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Particulates in Biotech Products: Standard Setting Effort Gaining Traction

Visible and sub-visible particles in parenteral products and the need for developing measurement standards is drawing attention from regulators and industry at biotech conferences.

At the AAPS National Biotech meeting in San Francisco on May 18, FDA Office of Biological Products Division of Therapeutic Proteins Deputy Director Barry Cherney underscored the need for particle standards. Noting the lack of standards for protein particles, Cherney pointed out that an effort is taking shape in which FDA, The National Institute of Standards and Technology (NIST), and industry will partner to develop these much-needed standards. A proposal by NIST to assist on this front drew discussion at CASSS' annual WCBP conference in January.

At the same meeting, FDA Center for Drug Evaluation and Research (CDER) Principal Investigator and Senior Regulatory Research Officer, Jack Ragheb, commented on why FDA is concerned about particles. He cited the potential for immunogenicity, and added that the level of particles in an injectable product also serves as "a sentinel of product quality."

[Editor's note: The opportunities & challenges around standards development for biotech product particulates and NIST's potential role are explored in the May 2010 issue of IPQ as part of its analysis of the changing CMC landscape.]

NOTE: AAPS members can receive a complimentary copy of the IPQ "Monthly Update – July 2010" in which this article appeared, by clicking here.

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