SINGLE USE SUPPORT.

PIONEERING BIOPHARMA

Qualification & Validation

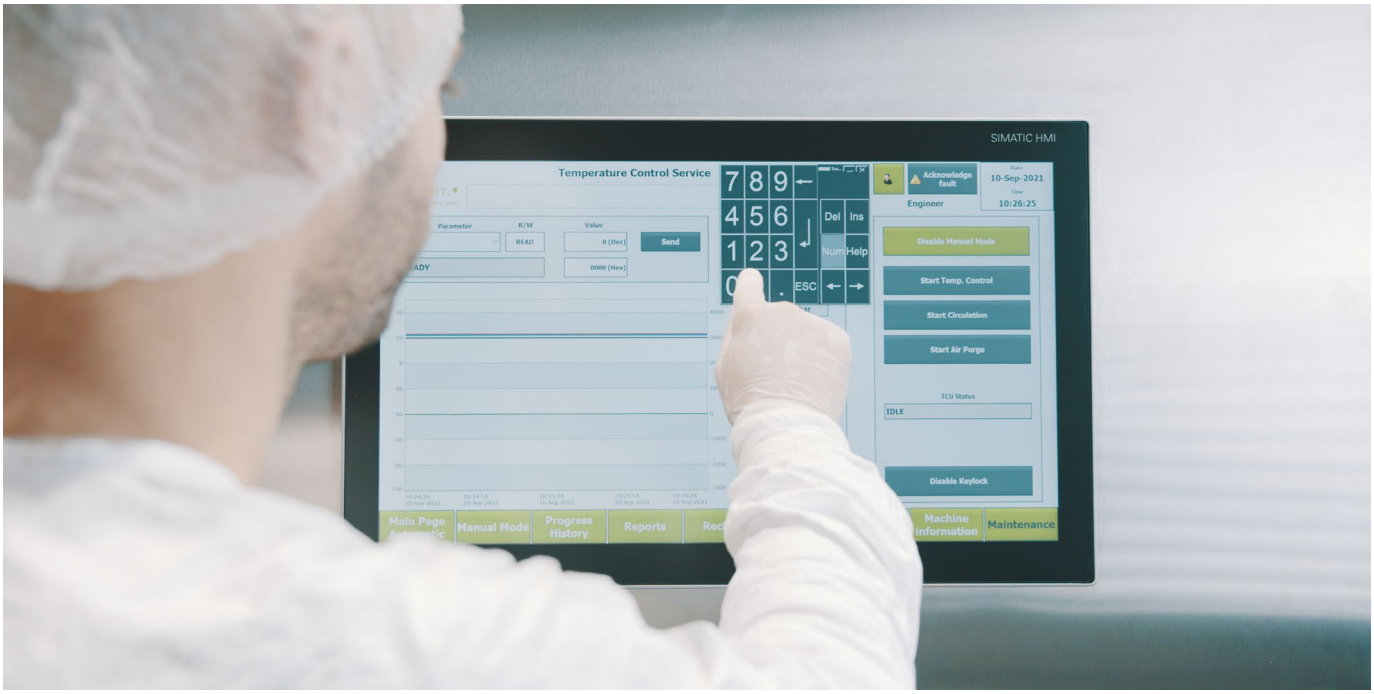
FAQ Sheet

Does Single Use Support have a quality system and standard qualification procedures?

As an ISO-certified company, Single Use Support has introduced a qualification procedure to verify that the employed manufacturing system is fit for its intended use and has been properly built and installed in order to ensure correct operation.
Single use Support strives to offer a time-saving, cost-effective and value-adding ISO 9001:2015 implementation process for GMP manufacturing systems. Thus, Single Use Support fully supports risk-based approaches where the verification level and extent are based on scientifically assessed risks that specific processes, equipment or systems might pose to either the pharmaceutical product or the patient. The test results, which are documented by Single Use Support, may be fully leveraged by the customer.

Are Single Use Support's computerized filling and freezing/thawing systems compliant with the 21 CFR Part 11 requirements?

21 CFR part 11 contains the US FDA's regulations on electronic records and electronic signatures (ERES) resulting in a set of technical and procedural controls for data protection. All critical functionalities required for data integrity assurance are integrated in our computer-based systems, such as RoSS.FILL and RoSS.pFTU. Moreover, we offer customer-specific configuration options regarding access control, system security, user management, data storage and backup strategies.



Which principles will be applied when developing and validating the systems?

We follow the most current **“Good Automated Manufacturing practice”** (GAMP5) guide. Additionally, we qualify our systems in accordance with applicable EU GMP** (European Good Manufacturing Practice) and US-FDA CFR (Code of Federal Regulations by the FDA) regulations. Further customer- or country-specific requirements will be considered on request.

Is it possible to do only part of the qualification? Or is it possible to hand over the entire qualification process to Single Use Support?

In case you appoint Single Use Support to take care of the entire qualification/validation process, Single Use Support is capable and experienced in doing so.
The project quality plan helps define responsibilities, mutual expectations, the timeframe as well as level of services prior to the project’s initiation.

What does the standard qualification process of Single Use Support look like? (high-level description)

In order to ensure adequate support during the early stages of the planning phase, Single Use Support provides its customers with URS templates.

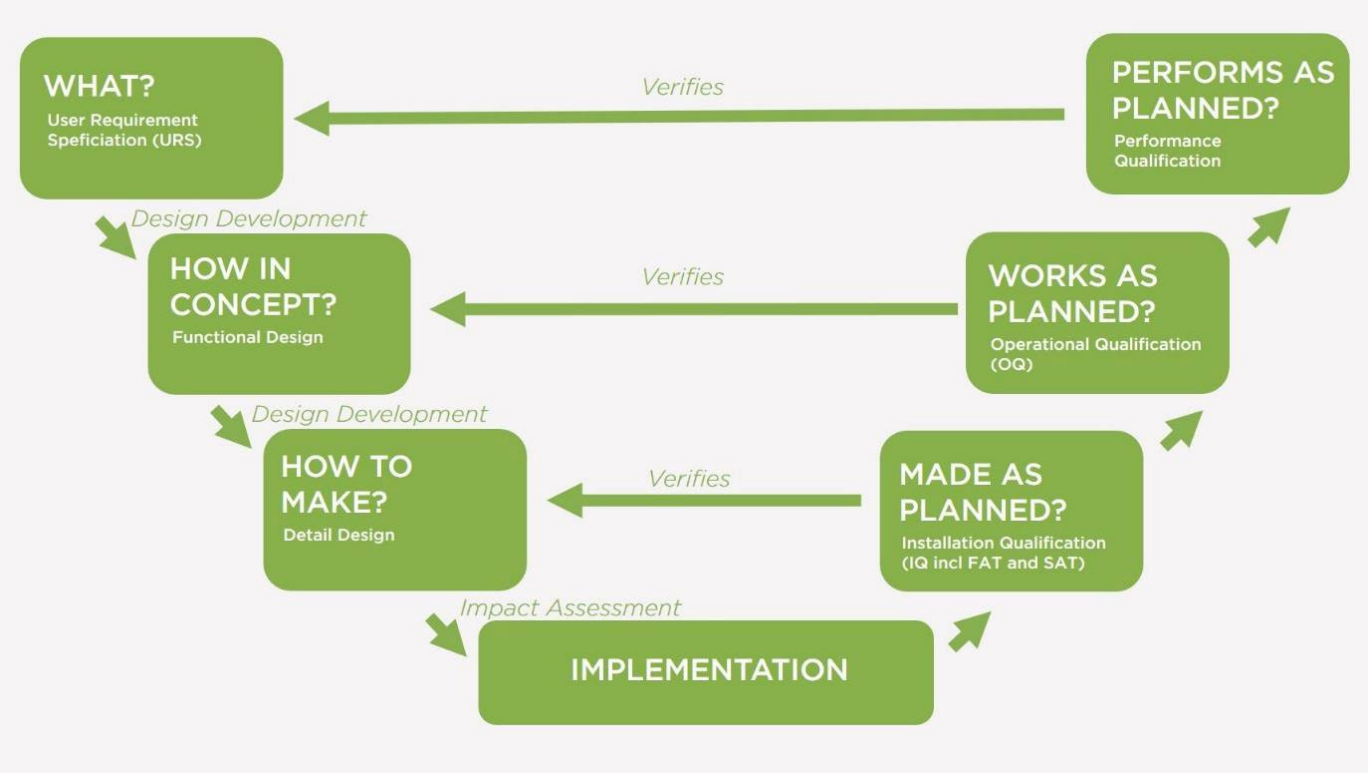
- The **URS** defines what the customer requires the system to do with regards to e.g. operation, function, performance, data integrity, environment, and security. It constitutes the basis for the entire risk-based qualification process.

- Specifications like **FS, HDS, SDS** document the system’s functionality and design and describe how defined requirements regarding hardware, software, and configuration are met.

- A functional **risk assessment** with a focus on the system’s critical aspects is performed to identify and manage risks with regards to patient safety, product quality, data integrity and process safety that may be the consequence of functionality failures. RA benefits are: a better understanding of potential risks, proposed controls and the business process as well as improved scaling of life-cycle activities and deliverables according to system impact and risk.

- **FAT** is performed at Single Use Support prior to delivery in order to verify that the system is fit for implementation and testing on-site at the customer's premises. **SAT** demonstrates that the system is working in its designated operational environment and interfaces correctly with other systems and peripherals. Scope and extent have been defined during risk assessment and focus on critical technical and functional aspects. **IQ/OQ** aims to verify and document that system components are combined and installed in accordance with specifications, and that a system operates as intended.

Our experts will of course be available to further support customers with regards to system maintenance or performance qualification testing.



What is the difference between FAT/SAT and ICQ?

FAT/SAT	ICQ
FAT is performed at Single Use Support's premises prior to delivery in order to verify that the system ready to be installed and tested on-site at the customer's premises.	ICQ covers configuration testing and functional testing with regards to customer configuration and operational requirements (eg. scalability), also including detailed CFR part 11 testing.
SAT demonstrates that the system is working in its designated operational environment and interfaces correctly with other systems and peripherals.	The aim of the IOQ: all customer-specific aspects and quality compliance requirements are covered, so that the system can subsequently be released for operational use in a GMP environment.
FAT and SAT focus on critical technical and function aspects from the manufacturers point of view, which means that the system was build and is working as intended.	

Single Use Support offers its customers a combined IQ/OQ package on an optional basis. The ICQ complements FAT/SAT as a complete "quality carefree package" so that our customers benefit from our technical knowledge and expertise. You do not need to worry about additional risk evaluations, gap assessments or test plan creation!

How is the testing strategy developed?

A functional risk assessment is performed to focus on the system's critical aspects concerning patient safety, product quality, data integrity, and process safety. The RA's aim is to reduce the combination of severity (possible consequences), probability of occurrence, and detectability of failures to an acceptable level.
Thus, the RA's result determines the extent and depth of testing/verification.

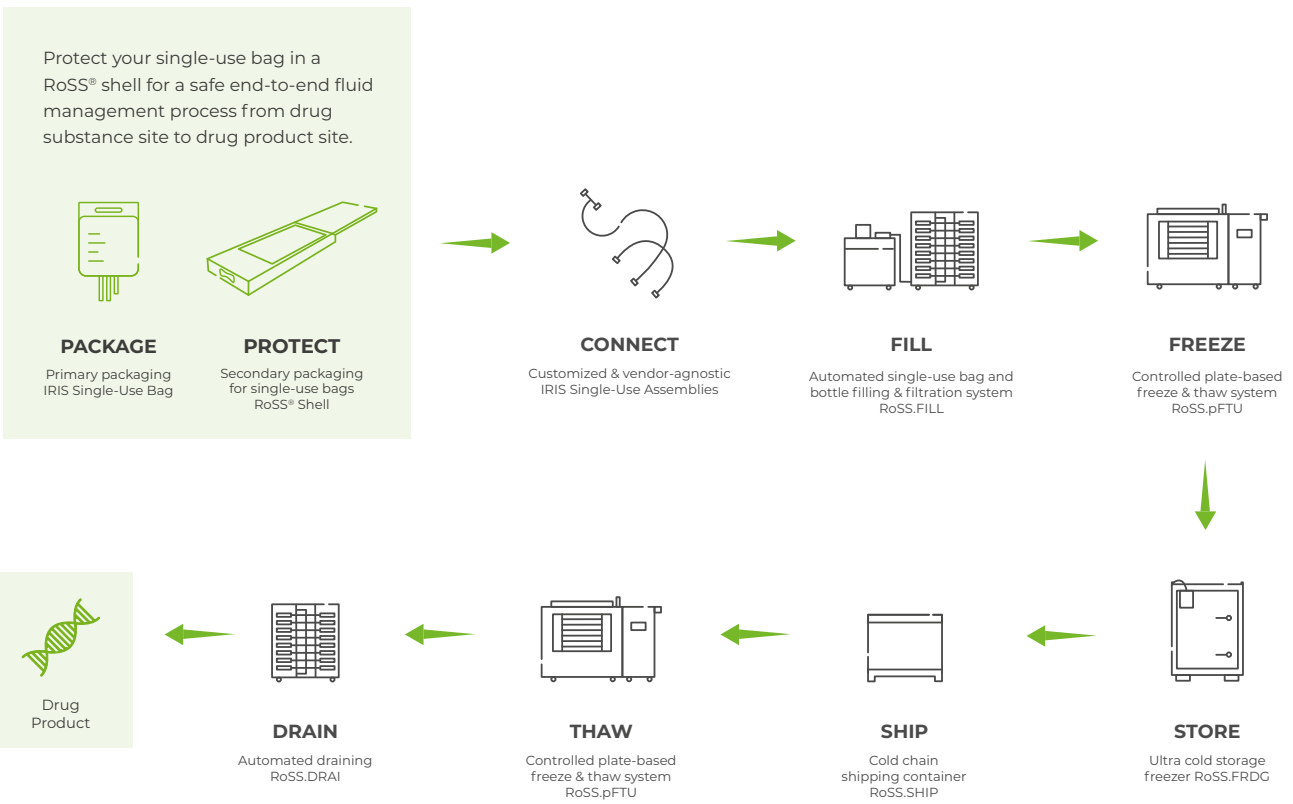
Who can help us draft a URS in case we are interested in a computer-based system?

Single Use Support offers upfront consultancy and can draft a URS for the customer that fulfills all customer requirements. In most cases, the URS is compiled in collaboration with the customer.

Do you also assist with maintenance and troubleshooting?

Certainly! We offer different service level agreements that include services such as regular maintenance and troubleshooting availability. The service level Will be defined based on our customers' requirements and needs.

Single Use Support assists you from beginning to end, offering highly qualified support all along the way. Contact us for further details!



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