

# 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.

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- **USP-NF:** General chapters for CQAs on both viral and conjugate vaccines such as:

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

## 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 for mRNA 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.

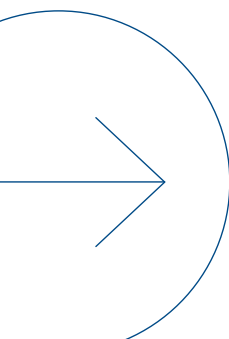
## To order

Visit <https://www.usp.org/biologics/reference-standards>

## For more information

Visit us online at <https://www.usp.org/biologics/vaccine-standards> to learn more

[usp.org/biologics](https://www.usp.org/biologics)



**USP welcomes public comments** on [Analytical Procedures for mRNA Vaccines Quality](#) and [Viral Vectored Vaccines Quality](#).