

# Support & Services

## Qualification & Validation



### EXPERIENCE AND INNOVATION

The key to success is to integrate the concept of **Validation** right from the start of a project. This has led DCI-Biolafitte to the creation of a **Validation Guide**, which governs our products (fermentors, mixers, CIP units and other equipments used in the pharmaceutical and biotech industry) through every phase of their design, manufacture and installation. This validation approach is entirely based on our **Quality Assurance System**.

### INSTALLATION QUALIFICATIONS (IQ)

Equipment systems and subsystems undergo a static check and documents are compiled to demonstrate that system characteristics comply with predefined specifications and regulatory requirements.

The Construction and Inspection File is compiled as soon as the first manufacturing operations begin and follows the equipment up to its completion. This file undergoes final inspections before the equipment is released for first qualification tests.

### OPERATIONAL QUALIFICATION (OQ)

Equipment systems and subsystems undergo a dynamic check to ensure that they are in good working order and operate within the tolerance limits stipulated in the predefined specifications and customer requirements.

These tests are performed by a specialized team from DCI-Biolafitte and are designed to check the performance of all-different systems and automatic control components once they have been installed.

### PERFORMANCE QUALIFICATION

Dynamic tests are run to check that the equipment as a whole is capable of performing the process in a reproducible manner and that all critical parameters remain within tolerance limits.

DCI-Biolafitte provides the technical assistance to required to run off-load cycles on site (with the product replaced by a placebo) in order to reach the required performance levels and check the reproducibility of results.

### BENEFITS

The DCI-Biolafitte is built upon the ISO 9000 baseline. It applies to the entire organizational structure of the company of the company and encompasses all business activities.

The integration of Qualification operations into the Quality System is the original feature of DCI-Biolafitte's system. The stringent requirements applicable to design, construction and inspection methods have extended to the equipment qualification protocols, both for the preliminary test carried out in the factory and for the on-site tests performed before the beginning of industrial production.

In addition to this, total control of product traceability ensures that components, subassemblies and materials can be identified at all stages of fabrication and after the equipment has been delivered.

