Mobile water treatment possible even in the GMP area for the first time!

6 mins. reading time

by Fritz Röder

Pharmaceutical manufacturers increasingly require mobile systems for the GMP compliant water treatment. These should be available shortly, and should be rented on a weekly basis. In other industrial sectors this is common practice – in the GMP sector it was not available until now. The reason is the insufficient qualification procedure for the short term installation of such systems. A special qualification concept now allows this. It was developed and afterwards discussed with experts from the German and American authorities (FDA). Furthermore, there is positive feedback from the US Pharmacopeia and the ISPE. Pharmaceutical manufacturers and system manufacturers can now build temporary water treatment systems quickly, in accordance with GMP. The period between delivery of the system and releasing the water for manufacturing can be reduced to three weeks. With this new qualification concept, a new market is created for the short term installation of temporary water treatment systems.

Which problems does the new concept solve, and who can use it?

In pharmaceutical manufacturing, there are situations, where a temporary, GMP compliant water system is useful. Some examples:

- Replacement of existing water treatment systems without stopping production
- Backup in the case of failed performance qualification, for existing water treatment systems (to buffer economic risks)
- Conversion of sculleries and/or temporary washing processes, where no water was available until now
- Threat of bacterial contamination of existing treatment systems

Pharmaceutical manufacturers, but also water treatment companies are addressed. Apart from the water treatment of GMP compliant water, system manufacturers from other industrial sectors can also use this concept. Rental systems on racks, in containers or on trucks can be qualified in this way, and serve a new market. In other industrial branches (e.g. power stations), temporary water treatment is already usual practice.

Why wasn't this possible until now?

Manufacturers that have to comply with GMP must first extensively qualify a water treatment system before use. This can take three months or longer, before the water can be released for pharmaceutical production. So, it is not possible to react to operational requirements in the short term. With the new concept, this period can be shortened to three weeks, and at the same time, the current GMP regulations can be fulfilled.

In this context, risk assessment from the point of view of quality assurance is important. In conversation with the experts of the ZLG (German inspectors group qualification/validation), FDA, USP (Chemical Expert Committee) and ISPE (German expert group water & steam), numerous tips and possible risks when operating temporary systems were identified, which have to be considered beforehand. From this, a catalogue of measures is derived, which is considered in the detailed concept.

Examples of possible risks are:

- For mobile systems there is no long term experience and data available on site. This results in a significant risk, and a possible loss of control.
- Some system designs lead us to assume that the system manufacturer is now responsible for the whole topic of "data integrity" – additional installations and instructions are required.
- There are no prior details about the feed water quality to be expected. In addition, at the time of system construction, no user requirements specification (URS) from the pharmaceutical manufacturer can exist yet.
- What does the system manufacturer base the design on? How does the pharmaceutical manufacturer deal with the water data for batch release and Product Quality Review (PQR/APR)?

The concept highlights this and further topics, as well as tips from the experts. All findings are transferred into usable qualification plans. The documentation can be easily adapted by the system manufacturer or the pharmaceutical manufacturer, and used for the qualification of the system. The majority of the qualification work (planning and application of the tests) is therefore already done.

What is the exact difference now compared to before?

The author is aware of individual cases of rental concepts for water treatment systems. However, these system types have always been ordered and planned long in advance, and rented for longer periods (e.g. years). Shorter and more flexible set up and rental times were previously not possible, due to the extensive qualification works. The new concept makes this possible. The time of installation and qualification on site, until the release of the water for manufacturing, can therefore be reduced to three weeks.

What does the implementation look like in practice?

A second water treatment system on a rack, in a container or on a truck will be delivered, connected to the media on site and commissioned, then the qualification can start. This way the

maintenance or conversion of the existing system can be carried out, without stopping operation. After the use of the temporary water treatment system is completed, you change back to the stationary system. Using such systems can save a great deal of time, effort and a production stop.

The author is happy to speak to any interested parties.

Author:

Fritz Röder
E-mail: roederfritz@gmail.com

