

Adenovirus Reference Material Update

A Working Group, whose membership includes academia, industry (biotech and pharma), suppliers, contract manufacturers, contract testing organizations, FDA, and organizations such as ATCC, the U S Pharmacopoeia, and the NIBSC (National Institute of Biological Standards and Controls), is overseeing the production and characterization of an adenovirus reference material. This material should be available for use in validating adenoviral vector particle and infectious titer assays early in 2002. The purpose of the reference material is to define the particle unit and the infectious unit for adenovirus vectors. The reference material will consist of purified Adenovirus 5 WT virus in a formulation that is amenable to assays, multiple freeze-thaws, and ease of use. Production of the reference material is already in progress.

The Working Group will invite in June via a website, www.wilbio.com, the submission of specific proposals to participate in the characterization phase of the reference material. The requests for proposals focus on participation in assignment of particle number and infectious titer, as well as a call for all other types of characterization and participation in the stability monitoring phase. Those institutions submitting to participate in characterizing the particle concentration will use a single OD260nm/SDS method provided by the Working Group. Other methods of particle determination are also encouraged per the requirements set out in the request (RFP 8.0). Those institutions wishing to participate in characterizing the infectious titer of the reference material will use a single 96-well CPE-based method provided by the Working Group.

The Working Group is also requesting proposals for all other types of characterization, including methods to assess purity and identity (such as sequencing). The Working Group will also be requesting participation in monitoring the stability of the reference material via a protocol provided by the Working Group.

If you are interested in learning more about the Adenovirus Reference Material project, contact Keith Carson at *The Williamsburg BioProcessing Foundation* at www.wilbio.com, or inquire at the CBER/FDA information booth. You can also contact the Working Group *Co-Chairs*: Estuardo Aguilar-Cordova (Harvard University) and Beth Hutchins (Canji, Inc.), whose information is listed in the conference directory.