



VALIDATED SERVICES

MASON-GREY has significant experience in the implementation of integrated software development/validation projects in **Pharmaceutical** and other **FDA regulated industries**. Our approach takes advantage of our **GAMP compliant project execution methodology** (Project Complete) and significantly reduces validation costs by integrating validation steps into the overall project plan to add value, not paperwork.

Why **MASON-GREY** for your validation needs? We apply multi-system experience, our proven project execution methodology and in-house tools to integrate the **IOQ execution** into the project deliverables. The project execution methodology includes documented testing with software/document change control beginning at the start of FAT through the completion of the project. Using a project team already familiar with the customer's process, procedures, expectations and personnel, etc. we can compress the overall project timeline.

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We use your systems, your standards and will integrate with your culture. During project definition, we will not only understand the project scope, we will understand how your organization views the project from all angles and how you define success. **MASON-GREY** understands that projects must fit your engineering, operations and quality assurance needs. **We listen, understand, define** (document), get your buy-in and then execute. We will constantly review deliverables with you as they are developed, ensuring a common project vision.

MASON-GREY systems are designed to comply with 21 CFR Part 11 requirements as interpreted by the customer. Below are typical methods of addressing 21 CFR Part 11 within control systems:

- Operator stations auto log-off after periods of inactivity.
- Operator stations require authenticated passwords to access data entry or control related to the process. All entries are stamped with date, time and username.
- Operator stations require authenticated supervisor/administrator passwords to access the operating system even on system boot up.
- Direct access to system databases is disallowed. Edits can only be done through external interface required security and change tracking.
- Packages such as Tripwire to monitor server changes.
- Software packages for database audit trails.
- Customer SOPs pertaining to security, electronic identification agreement, etc. are updated.

MASON-GREY Project Execution Methodology

The engineering quality system developed by **MASON-GREY** is a culmination of our experience with automation and information technology systems. It is used for all our projects and provides a framework for consistent high quality deliverables.

- Based on Project Management Institute (PMI) methodology
- Browser enabled and linked
- Work Breakdown Structure (WBS) with detailed instructions for tasks
- Fully integrated with **MASON-GREY's** estimating tools, proposal templates, time reporting, and project scheduling. It is the way of doing business at **MASON-GREY**.
- Audited by third party auditors and our customers auditing groups.

Delivering Value

MASON-GREY's proven approach saves money, time, and meets your requirements.

- Project Execution coupled with Validation deliverables saves time and money
- Project Execution Methodology ensures conformance to requirements and meets pharmaceutical industry standards
- **MASON-GREY** addresses the business case first, understanding your drivers allows us to meet your needs
- **MASON-GREY's** staff is always focused on business value

User Requirements and Functional Specification

MASON-GREY has developed numerous specification documents, and we have excellent formats that integrate very well with testing. Programming guidelines (PLC, HMI, Database, etc.) are included to ensure that all developed code is properly structured and documented. Customer approval of the specification prior to implementation guarantees that our approach meets the expectations stated in the project proposal.

Project Database

MASON-GREY has developed a project database structure that integrates into generic test protocols to expedite the creation of test plans (FAT, SAT, and IOQ). Additional benefits of this database are: I/O list, instrument index, PLC/DCS imports for I/O addressing, HMI I/O addressing, automatic generation of Instrument Loop Sheets, and more.

Factory/Site Acceptance Testing

MASON-GREY has developed a testing methodology that requires rigorous documentation and change management throughout all phases of testing. Customer approval of the test plan prior to execution ensures that our approach meets the expectations stated in the project proposal.

Validation Plan (VP)

The Validation Plan includes topics such as the following: Site Description, Process Description, System Description, Definition of Scope for Validation, Overview of Validation Methodology, and Validation Timeline.

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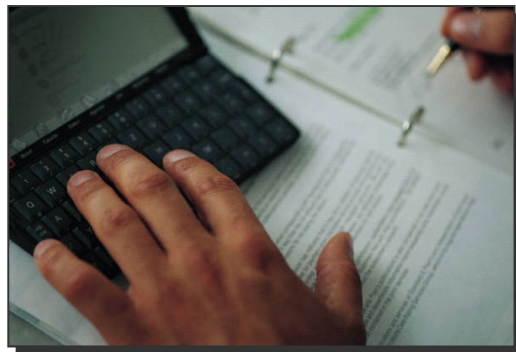
Installation/Operational Qualification (Validation IOQ)

The Validation IOQ applies the relevant guidelines of the Good Automated Manufacturing Practice (GAMP) to verify that all equipment and procedures are identified and in place; the computerized system has been developed according to specification and design; and the computerized system has been executed according to the manufacturer's instructions. A minimum of three successful consecutive test runs is included in the IOQ to ensure that the equipment/systems function properly during normal and adverse conditions.

Objectives

Offer experienced resources for the effective implementation of Validated Control Systems for FDA Regulated Applications. **MASON-GREY** personnel follow a structured project execution Methodology (Project Complete) to ensure on-time, on-budget projects that exceed our customer's expectations:

- **Structured format** and documentation. **Standards** for consistent implementation and quality.
- **Validation Plan Development**
- **Installation** Qualification (IQ)
- **Operational** Qualification (OQ)
- **Field Validation** Execution
- **21 CFR Part 11** Compliant



Results

The following benefits have been achieved from the use of experienced resources:

- Projects **completed on time** and within initial scope/budget.
- Utilization of **quality system** to achieve **GAMP** and **FDA** validation where required.
- **Complete understanding** of initial scoping and definition.
- **Standards** defined for common development and operation.
- Full use of **technology and integration** offered by product software suite.