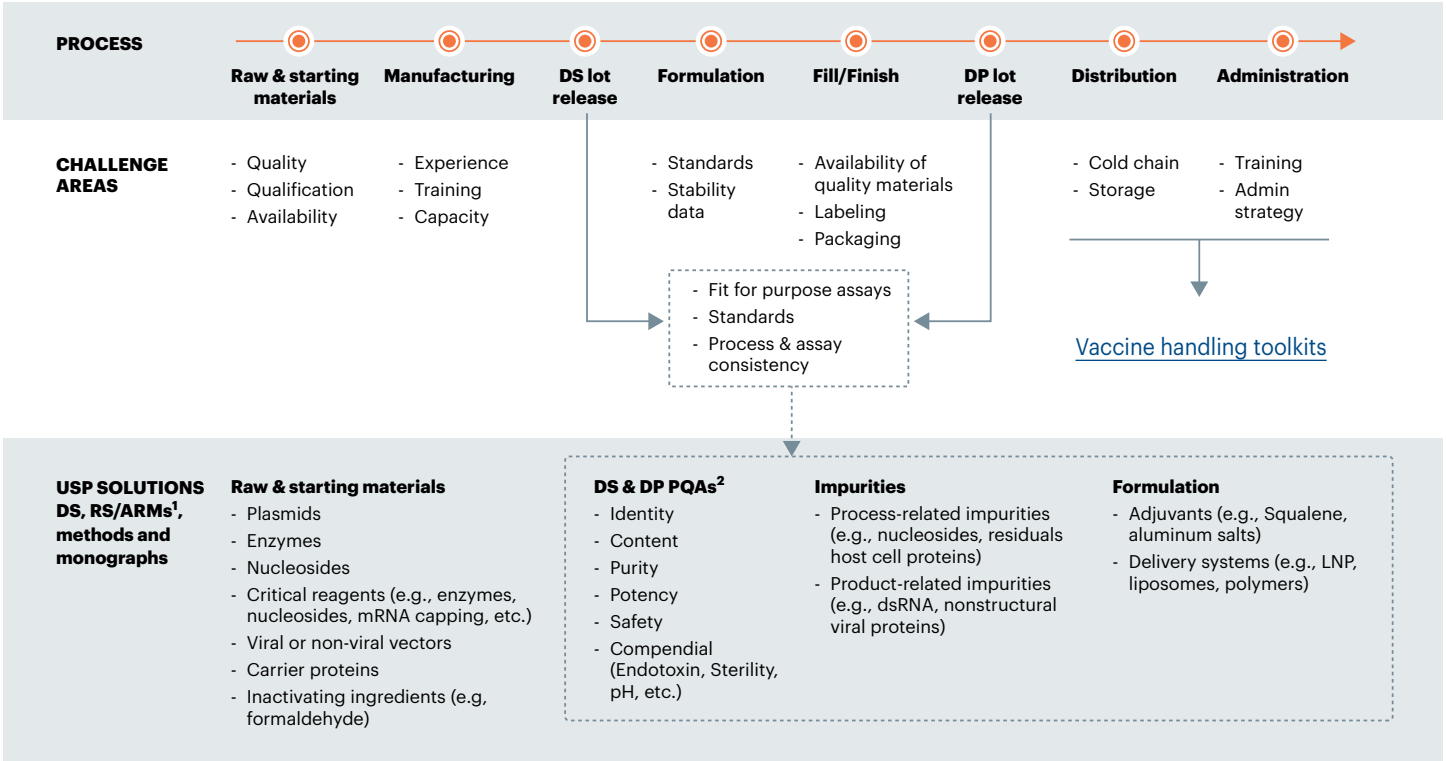
Biologics™

USP vaccine standards

There are risks that should be considered in every step of manufacturing a vaccine. These risks can be mitigated by using USP quality standards during characterization of the drug substance or drug product, stability testing, validation, and in post-market surveillance.

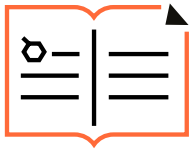
Potential risks to vaccine manufacturing and distribution



[1] DS (Documentary Standard); RS (Reference Standard); ARM (Analytical Reference Material)
[2] DS (Drug substance); DP (Drug product); PQAs (Product Quality Attributes)

Vaccine documentary and reference products

For general guidance on making a vaccine or common methods used to control the quality of vaccines, refer to the following USP General Chapters.



- <1235> *Vaccines for Human Use—General Considerations*
- <1234> *Vaccines for Human Use—Polysaccharide and Glycoconjugate Vaccines*
- <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*
- <1040> *Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies PF49(6)*

Quality assessment toolkits for vaccines

Various **platforms** are used to develop vaccines, each with its unique set of critical quality attributes (CQAs) that require thorough assessment. USP Vaccine Quality Assessment Toolkits can help you navigate USP's documentary standards and reference standards/analytical reference materials (ARMs) to support the different vaccine platforms. The toolkits include common quality tests, standards and other information to support development and validation of analytical tests commonly used to ensure the quality of vaccines, reduce risks from substandard and falsified vaccines, and, ultimately, increase public trust. They also indirectly ensure the safety and efficacy of the vaccines. The quality of the process directly impacts the quality of the product. **USP has additional resources that complement these toolkits (Table 1).**

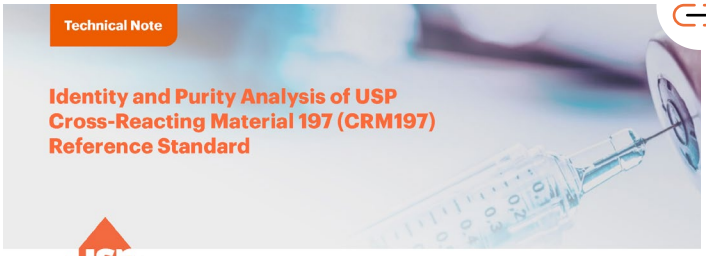
Table 1. USP Reference Standards/ARMS to support various vaccine platforms

Vaccine type	Vaccine platform	Carrier protein	Identity	Molar mass and sizing standards			Formulation assessment	Impurities	
		CRM197[1]	PS NMR SS[2]	Thyroglobulin	BSA	Pullulan	Squalene	Octoxynol-9	gDNA
Viral	Inactivated			x	x		x	x	x
	Attenuated virus			x	x				x
Nucleic acid	Viral vector			x	x			x	x
	mRNA		x						x
	DNA		x						
Isolated antigen presentation	Subunit	x	x	x	x	x		x	x
	VLP			x	x	x			

[1] CRM: Cross-Reacting Material 197
[2] PS NMR SS: Polysaccharide Nuclear Magnetic Resonance System Suitability

Vaccine quality resources

Vaccine quality analytical procedures and application notes



USP Education

Guidelines and best practices for:

- Introduction to GMP Manufacturing and Characterization of Vaccines for Human Use
- Cell Banking for Manufacturing of Vaccines
- Production of Vaccines and Sterile Biologics
- Quality Control of Vaccines Manufacturing
- Regulatory and WHO Prequalification Considerations for Vaccine
- **And many more! Please visit us to read our white papers or watch our webinars**

To learn more, please visit our Vaccines page at:
www.usp.org/biologics/vaccine-standards