USP Vaccine Standards

Substandard and falsified vaccines erode the public's trust in vaccines and hinder our ability to control the COVID-19 pandemic. To help ensure the quality of vaccines, USP offers its quality standards, best practices, and insights to guide manufacturing, packaging, and release processes.

- **RS:** Raw and ancillary materials (e.g., polysaccharide NMR system suitability).
- **USP Education:** A five module course on cGMP providing guidelines and best practices on: Manufacturing, Characterization, Cell Banking, Production, Quality Control, Regulatory Guidelines. Additional courses address: The Quality Assessment Toolkits, Assay Development, Bioassays etc.

  Contact Narayan Srivastava at narayan.srivastav@usp.org for more information
- **USP-NF:** General chapters for CQAs on both viral and conjugate vaccines such as:

<1234>	**Vaccines for Human Use – Polysaccharide and Glycoconjugate Vaccines**
<1235>	**Vaccines for Human Use – General Considerations***
<1238>	**Vaccines for Human Use – Bacterial Vaccines**
<1239>	**Vaccines for Human Use – Viral Vaccines**
<198>	**Nuclear Magnetic Resonance Spectroscopy Identity Testing of Bacterial Polysaccharides Used in Vaccine Manufacture**

USP welcomes public comments on Analytical Procedures for mRNA Vaccines Quality and Viral Vectored Vaccines Quality.

Other resources:

Quality assessment toolkits for vaccines (resources for testing identity, purity, potency, concentration); preparation, storage, transportation, and waste minimization; and toolkit for COVID-19 vaccine administration for healthcare practitioners.

New USP-NF chapters:

mRNA and viral vector vaccines are in preparation. To build public trust and confidence in innovative technologies, they must be of good quality, safe and effective.

– To address the need for a common set of methods for determining quality formRNA and viral vectored vaccines, USP is developing a set of analytical methods to support developers, manufacturers, regulatory agencies and national control laboratories worldwide. A shared understanding of quality can help accelerate product development, guide successful scale-up of manufacturing and fuel regulatory confidence that manufacturers are employing best practices and appropriate quality controls when using these is new technologies.

To order

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For more information

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