

Analytical Method Validation for Biopharmaceuticals, Part 3

By [Drew N. Kelner](#) [Ira S. Krull](#) [Robert J. Duff](#) [Tamer Eris](#) Apr 25, 2017 10:24 am PDT



Over the history of the biotechnology industry, biopharmaceutical companies have expended considerable effort characterizing and tracking the entire suite of product attributes using available technology, uncertain of the biological significance of the various attributes. Product specifications for purity were based on chromatographic patterns capable of tracking the consistency of manufacturing, but unable to track specific attributes, due to the heterogeneous nature of the chromatographic peaks.

IVT's [Analytical Procedures & Methods Validation](#) event on 20-22 June, 2017 in Dublin, Ireland offers attendees interactive workshops and critical discussions, including an FDA keynote address and breakdowns of global regulatory updates.

This content is only available to IVT members.

Get help maintaining your knowledge . [Read More!](#)

If you are already a member and you do not have access to this article, [upgrade your membership](#).

Need help? [Read our FAQs](#).

[You May Also Like: Part 2](#)

[Drew N. Kelner](#)

Drew N. Kelner, Ph.D. is the President of Colorado Biotechnology Consultants, LLC.

[View Author Bio](#)

[Ira S. Krull](#)

Professor Emeritus Krull retired in 2008 from the Department of Chemistry and Chemical Biology at Northeastern University, Boston, MA but continued teaching, part-time until about 2013. He now offers training courses in...

[View Author Bio](#)

[Robert J. Duff](#)

Robert J. Duff is a Principal Scientist at Amgen, Inc.

[View Author Bio](#)

[Tamer Eris](#)

Tamer Eris is a Principal Scientist at Amgen.

[View Author Bio](#)

Source URL: <http://www.ivtnetwork.com/article/analytical-method-validation-biopharmaceuticals-part-3>