(III) Promote Global Access to Quality Vaccines for COVID-19

- Regional technical support
- Support regional training of technical skills and requirement for local vaccine production and administration

USP vaccines standards



USP standards are publicly available tools that vaccine manufacturers can use to help answer questions such as:

1 Ingredients

How can I be sure my ingredients are appropriate for my vaccine process? Are they pure? Is there a consistent supply from a reliable supplier?

2 Containers

Will the items used, such as syringes, make it easy for the patient to get the vaccine? Do they leak? Does the container react with the vaccine and change its quality?

3 Sterility

Is the vaccine sterile? For multi-dose vials, is the antimicrobial agent effective?

4 Labeling

Does the label clearly and accurately indicate the name, dose and how it should be administered?

5 Packaging and distribution

Is the vaccine packaged correctly to avoid damage and temperature fluctuations during storage and shipping?

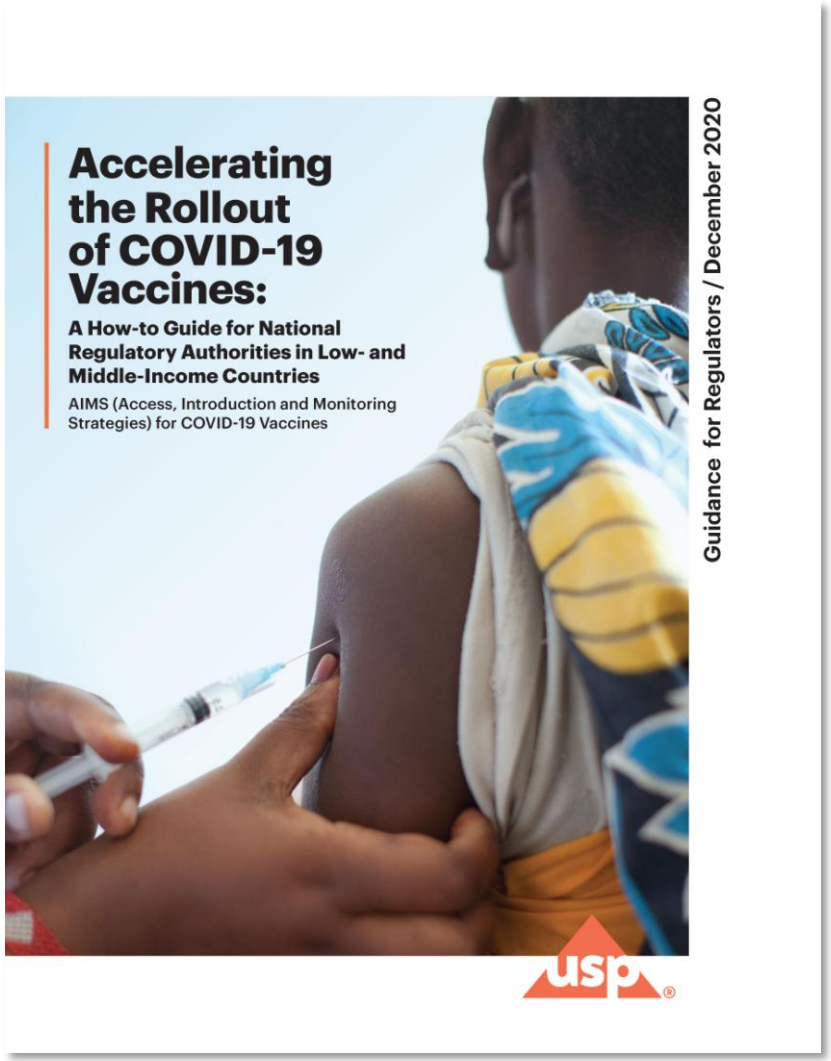
** List not exhaustive*

Collaborations:

- COVAX (GAVI, CEPI, WHO)
- Manufacturers
- Regulators
- Quality control labs
- Trust collaboratives

COVID-19 vaccines' global rollout

- NRA's are critical to safeguarding the quality, safety and effectiveness of COVID-19 vaccines
- Policy paper outlines NRA's can take now to expedite the review, approval, and ultimately availability of COVID-19 vaccines
- Discusses access, introduction and monitoring strategies
- Practical approaches to consider while responding to the pandemic
- Based on experience with NRAs through the USAID funded PQM program.



COVID-19 Vaccine Handling Toolkit: Operational Considerations for Vaccine Administrators

- **Challenge:** preparing, transporting, and consistently administering COVID-19 vaccines (mRNA)

- **USP** toolkit for practitioners
  - Preparation and labeling
  - Storing, handling, and transporting vaccine
  - Waste prevention and disposal

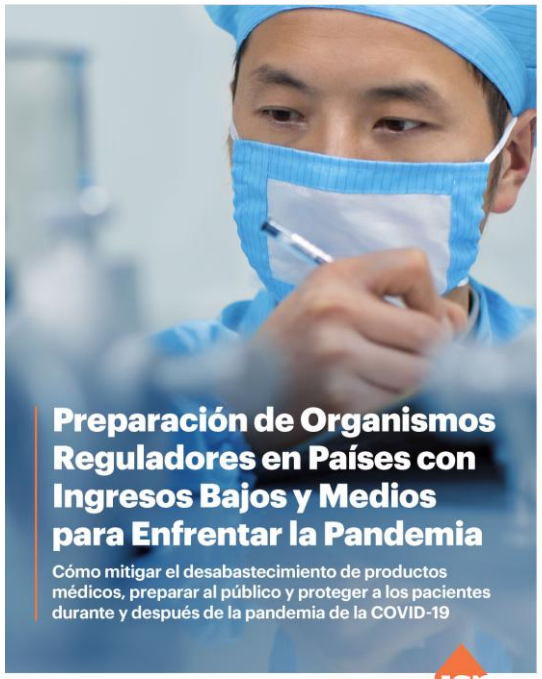
- **Collaborations:**
  - USP's Healthcare Safety and Quality Expert Committee
  - Centers for Disease Control and Prevention (CDC)
  - U.S. Food & Drug Administration (FDA)

- Expansion
  - Revisions to include additional vaccines

Preventing substandard and falsified COVID-19 treatments & preventatives

Challenge: quality and effectiveness of Covid-19 treatments and hand sanitizers

- Authorized medicines and monographs
  - Investigational COVID-19 drugs in world pharmacopeias dashboard
- Methods to identify poor quality treatments
  - Analytical toolkit to prevent SS&F treatments
- Supply of quality hand rubs
  - Toolkit developed with US FDA
  - For compounded and distiller hand sanitizer
  - Training forums worldwide
- Policy guidance
  - Pandemic preparedness for regulators in LMICs



Here are some links

- Information and training for global regulators
- Increasing transparency in the medicines supply chain
- Key elements to building a more resilient supply chain
- COVID Connect
- Authorized medicines and monographs : Investigational COVID-19 drugs in world pharmacopeias dashboard
- Pandemic preparedness for regulators in LMICs

Thank You

Empowering a healthy tomorrow