

LOUIS FLECK

TRACE ORGANIC ANALYSIS MANAGER

PROFILE



ABOUT

Louis has 20+ years of experience in contract laboratories performing and managing activities to directly support the pharmaceutical industry, which includes chromatographic method development and validation, and E&L testing for container closure systems and finished pharmaceutical products

EDUCATION

**Bachelor of Science, Chemistry • 1998 •
Millersville University •
Millersville, PA, USA**

EXPERIENCE

Trace Organic Analysis Manager • Intertek Pharmaceutical Services (IPS) • 2018 – Present

Directs and coordinates activities of lab operations. Supports development of proposals, protocols, and reports for extractable and leachable (E&L) projects. Supports cGMP compliance activities such as timely calibration of equipment and personnel trainings. Performs review of analytical data and trainings. Business development responsibilities.

Research Scientist • Intertek (IPS) • 2011 – 2018

Designed E&L studies. Utilized LCMS for evaluation, determination, and identification of E&L from container closure systems and finished pharmaceutical products. Designed and executed instrument and equipment validation/qualification requirements (IQ/OQ/PQ). Assisted with development and expansion of new service offerings for a defined technology. Lead and directed work of others.

Chemist II • Skillman • 2010 – 2011

Supported Consumer Health Care and Intimate Health Franchises. Assisted in method development, validation, and optimization of UV and HPLC methods. Utilized HPLC, UV, and FTIR to support development of consumer products.

Scientist / Research Scientist • Intertek d/b/a QTI • 2007 – 2009

Planned, performed, and completed multiple complex projects. Developed and validated chromatographic methods. Reviewed analyses and documentation on completed projects. Wrote technical reports. Resolved problems and performed investigations. Client liaison. Lead and directed work of others. Oversaw development and validation of analytical methods. Assisted with evaluation and selection of instrumentation, equipment, or software, and design and execution of instrument and equipment validation/qualification requirements (IQ/OQ/PQ).

Various Positions (Analyst to Scientist) • Quantitative Technologies, Inc. (QTI) • 1998 – 2007

Developed and validated chromatographic methods. Communicated problems to management and clients. Assisted with evaluation and selection of instrumentation, equipment, or software, and design and execution of instrument and equipment validation/qualification requirements (IQ/OQ/PQ). Lead and directed the work of others.



louis.fleck@intertek.com



+1 908-534-4445

