



NEW OAKS  
CONSULTING

# CQV Process Overview

# INTRODUCTION

CQV (Commissioning, Qualification, and Validation) is a structured, risk-based framework designed to ensure that facilities, utilities, equipment, and systems are suitable for their intended use, compliant with regulations, and ready for commercial operation. The CQV process ensures a smooth startup by verifying that facilities, systems, and equipment are suitable for their intended purpose, consistently deliver quality, improve operational efficiency, lower costs, and establish best practices. This is achieved by verifying the proper design, installation, and performance for quality assurance.

In regulated and capital-intensive industries, it's essential to ensure that facilities, systems, and equipment function correctly from the outset. This is achieved through three interrelated but distinct disciplines: Commissioning, Qualification, and Validation (CQV). Although these terms are often grouped together, each serves a different business purpose. Commissioning confirms that systems are built and operate correctly; Qualification demonstrates regulatory compliance; and Validation ensures consistent and reliable performance. Understanding these differences is crucial for managing risk, protecting quality, and successfully delivering projects, which ultimately results in measurable impact & value creation.

# PURPOSE

The primary purposes of CQV include:

- **Operational Reliability:** Systematically verifying that equipment is installed correctly and operates according to the owner's design specifications.
- **Risk Mitigation:** Identifying and fixing technical issues early in the project lifecycle to prevent costly downtime, equipment failures, or safety incidents later in production.
- **Efficiency and Performance:** Optimizing system performance to improve efficiency and reduce waste, which contributes to long-term cost savings.
- **Quality Consistency:** Ensuring manufacturing processes can repeatedly produce goods that meet internal quality standards, even when external regulations are not strictly applicable.
- **Project Handover:** Developing a structured "Turn-Over Package" (TOP) that contains all necessary documentation and training for operations teams to efficiently manage the timely startup of new or modified facilities.

# CORE PHASES

## 1. Commissioning (C)

**Objective:** Verify that systems are installed, integrated, and operate as designed.

- Confirms mechanical and functional readiness
- Identifies and resolves issues early
- Led primarily by engineering

**Outcome:** Systems are operational and ready for qualification

## 2. Qualification (Q)

**Objective:** Demonstrate that systems consistently perform according to predefined requirements.

- IQ – Installed correctly
- OQ – Operates within defined limits
- PQ – Performs effectively under real-world conditions

**Outcome:** Documented evidence of system performance and control

## 3. Validation (V)

**Objective:** Confirm that end-to-end processes reliably produce compliant outputs.

- Focuses on manufacturing processes, cleaning, and computerized systems
- Show that the systems perform reliably across different operators, packaging lots, and process variations.
- Lifecycle-based approach (not one-time testing)

**Outcome:** Processes are validated and defensible for regulatory inspection

# CQV PRINCIPLES

- **Risk-based:** Align efforts with product goals and business risks
- **Integrated:** Commissioning activities leveraged to reduce qualification effort
- **Lifecycle-oriented:** Maintained through change control and continued verification
- **Digitally enabled:** Use of electronic protocols, data integrity controls, and traceability

## BUSINESS VALUE

- Accelerates **time to market**
- Reduces **rework and cost**
- Improves **inspection readiness**
- Enables **scalable, compliant operations**

## CQV IMPLEMENTATION CHALLENGES

- **Late Integration into Projects:** CQV is often introduced too late, leading to rework, schedule delays, and higher costs. according to the owner's design specifications.
- **Unclear Ownership and Governance:** Misalignment between Engineering, Quality, Operations, and IT creates gaps in accountability and slows decision-making.
- **Poor Requirements Definition:** Incomplete or ambiguous user and regulatory requirements result in testing inefficiencies and inspection vulnerabilities.
- **Documentation Burden and Quality Issues:** Manual, paper-based processes increase effort, introduce errors, and reduce traceability.
- **Limited Leverage of Commissioning Data:** Failure to reuse commissioning activities for qualification leads to duplicated testing and wasted effort.
- **Change Management:** Late design changes or uncontrolled modifications disrupt validation status and extend project timelines.

## CQV IMPLEMENTATION CHALLENGES

- CQV ensures that critical systems and processes are engineered, tested, and maintained to consistently deliver compliant, high-quality outcomes while minimizing risk and maximizing operational efficiency.
- CQV challenges are rarely technical; they stem from **timing, governance, and execution discipline**. When addressed early with a risk-based, integrated approach, CQV becomes a schedule and risk enabler rather than a constraint.