Initial call for stakeholder input on a potential standard

Path forward determined with additional input, e.g. workshop, stimuli article, notices

No standards to be developed**

Monograph or chapter published in Pharmacopeial Forum for public comments

Performance standards

General Chapter

Stand-alone Reference Standard

No Standards**

Multiple monographs

Flexible monograph

Single monograph*

General Chapter

Stand-alone Reference Standard

* USP will not publish as official new monograph standards for specific biologics products unless supported by FDA and stakeholders.

** Even if no USP standard is developed, scientific information gathered could be made available as best-practice document.