

DESCRIPTION

extraktLAB offers the highest quality commissioning and training package on the market. The commissioning phase of the facility and equipment under cGMP regulation involves the verification that operations and facilities are working according to the specified design. The activity supports qualification efforts of the customer and gives them methods to verify that the equipment is suitable for the intended purpose.

Commissioning verifies the specifications for the equipment have been met and accepted by the customer.

Operational qualification of equipment takes place in two separate phases. The first phase is Factory Acceptance Testing that is typically conducted in conjunction with the customer to ensure the equipment is operating according to the manufacturers standards. Site acceptance testing is a verification of the factory acceptance test and often takes place after the equipment has been installed and verifies that nothing has changed since the equipment was tested at the factory.

Phase 1: Factory Acceptance Testing

Conducted in conjunction with the customer & ensures the equipment is operating according to the manufacturers standards.

Phase 2: Site Acceptance Testing

Verification of the factory acceptance test & often takes place after equipment installation. Verifies nothing has changed since the equipment was tested at the factory.



DELIVERABLES

Onsite Training

On Equipment with Operator Certification
On SOP Usage with Operator Certification

SOPs

SOPs for Operation of Equipment
SOPs for Cleaning
SOPs for Sampling
SOPs for Maintenance
FAT (Operational Qualification)
SAT (Installation Qualification)



Please Note: Product is training in specialized knowledge, with operator certification. Is sold per piece of equipment and does not include equipment cost, nor is it time to certify all operators onsite.

ADDITIONAL NOTES:

- GMP Equipment Commissioning & Training shall not exceed 3 days and is for one piece of equipment. If the commissioning and training exceeds this time frame, there will be additional costs per day of training.
- Additional training will be charged \$2,500 USD per day (Part #80-9614).
- Commissioning & Training is available for extraktLAB equipment only.
- The customer is responsible for preparing the site and all personnel in advance of training start.

 **extraktLAB**
SERVICES

Manufacturing Line Commissioning (GMP)
To Order: Part #80-9629

651-600-0036 | EXTRAKTLAB.COM
500 SIMMON DR. OSCEOLA, WI 54020

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www.unitedscience.com