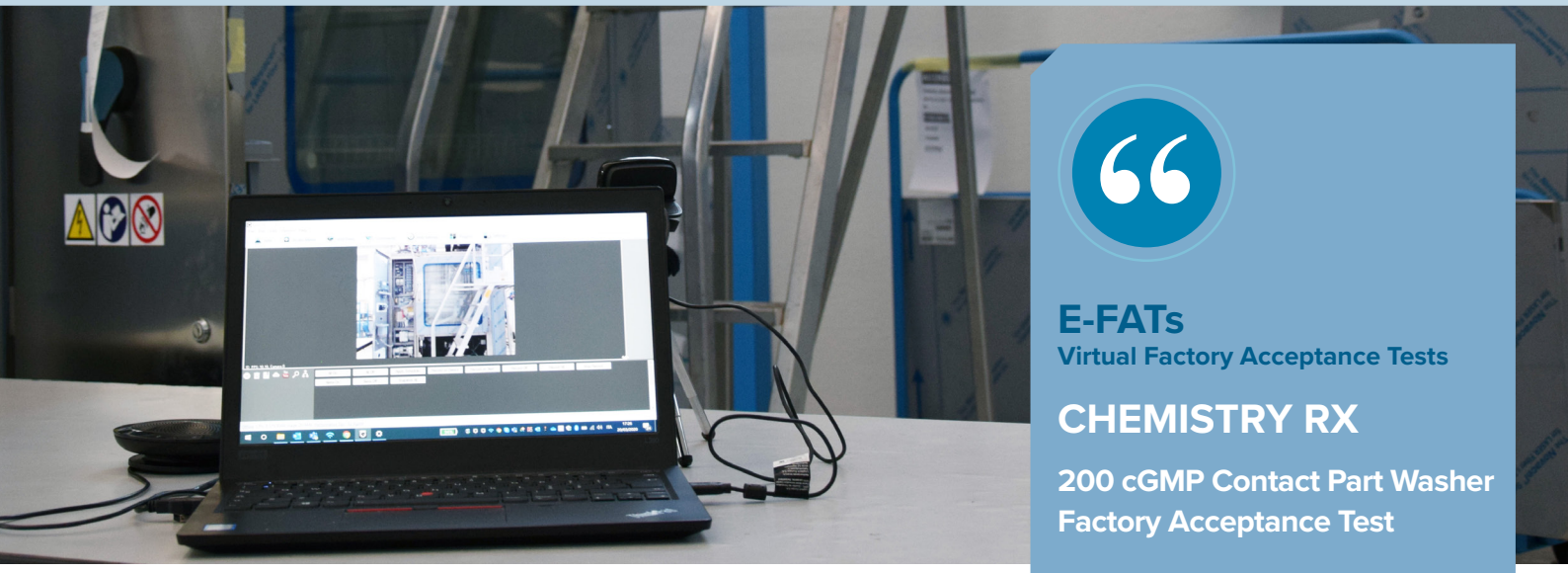


E-FATs
Virtual Factory Acceptance Tests

CHEMISTRY RX

200 cGMP Contact Part Washer Factory Acceptance Test

Interview with

Savita Mehra, Director of Quality Assurance
Saji Jacob, Ace Validation Consulting

CHEMISTRY RX

As the name suggests, FAT - Factory Acceptance Test - is generally performed at the manufacturer's site. During a factory visit, customers verify that the equipment is built and operating in accordance with URS and design specifications, and meets relevant Good Manufacturing and Engineering Practices. This is the first step of formal acceptance from a contractual point of view, therefore it goes without saying that under no circumstances should this step of the equipment qualification process be missed.

When travelling is not possible for different reasons (lack of time; cost constraints; travel restrictions, etc), an E-FAT process is the perfect solution. At IWT, E-FATs have been a consolidated practice for many years and now "Remote FAT's" are integrated into our service offering.

FAT: DEFINITION AND SCOPE

The FAT – Factory Acceptance Test – is one of the most important steps of the qualification of a new piece of equipment, recently procured but not yet delivered to the customer site.

The FAT is mentioned in the EUdraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 15: Qualification and Validation, in the FDA Process Validation guide, FDA 21CFR Parts 11/210/211, as well as in other industry guidelines released by ICQ and the ISPE Baseline Guide, Volume 5-Commissioning and Qualification. According to the Annex 15 of the EU GMP:

Factory acceptance testing (FAT) /Site acceptance testing (SAT)

3.4. Equipment, especially if incorporating novel or complex technology, may be evaluated, if applicable, at the vendor prior to delivery.

3.5. Prior to installation, equipment should be confirmed to comply with the URS/ functional specification at the vendor site, if applicable.

3.6. Where appropriate and justified, documentation review and some tests could be performed at the FAT or other stages without the need to repeat on site at IQ/OQ if it can be shown that the functionality is not affected by the transport and installation.

3.7. FAT may be supplemented by the execution of a SAT following the receipt of equipment at the manufacturing site.

Source: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2015-10_annex15.pdf

Part of the requirements listed in a client's URS, a binding document, the **FAT & SAT are fundamental steps.** Not only are these critical for the technical verification of the equipment, but also in its compliance to the client URS requirements. Executing these verifications prior to the unit leaving the factory is fundamental should corrective actions be required, which is why the FAT assumes a key role in the validation process.

Following a deeper analysis of the current Annex 15, points 3.6 and 3.7 above, it is clear that **the tests performed during FAT & SAT, if exhaustive and formally documented, can be referenced in the IQ / OQ activities without the need to be repeated, resulting in a leaner and faster site qualification process.**

Beside formalities and compliance with the guidelines, it is important to note that **the FAT represent the first time the customer sees the equipment fully assembled and operational** after months of documentary and design work. This first verification step of an "idea" listed in the URS that becomes "reality" allows mistakes and misunderstandings to be cleared up.

The machine is still at the supplier's site, so any modifications can be done with minimal impact on project times and costs. At the completion of the FAT, the green light to ship the equipment is given. **This is the first step of formal acceptance from a contractual point of view,** and usually represents a contractual milestone.

Therefore, it goes without saying that under no circumstances should this step of the equipment qualification process be missed. As there are often some customer constraints, different solutions can be offered by the vendor to allow the customer to attend the FAT, either at the manufacturer site or remotely.

In recent years, travelling has been straightforward, so visiting the vendor site for the FAT offers an opportunity for the customer's representatives to see the factory and assess the manufacturing steps, including (but not limited to) processes for welding and material traceability, etc., as well as familiarize themselves with the technicians and the project teams.

When travelling is not possible for different reasons (lack of time; cost contrains; travel restrictions, etc), an E-FAT process is the perfect solution. Thanks to the latest technologies, such as remote access via web based platforms, the customers can witness the different tests required by the protocol, as well as interact from a distance, asking questions and getting explanations, through the final review meeting.

Remote FAT is a smart alternative that simplifies the process, reducing the time required for staff to be away from the office and the associated costs including: travel, accommodation, visa application etc.

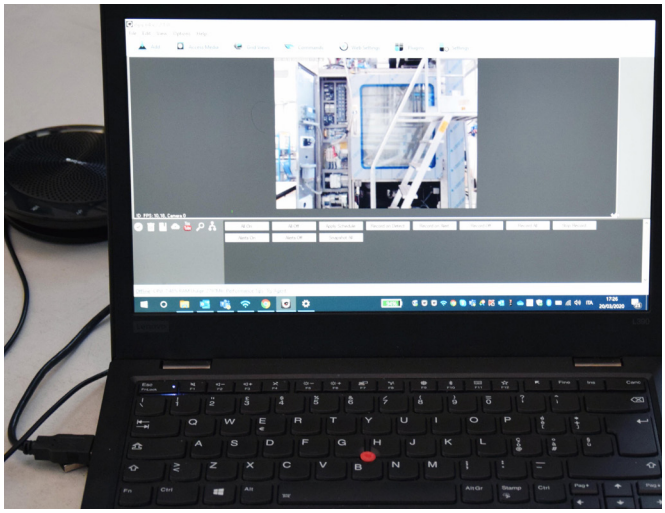
E-FAT: HOW IS IT PERFORMED?

E-FAT is based on a unified communication and collaboration digital workspace that combines chats, real-time meetings, videos and screen sharing, as well as files storage.

By using a combination of different high-quality webcams (at least a static one, placed in front of the equipment, and a mobile one, allowing to shift the focus to different components), managed through a software normally intended for video surveillance purposes, clients can effectively enjoy the same opportunities and that sort of all-inclusive approach that they could experience travelling to IWT.

Some of the softwares and web-apps in use:

Skype Microsoft Teams iSpy Connect



To properly run an e-FAT, we organize the activity in different steps.

- Before the FAT execution, we share with the customer the FAT protocol: it's the starting document, which describes the agreed tests that we'll perform during the FAT day(s).

- Then, a couple of days before the FAT, we organize a 30-minute web call to share the documents we are going to use during the FAT. These documents include the User and Maintenance manual, the PID, the pneumatic diagram, the wiring diagram, the layout, etc. During the call we take the opportunity to introduce the actors of the FAT, to know each other's and define the goals of the next days.

- The day(s) of the FAT we start the activity at IWT in front of the machine(s): usually static tests (such as documentation checks/correspondence between the machine and the PID/wiring diagram) are performed autonomously, while functional tests (such as the washing challenge test - riboflavin, safety checks and alarms tests) are performed "live". During this phase the interaction among participants is very high: at IWT site, the Service engineer together with the Validation Manager and the Project manager run the machine and perform the tests on the basis of the indications received by the client. At the same time, the client witnesses all the activities asking for explanations, further details, possibility of viewing a message on the touch screen or the water at the drain during the washing cycle, etc. The FAT protocol is filled in as tests are performed: at the end of the live remote FAT, all the documentation is shared with the customer for review.

- Finally, one or two days after the e-FAT, a closure meeting is scheduled: the customer expresses all his comments on the shared documentation and eventually approves it.

Through the years, IWT has performed several e-FATs following this methodology, always with excellent feedbacks.

ABOUT THE CLIENT: CHEMISTRY RX

Chemistry Rx is a 503A Compounding Pharmacy.
They provide therapies based off of prescriber prescription for individual patients, all non-sterile.
Currently they are building a new site to expand their business. Future business for the new facilities outsourcing side will include sterile compounding with the customer base relying on hospitals, pharmacies, and physician groups.

Luca Fumagalli, IWT Area Manager, comments:
The customer needed to automate the cleaning process in order to easily meet regulatory compliance, as well as reduce as much as possible both downtime for changeover and quality assurance tests.
Thanks to the high flexibility of IWT 200, the final tailor-made configuration of the washer was achieved by combining different features.
Loading baskets to process all the change parts from process equipment were developed on purpose taking into consideration the different batches of parts.
The parts to clean are mainly from filling lines installed in classified environments for the primary packaging of:
- *Vials*
- *Pre-filled syringes*
- *Creams*
- *Lotions.*

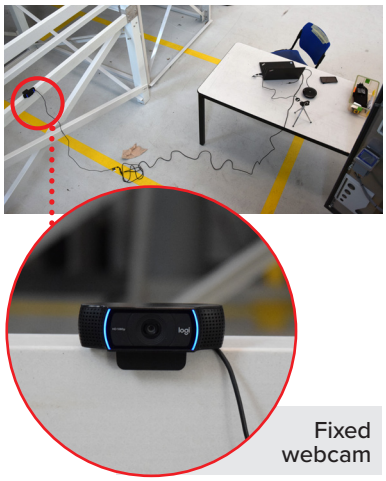
CLIENT'S FEEDBACKS

What specific concerns did you have with the virtual FAT compared to attending in person? Were these concerns resolved?

Savita Mehra - One of my concerns was related to the legibility of some screenshots from the HMI panel.

> **Gabriele Bardelli**, IWT Installation & Validation Manager, comments:
> *Validation activities are still pretty much based on physical presence of the stakeholder.* ***The interesting challenge when performing e-FATs is therefore being able to re-create "live" conditions, both in terms of visibility and approach****.*
> *To do so* ***we decided to steer in the direction of giving a remote supervision****: we selected a software that is normally intended for video surveillance, this allowed to have a comprehensive vision of multiple webcams and the possibility to select the most suitable camera. For the time being we have been using 2 different high-quality webcams, one (fixed) with an "eagle-eye view" placed in front of the machine at an high altitude, plus a second one connected to the computer through a 5 meter long cable that allowed movements all around the machine (on the HMI, inside the chamber, on the top of the equipment). We are now also implementing a third camera that, worn on the chest of the engineer working on the machine , will give the POV visual in almost every condition of light.*

Mobile webcam



Fixed webcam

Saji Jacob - The biggest advantage of an FAT, outside of testing functionality, is to get familiar with the equipment, its operations and bounce questions with technical folks at the factory. Video conference helped address this to some extent.

Did you consider the possibility of putting your project on hold, until you were notified IWT could perform a Virtual FAT?

SM - I have personally used this format in the past and suggested it as soon as the current HEALTH issue arose in ITALY otherwise yes, this project would have been delayed.

Saji Jacob - Not to my knowledge.

> **Rich Brunetti,** STEQ America Project Manager, comments:
> *With the current situation rapidly developing, I need to consider all options available for the customer and their impact on the overall project. The FAT is a critical component of the project and IWT's ability to perform a Virtual FAT gave ChemistryRX a viable solution to keep the project on track.*

Considering past experiences, how would you compare this virtual FAT with an onsite FAT at supplier location?

SM - Onsite FAT provides a more holistic approach of the organization's culture, practices, understanding the quality system in depth, plus gives the customer an opportunity to develop relationship with the supplier(s).

> **"IWT team was thorough in explaining every aspect of the FAT. Companies need good communicators and competent staff like IWT one to do an outstanding job!"**

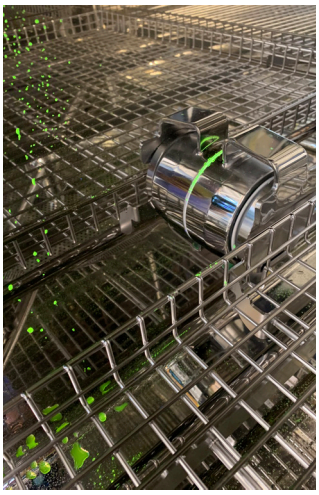
SJ - I would think this is a big step in the right direction in making FATs online. However complex equipment with HMI and multiple functions/sequences, would benefit from an onsite FAT. Possible to perform a detail online FAT with a short onsite FAT to address training and operational needs.

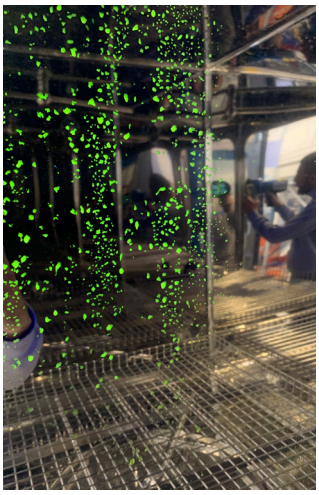
Which tests and checks were you able to perform? Is there anything specific you have been impressed with and/or anything you think it might be improved?

SM - I was impressed with the Riboflavin test.

SJ - Riboflavin test was a good accomplishment to see coverage.

Alessandra Fervorini, IWT Project Manager, comments:
Using a combination of different cameras, customers can effectively witness the preparation of the solution, the spraying of the riboflavin inside the chamber, a detailed view of the chamber before and after the cycle with a particular overview to the critical areas and a view of the HMI throughout the cycle.





Would you suggest this validation method to other institutions, and would you consider repeating this process in the future, even it was not required by the current condition with COVID-19?

SM - Yes, as it saves travel cost.

> **“ This format is definitely acceptable provided the preparation is thorough, with robust validation protocols approved by the customer and the end result meets the Design Specifications along with good documentation provided to the customer upon completion. ”**

Considering that the virtual FAT was a different approach than originally planned, did you ultimately realize the benefit of time and financial resources saved by agreeing to a virtual FAT?

SM - Absolutely, I as mentioned above I suggested this format since the time I was asked to visit IWT.

SJ - Yes.

Would you consider a virtual FAT as a way to involve a larger team of people during a future FAT with a mix of physical and virtual presence?

SM - That would certainly enhance the process.

> **“ Overall, I felt the IWT team did an outstanding job of facilitating an on-line FAT. They had multiple cameras looking into the machine and was keen to point out how the system works and was setup.**
> **IWT Project Managers, did an outstanding job, under these difficult times with travel restrictions due to the pandemic, to explain tests, acceptance criteria, setup and results, as we witnessed key washer functions and tests remotely. Thank you to the IWT and STEQ America team for an outstanding job! ”**

Rich Brunetti, comments:
The e-FAT has exceeded my expectations. Moving forward this can be an efficient and inexpensive method to supplement a customer's on-site presence at an FAT. The potential to involve more members of the quality team in the process may help to leverage FAT testing and result in streamlining on-site requirements.