IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

Analytical Method Validation for Biopharmaceuticals, Part 2

By **Drew N. Kelner, Ira S. Krull, Robert J. Duff, Tamer Eris** **Feb 17, 2017 6:34 am PST**

Photo by Geoffrey Whiteway

The FDA Guidances for Industry states that results from robustness studies should be provided, along with the method validation results, upon submission of the Biologics License Application (BLA) (17,54). However, the guidance also advises that the evaluation of method robustness may be conducted as part of method development or it may be performed as part of a planned method validation study. Therefore, it is up to each method developer to justify the robustness data of the method being submitted for consideration, using data from either method development and/or from a planned robustness study conducted as part of method validation.

Read Part 1 Here