

SUCCESSFUL INTEGRATION OF XILTRIX IN THE ERASMUS MC ATMP LABORATORY



Customer: Anouk van Dapperen

Company: Erasmus MC, Rotterdam

Industry: Pharmacy, ATMP Lab

Video: N/A

Solution: XiltriX Clean Room Monitoring and Alarm System

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Over the period of 2019 to 2021 the Erasmus MC in Rotterdam built and validated a new Advanced Therapy Medicinal Products (ATMP) Laboratory. This facility boasts 4 fully equipped clean rooms which are qualified for handling of ML-1 and ML-II level genetically modified organisms. The quality system used is GMP compliant, which means the lab has to prove it is continuously in control on all levels. Parts of this quality system is the monitoring of temperatures, CO₂, humidity, differential pressure and particle counting (Environmental Monitoring System). XiltriX was chosen as the system to provide the real-time monitoring and alarm services. (Source: <https://www.erasmusmc.nl/en/research/facilities/atmp>)

The Story of the Erasmus MC Pharmacy

The Pharmacy department of the Erasmus MC is one of the largest departments of the hospital,

employing over 300 staff which work in different groups. Some groups work in the back office in medicine production and preparation, clinical trials and pharmacology- and toxicology lab. Others in the front office provide medications and handle logistic throughout the hospital. As a teaching hospital the Pharmacy department also has an advanced training program.

Having worked in the Erasmus MC Pharmacy for over 6 years, Ms. van Dapperen has gained experience in the production of medication, as well as guiding Medical Trials. In recent years she has become responsible for Quality Assurance which touches all parts of the Pharmacy. The XiltriX system has already

been used for 15 years in the Erasmus MC Pharmacy, the challenge now was to perfectly integrate it in the new ATMP laboratory that needed to adhere to the highest accreditation and quality standards in this field.

Challenges overcome during implementation

In the process of building the new ATMP laboratory a large number of people were involved. There was a lot of pressure on the project to be completed in time. A major challenge in this process was the communication between all the stakeholders was done on time to synchronize expectations on all levels. **Ms. Van Dapperen commented:** *“Even though we had a very experienced team working on this project from both the Erasmus side as the XiltriX side, correct and timely communication was a constant challenge. By leveraging the experience of the XiltriX team in close cooperation with the Erasmus team, all technical and planning challenges were eventually successfully overcome.”*

During the construction and validation phase of the ATMP laboratory, not all systems were working according to specifications directly. Because of the increased number of alarms there was a risk of alarm fatigue which would lessen the response in case of an actual critical alarm. Making sure no alarm goes unnoticed was imperative for the department. Setting up a fine-grained alarm cascade was a prerequisite for the Pharmacy, but this is not an easy task.

Ms. Van Dapperen noted: *“Making sure alarms limits and SMS programs were set up and handled correctly took quite a bit of time. We needed to make*



sure SMS messages are sent to the correct cascade of people at all times. The help of Mr. Pascal van Elzakker (XiltriX Functional Administrator of Erasmus MC) was invaluable in this process.”

Aside from the ATMP lab construction, the XiltriX system needed to integrate with the Erasmus MC IT infrastructure. This is a team with different competences and different accreditations. Where IT staff worries most about IT security and data integrity on an IT level, the Pharmacy needs to worry about a whole different set of accreditations. The GMP and FDA 21 CFR part 11 regulations do specify the setup and qualification processes of electronic data acquisition systems. These regulations are mostly not known or understood by the IT department.

Ms. Van Dapperen said: *“In the validation process I could guarantee if all GMP elements were met in the XiltriX IQ and OQ documentation. The help of XiltriX though in translating IT requirements and GMP requirements into one manageable validation approach that would tick all the boxes was of great value to our department.”*



Why Erasmus MC Pharmacy Chose XiltriX

The XiltriX system in Erasmus MC has been rolled out campus wide in dozens of departments. The system was already in use in different parts of the Pharmacy for many years. XiltriX is able to provide a real-time monitoring of all critical parameters in equipment and other environments with compliance to all relevant national and international standards. Even capable of digitally integrating particle counters, XiltriX can be used in laboratories having to adhere to the strictest accreditation standards. **Ms. Van Dapperen commented:** *“XiltriX International has been a partner for our monitoring and alarm solution for many years. In a continually changing organization like the Erasmus*

MC and always changing regulations the partnership with XiltriX is a prerequisite for success.”

How Erasmus MC uses XiltriX

XiltriX is used by the Pharmacy throughout the department. This means multiple hundreds of sensors need to be managed by dozens of people. The Erasmus MC has created a Functional Administration Department that is responsible for XiltriX Management. By their own calculations the combined stored samples & medication value in the whole of the Erasmus MC exceeds 10 Billion Euros. Making sure alarms are sent out correctly, understood and acknowledged correctly is imperative to prevent damage from occurring. **Ms. Van Dapperen said:** *“When an alarm event would be missed the financial damage could run into hundreds of thousands of Euros, let alone the risk of patient safety. XiltriX gives me the tools to create a KPI that allows me to track the response times of users. The Pharmacy has created a program of continuous improvement in which users are trained and guided in how to use systems like XiltriX most effectively.”*

Handling alarms in departments like the Pharmacy correctly is not easy for a user. When a pressure alarm is activated, a user is notified. This user is not always able to determine immediately if the alarm is caused by a door left open or a technical issue with the HVAC system. With a growing number of technically complex measurements the gap between technology and staff knowledge is growing. **Han Weerdesteyn CCO of XiltriX commented:** *“The information gained with*





project like this shows that the combined knowledge and experience of the XiltriX team is beneficial to customers like the Erasmus MC Hospital. Working closely with the different stake holders, XiltriX is designing training programs to transfer this knowledge onto the teams at customer sites. This way XiltriX usage can be optimized resulting in time and costs savings and reducing risk.”

The Results

After months of testing and validation, the ATMP lab is almost ready for operation, putting the Erasmus MC at the forefront of Advanced Medicine Development. The system for regulating for example the room pressure and the system for monitoring are separate. The Pharmacy organization has created a compliant and manageable operation in which there is proper accountability for critical measurements supported by a SafetyNet in case primary alarms are somehow missed.

This is by no means the end of the road, it is merely the beginning. Fine-tuning the operations of the Pharmacy will reduce the number of preventable alarms and will save time, also reducing the chances of alarm fatigue. By adding another layer of alarm follow-up the risk of an alarm going unnoticed ever are further reduced. Finally, integration of additional data sources will allow XiltriX to go from reactive monitoring to pro-active, even predictive monitoring.

Ms. Van Dapperen observed: “We are very proud of the result to date, but we see room for improvement. Further implementing automation of reports can save time and money. There are more fields in which improvement can be made. We are happy to work with our partner XiltriX International in the optimization of this process in the upcoming years.”



Would you also like to have support in setting up an ATMP or other type of laboratory? Please contact XiltriX at sales@xiltriX.com, or visit our websites www.xiltriX.com