

Reference Table

These references provide regulatory and compendial context for the LC-MS series, including FDA guidance, USP General Chapter <1058>, and European Commission EudraLex Volume 4 Annexes 11 and 15. Laboratories should assess applicability based on their products, workflows, quality procedures, and regulated environment.

No.	Issuer	Reference	Date	Use in series	Link
1	FDA	General principles of software validation; Final guidance for industry and FDA Staff	January 11, 2002	Supports lifecycle validation, intended use, supplier assessment, validation after change, maintenance, traceability, configuration management, and Part 11 validation principles.	Open FDA source
2	FDA	Computer software assurance for production and quality management system software	February 3, 2026	Supports a risk-based approach to software assurance and ongoing confidence that software remains fit for intended use.	Open FDA source
3	FDA	Data Integrity and compliance with drug CGMP: Questions and answers, guidance for industry	December 2018	Supports data integrity controls across the CGMP data lifecycle, from creation through retention and retrieval.	Open FDA source
4	United States Pharmacopeia	USP general chapter <1058>, analytical instrument qualification	Official chapter version referenced by USP as effective August 1, 2017	Supports risk-based, integrated qualification and fitness for intended use principles for analytical instruments and systems.	Open source
5	European Commission	EudraLex Volume 4, Annex 11: Computerized Systems	Revision 1; operation date June 30, 2011	Supports application validation, IT infrastructure qualification, lifecycle risk management, supplier responsibilities, and data integrity expectations.	Open source
6	European Commission	EudraLex Volume 4, Annex 15: Qualification and validation	Operation date October 1, 2015	Supports lifecycle qualification and validation, documented risk assessment, planned change control, validated status impact assessment, and Annex 11 alignment.	Open source