

USP Biologics Roundtable on Visible Particles
November 2, 2018
USP–U.S. Headquarters, Rockville, MD

Executive summary: USP hosted representatives from industry and government organizations at a roundtable to explore development of standards for visible particle detection. The goal of the meeting was to facilitate a robust discussion on possible ways that documentary and performance standards could help standardize and harmonize the approaches to visual inspection taken by individual organizations. The roundtable participants shared challenges and discussed the need for best practices and methods in addition to physical reference standards that could be available through USP. Production of physical standards for system suitability, along with a round robin study in various facilities, was the highest ranked opportunity.

Main bullet points from the discussion:

- Industry lacks a definition for “visible”
- There is a paucity of data on manual particle detection and visual performance varies widely among inspectors
- Workstations and methods for inspection require standardization to reduce variability
- There is movement towards semi-automated and automated systems for larger manufacturers but manual inspection will be in use for the foreseeable future
- Standards such as polystyrene spheres are available but do not correspond to particles seen during actual inspections in terms of shape, color, buoyancy, and movement in solution
- NIST is working to produce stable surrogates for visible protein particles and these should be available soon
- Other groups, such as the European biopharmaceutical enterprises (EBE), are active in this area and additional data should be available soon

Path forward:

Several ideas were generated, discussed by the participants and prioritized in terms of impact/need and feasibility. The two ideas for standards that were ranked highest by participants were physical standards for system suitability and for training. These standards would be incorporated into a round robin study for further evaluation. The next steps are for USP to gather individual feedback regarding the composition of proposed standards and design of round robin studies.

We ask that interested individuals please contact Jim Richardson at jim.richardson@usp.org if you have questions or clarifications for the above summary or additional thoughts on the topics that were discussed.