

# Software Validation Service

## Case Study

Domain: Regulatory Compliances

Type: Software Validation

***“Validation of software that mandatorily required US FDA requirements to be fulfilled”***

B.A.T. to provide validation service for the software that controls LC-MS/MS instrument, data acquisition, processing, reporting

The purpose was to fulfill the US FDA requirements for activities in Clinical Trial for drug discovery and development.

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### Challenges

- The fundamental of software validation were unclear with the Client.
- Validation activities needed to be scheduled meticulously to minimize the down time of instruments.
- Lack of clarity about data management (data storage, backup and archival).
- Synchronization of validation activities with outsourced IT services.

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### Solution

- B.A.T. scoped the client’s need with respect to their regulatory requirements and intended use of the software application.
- Considering customer’s potential risks and time constraints, thorough planning was done. The downtime of the instruments was maintained well under control throughout the project duration.

## Assessing the Solution:

The client is a leading contract research and testing organization, based in Hyderabad, India. The organization has state-of-the-art clinical research laboratories providing full service in clinical research. The client has a large bioanalytical setup, with more than 15 LC-MS/MS instruments functioning at two operational sites running round the clock.

B.A.T. assessed the software validation requirement of the client and adopted an effective strategy to fulfill the regulatory and business needs of the client.

The customer being player in a domain that demands utmost accuracy and care, B.A.T. had to ensure authenticity and quality of the services offered.

## Strategy:

### Step 1: ASSESSMENT

#### Requirement Assessment

Communicating with the customer to understand their business needs, compliance needs and user needs. The client was made aware about software validation, its work flow and the activities.

#### Evaluation

The requirements were analyzed and high level requirements were defined so as project scope can be outlined.

#### Requirement Analysis

Analytical laboratory system information and system inventory was gathered to complete the User Requirement Specifications (URS).

## Delivering the Solution:

Client approached B.A.T. for assistance. B.A.T. scoped the client's need with respect to their regulatory requirements and intended use of the software application. The basic project management approach i.e. "Plan Do Check Act" was adopted.

Planning was thoroughly done considering customer's potential risks and time constraints. As per the defined scope, validation was executed. The gaps in the system were identified and corrective actions were suggested. The downtime of the instruments was maintained well under control throughout the project duration as many projects were ongoing and it was difficult for the client to interrupt them.

With vast experience and strong expertise in analytical software development and verification, project management, documentation, pharmaceuticals domain and in-depth knowledge of the compliances (FDA, GLP), B.A.T. worked out quick and efficient validation solution. The core knowledge of the domain helped B.A.T. to plan and adopt the most effective validation strategy.

## B.A.T. Capabilities

1. Qualified professionals having a sound knowledge of:
  - Analytical Domain and Laboratory flow,
  - Compliance Systems such as GxP, ISO, 21CFR etc.
  - Software verification and validation practices
2. In-house state-of-the-art laboratory facility consisting high throughput Analytical, Chromatographic, Spectrometric instrumentation and Laboratory Management applications.
3. In-house software development centre.
4. Capabilities to customize with user's system and application.

**Step 2: PLANNING**

Risk based approach was adopted. Planning was done based on the URS.

**Step 3: DESIGNING**

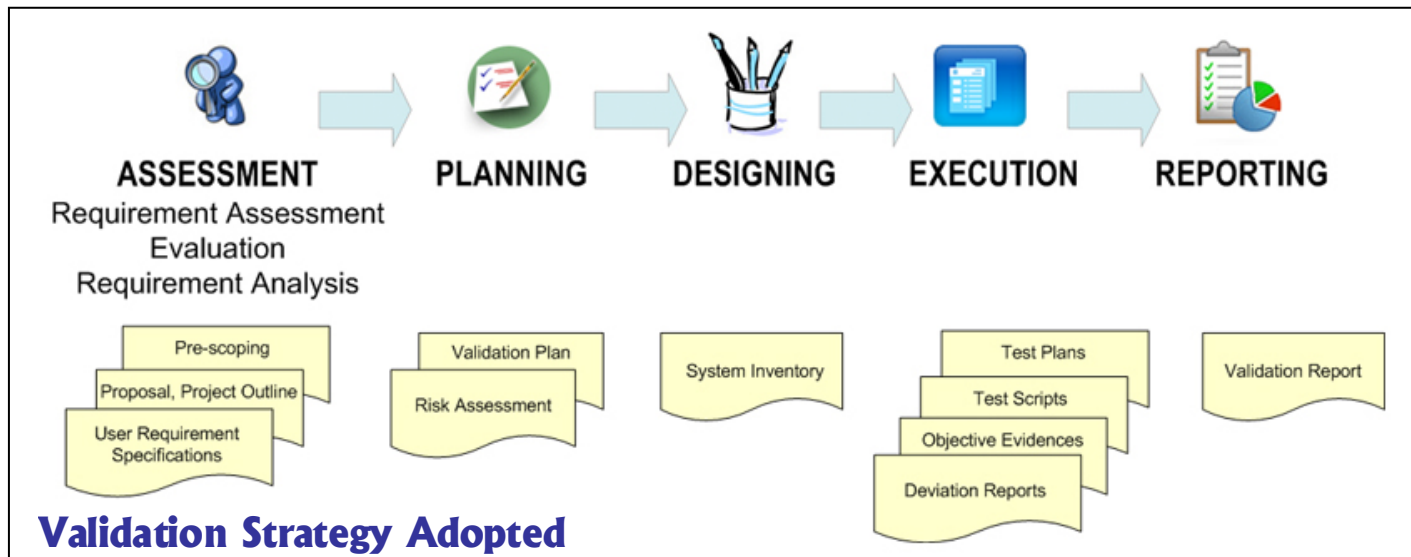
This involved verification of pre-requisites such as system environment, set up, configuration.

**Step 4: EXECUTION**

Verification of IQ, OQ, procedures, and policies was done. The major software functions were tested as per test scripts. The deviations were logged and corrective actions were suggested accordingly. Systems were released after completion of validation tasks.

**Step 5: REPORTING**

The validation data was compiled and reported in report formats. The reports were sent for Quality Assurance Review and then to Head for approval.



**Benefits to client:**

- Quick and efficient validation solution.
- The US FDA and 21CFR part11 requirements for the software were successfully identified and validated.
- B.A.T. identified and planned mitigation actions for the post validation risks too.
- The downtime of the instruments was maintained well under control without interrupting the ongoing projects at client's end.