

TECHNICAL REQUIREMENTS

URS#	Description
U-01	The system must have a database server to host the database.
U-02	The system must have an application server.
U-03	The system must have license server.
U-04	The system must have remote desktop capabilities (Terminal Server).
U-05	The system must have desktop computers client to control instruments.
U-06	The system must be able to control chromatographic instruments.

BUSINESS REQUIREMENTS

URS#	Description
U-10	The system must allow authorized users to create and modify chromatographic systems.
U-11	The system must allow an authorized user to create, modify, or copy projects (folders).
U-12	The system must have the ability to create, modify, or copy instrument methods.
U-13	The system must have the ability to create, modify, or copy processing methods.
U-14	The system must have the ability to create, modify, or copy sequences.
U-15	The system must be able to use pre-selected methods and report(s) in the sequence.
U-16	The system must require a user to enter a comment when saving changes to the sequence objects.
U-17	The system must have the ability to control a sequence.
U-18	The user must have the ability to see a chromatogram currently being collected.

7.0 SECURITY AND COMPLIANCE

URS#	Description
U-40	21 CFR 11.3(b)(4) The system must be a closed system in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.
U-41	21 CFR Part 11: 11.10(b) The system must provide the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying.
U-42	21 CFR Part 11: 11.10(c) The system must provide a mechanism for the secure archiving and retrieval of the data including all metadata (including audit trail).