



Mike Molloy – Technical Director

Mike Molloy has been with Boston Analytical since 2012 and started out as the Director of the QC Chemistry Laboratory. Prior to that, he spent 20 years at Biogen, working to become the Head of Laboratory Operations in the Preclinical and Clinical Developments Sciences Group at Biogen. Molloy has a master's and bachelor's in biology from Umass Lowell and UNH, respectively.



Karina Allen-Ludwig, PhD - Senior Scientist

Karina Allen-Ludwig, PhD, is a Senior Scientist in the Biologics Laboratory and manages Method development for quantitative and qualitative analysis of pharmaceutical products according to FDA and cGMP guidelines. Karina holds a Ph.D. from the University of Massachusetts Lowell - Kennedy College of Sciences in Chemistry - with a focus on Biochemistry.

PDA Pacific Northwest Chapter Presents

DETERMINATION OF IMPURITIES IN GENE THERAPY PRODUCTS WEBINAR

November 11, 2020 from 11:30 a.m. to 12:30 p.m. PDT

WITH **Mike Molloy – Technical Director** AND **Karina Allen-Ludwig, PhD – Senior Scientist**
FROM THE **Biologics Laboratory at Boston Analytical**

Event Summary:

Analysis of impurities is one of the critical steps in ensuring the safety of pharmaceuticals, including biologics such as monoclonal antibodies, and gene therapy products. Traditional methods for measurement of impurities are useful for gene therapy products, but a few additional techniques are needed to specifically address potential impurities for gene therapy applications. We will look at approaches to investigate various potential impurities that may be a cause of concern in development.

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