

Method Validation of HPLC/UPLC Methods

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Instrumental liquid chromatography, either as HPLC or UPLC, are common techniques in laboratories that do regulatory-compliance work. For Good Laboratory Practice (GLP) or for ISO 17025 compliance, such methods must meet certain requirements. This presentation will cover the key elements to have a compliant method.

Instrumental liquid chromatography is an analysis that is widely used to determine purity, impurities, and the degradation of products of pharmaceuticals. The focus of most validation work is on the methodology, the standard operating procedure (SOP). But validation of the instrumentation and other associated items of column, solvents, and other reagents and chemicals is also an area of focus in an audit.

AREAS COVERED IN THIS WEBINAR

In order to meet US EPA or FDA requirements, a method must meet many stringent requirements. The more important of these for specific analytical methods are method validation and instrument validation. To not do so is a non-compliance in which any data is not usable or reportable.

INSTRUCTOR PROFILE

JOHN C. FETZER

John C. Fetzer has had over 30 year of experience in laboratory compliance, including developing methods, writing SOPs, training, and auditing. He has served on the editorial advisory boards of the Journal of Chromatography, Analytical Chemistry, and Analytical and Bioanalytical Chemistry. He has published over 50 peer-reviewed articles on liquid chromatography, with many dealing with the mechanisms of separation.



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