RAYPA

QUALIFICATION SERVICES FOR TOP LINE AUTOCLAVES

IQ-OQ-PQ QUALIFICATION SERVICES FOR AUTOCLAVE OPERATION AND IQ-OQ QUALIFICATION SERVICES FOR FDA/GMP COMPLIANCE OF THE CONTROLLER AND THE EXTERNAL MANAGEMENT PLATFORM DESIGNED FOR THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRY

Qualification services for Top line autoclaves

APPLICATIONS

+ **Produce documentary evidence certifying that the installation and operational performance of the autoclave present an optimal standards, and that all safety systems comply with the necessary regulatory requirements.**

+ **Produce documentary evidence certifying that the management of electronic records from the autoclave microprocessor, as well as the external management platform, comply with FDA and GMP standards.**

QUALIFICATION OPTIONS

The qualification of Top Line autoclaves encompasses two main elements: the functional performance of the autoclave itself and the management of electronic records within its software. Generally, a qualification service is contracted to ensure compliance with specific regulations, such as ISO 17665, which regulates sterilization processes, and/or FDA Title 21 CFR Part 11, which sets requirements for the management of electronic records and signatures in the pharmaceutical industry.

We provide two methods for performing the qualification of our equipment:

- **Comprehensive qualification executed by RAYPA:** our team of skilled technicians, or authorized entities, manage the entire qualification process. This service may include the commissioning of equipment, qualification of autoclave operation, and software qualification, accompanied by the generation of all necessary documentation. Each phase will be conducted to ensure full compliance with stringent quality standards and regulatory requirements.

- **Third-party qualification:** Alternatively, we can provide comprehensive documentation and protocols, enabling independent qualification entities, either internal or external to the client, to conduct the qualification process for our equipment. This option offers clients the flexibility to collaborate with a trusted agency for qualification services.

Both options are tailored to meet the specific needs of each customer, ensuring that their equipment not only meets regulatory standards but also operates efficiently and safely.

STAGES OF QUALIFICATION

- **IQ:** Installation Qualification involves determining whether the supplied unit complies with the manufacturer's specifications. It is the preliminary step to carry out a successful operational qualification. Maintenance, cleaning and calibration procedures, usually referred to as Standard Operating Procedures (SOPs), may be part of the IQ.

- **OQ:** Operational Qualification is crucial for establishing a reliable sterilization process. This stage involves testing to confirm the autoclave operates consistently within set parameters, producing reproducible results. Any deviations are identified and addressed by engineers.

- **PQ:** Performance Qualification is the third and final stage in the qualification process of an autoclave. This phase involves verifying and documenting that the autoclave is operating consistently and repeatably in a specific application. PQ tests, conducted over a specific period of time and under normal operating conditions, include simulations of actual production using the same materials, procedures and controls that will be used in daily production. Engineers address any deviations detected during this period to ensure ongoing reliability.

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AUTOCLAVE QUALIFICATION

To ensure that your autoclave operates at optimal performance and maximum safety, it is essential that it complies with the most stringent standards and current regulations. Autoclave qualification is particularly recommended for laboratories that must adhere to ISO 17665, a standard that sets the requirements for the safe and effective sterilization of healthcare products using moist heat processes. Compliance with this standard not only ensures the efficacy of sterilization cycles but also preserves product integrity and guarantees end-user protection.

We provide two methods for performing the operational qualification of our autoclaves:

- **Comprehensive qualification (IQ-OQ-PQ-TLV):** this comprehensive qualification service covers installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). The service is provided by RAYPA or an authorized commercial partner, ensuring that your equipment meets the highest standards of performance and safety.
- **Third-party qualification (IQ-OQ DOC-TLV):** this service is recommended for laboratories that prefer to manage autoclave qualification in-house or through a trusted external company. This package includes all documentation and protocols, and can be purchased either by laboratory managers or by external suppliers specialized in providing autoclave calibration and qualification services.

SOFTWARE QUALIFICATION

The qualification of software is essential for customers who must comply with FDA Title 21 CFR Part 11 regulations and/or Annex 11 of the Good Manufacturing Practices (GMP) of the European Union, which set standards for electronic record storage, electronic signatures, and the management of computerized systems.

Compliance with these regulations ensures data integrity, security and reliability, preventing risks that could compromise product quality or safety. Through software qualification, system failures can be identified and corrected, ensuring that the software consistently performs according to its specifications. This process is also critical for passing audits and obtaining regulatory certifications, supporting traceability and transparency throughout the software lifecycle.

In this context, we provide two distinct software qualification services:

- **Qualification of the controller software**
- **Qualification of the management platform**

In both cases, the documentation we provide includes the following sections:

- **Validation Plan (VP):** outlines the scope, approach, resources, and schedule for the qualification process.
- **User Requirements Specification (URS):** details the specific needs and expectations for the autoclave or software performance.
- **Risk Assessment (RA):** identifies potential risks in the system or process and assesses their impact on safety, quality, and compliance.
- **Installation Qualification (IQ):** verifies that the installation complies with the manufacturer's specifications and setup requirements.
- **Operational Qualification (OQ):** confirms that the system operates consistently within established parameters.
- **Installation and Operational Qualification Report (IOQR):** summarizes and documents the results of the IQ and OQ phases, providing evidence of compliance with specified standards and requirements.

This comprehensive documentation ensures traceability, supports audit processes, and confirms that the equipment or software operates in compliance with the regulatory requirements set forth in FDA Title 21 CFR Part 11.

Qualification services for Top line autoclaves

Qualification of the controller software

Service to validate that the information managed by the autoclave microprocessor complies with the requirements of FDA Title 21 CFR Part 11.

This software qualification service is compatible with the following digital quality management modalities. For more information on the available modalities, please refer to our dedicated document, accessible in the box below.

- **Private standard:** modality that installs the RAYPAcloud management platform on a local private server, which guarantees an absolute privacy and security, while enabling a centralized management. Access to the management platform is performed via a local area network. The server where the software is hosted may be provided by the customer or supplied by RAYPA. Modality recommended for clients in the pharmaceutical, biotechnology, cosmetics, and food industries working under FDA and GMP-regulated environments.

- **Cloud-comply:** modality in which data is stored both in cloud of AWS (located in EU or USA) and in the equipment controller. This configuration allows online access to the management platform from any device with internet access. The management of data by the controller strictly complies with FDA 21 CFR Part 11, but data storage in the cloud does not fully comply. This solution is ideal for customers who need a private, FDA-compliant system but also prioritize access to advanced connectivity, remote management, and remote diagnostics features.

- **Essential-comply:** modality in which data is stored exclusively on the autoclave controller. The management of data by the controller complies with the standards of FDA Title 21 CFR Part 11. Modality recommended for customers who need to comply with FDA standards but do not want the benefits of integrating our external management platform in their workflows (centralized management, remote access, automatic backups, etc.).

We provide two methods for performing the qualification of the controller software:

- **Comprehensive qualification (IQ-OQ SW/VAL):** comprehensive IQ/OQ SW/VAL qualification is performed by us or our authorized commercial partners, covering all documentation and including the execution of both the installation protocol (IQ) and the operation protocol (OQ). This service provides documentary evidence that the equipment, along with its control systems and software, performs optimally and according to the required standards.

- **Third-party qualification (IQ-OQ DOC-SW):** this service provides the necessary documentation to carry out the installation and operational qualification of the controller software. This service may be of particular interest to clients who conduct software qualifications internally or outsource software qualification to trusted external companies.

Qualification of the management platform

Service to validate that the information managed by the external management platform (RAYPAcloud) installed on a private server complies with the requirements of FDA Title 21 CFR Part 11.

This software qualification service is compatible with the following digital quality management modality. For more information on the available modalities, please refer to our dedicated document, accessible in the box below.

- **Private standard:** modality that installs the RAYPAcloud management platform on a local private server, which guarantees an absolute privacy and security, while enabling a centralized management. Access to the management platform is performed via a local area network. The server where the software is hosted may be provided by the customer or supplied by RAYPA. Modality recommended for clients in the pharmaceutical, biotechnology, cosmetics, and food industries working under FDA and GMP-regulated environments.

We provide two methods for performing the qualification of the management platform:

- **Comprehensive qualification (IQ-OQ SW/VAL-CLOUD):** comprehensive software qualification service provided by us or our authorized commercial partners, covering all documentation and including the execution of both the installation protocol (IQ) and the operation protocol (OQ). This service ensures that the equipment, along with its control systems and software, operates optimally and according to the required safety standards.

- **Third-party qualification (IQ-OQ DOC-CLOUD):** this service provides the necessary documentation to perform the installation and operation qualification of the management platform.This service may be of particular interest to clients who conduct software qualifications internally or outsource software qualification to trusted external companies.

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