HEMO
THE CLEANING SYSTEM

HEMO Supplies Hybrid Cleaning System for Pharmaceutical Autoinjectors

Cleaning of Autoinjectors: Hybrid at its Best

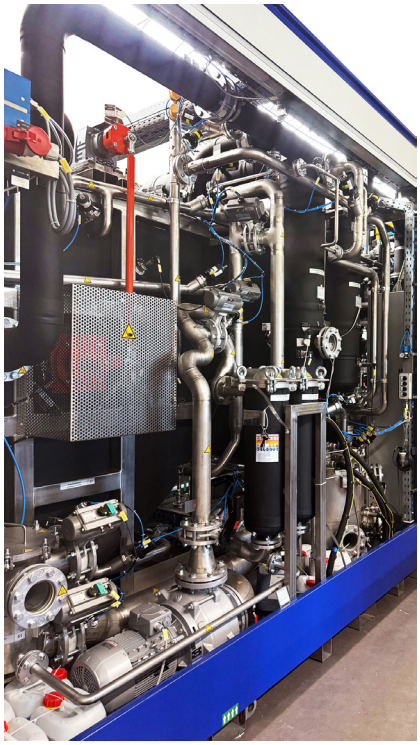
When exceptionally high cleanliness standards are required in industrial manufacturing, HEMO's hybrid cleaning and degreasing systems are often considered as benchmark. For a manufacturer of pharmaceutical autoinjectors, the precision cleaning specialist has now designed and built a dual-chamber system of the MODULAR type that not only ensures extremely thorough cleaning, but also fully complies with the stringent requirements of medical device production.

For people with allergies, an anaphylactic shock caused by an insect sting or a food intolerance can be life-threatening — unless an emergency kit with an autoinjector is available. This type of device is easy to handle and transport, as the needle is protected by a membrane, and it can be used safely without any medical training.

New Production Facility in Taiwan

A global leader in advanced self-medication solutions has been manufacturing autoinjectors since 1989 — used both for emergency treatment of allergic reactions and for long-term medication delivery in conditions such as multiple sclerosis, rheumatoid arthritis, osteoporosis, and type 2 diabetes.

As global demand for autoinjectors continues to rise, the company has recently expanded the capacity of its production facility in Taiwan, creating around 800 new jobs. In addition, there are concrete plans to establish entirely new manufacturing sites in both the United States and Europe.



Cleanliness According to Medical Standards

For all new construction and expansion projects in its autoinjector production operations, the company places top priority on two key factors: a very high degree of automation and the utmost cleanliness of all components. Accordingly, great care was taken in selecting both the manufacturer and the cleaning processes for the various spring elements used in the autoinjectors. Based on numerous references and recommendations, the company chose to collaborate with the precision cleaning specialist HEMO, headquartered in Ötisheim, Germany.

The task was to design an innovative cleaning system that, above all, would meet the strict standards of the medical technology sector. Andreas Fritz, Managing Director of HEMO, explains:
“Regardless of the required level of cleanliness, the entire process must be fully documented and traceability must be ensured. Our project engineers are thoroughly familiar with the standards in the medical device industry, thanks to extensive experience gained from a wide range of projects.”

Hybrid and Largely Automated Cleaning

Among the parameters defined during the project planning phase of the cleaning system were the quantity, variety, and geometry of the components to be cleaned, the degree and type of contamination, and the required cleanliness level with respect to various types of residues. The desired high degree of automation was also taken into account, along with full process documentation and traceability.

Andreas Fritz describes the result: “After the first cleaning trials in our technical center, it quickly became clear that the specific requirements could not be met with conventional parts cleaning technology — but they could be perfectly fulfilled with a hybrid dual-chamber cleaning and degreasing system from our MODULAR series.”

Based on the results of the laboratory trials, the appropriate cleaning media and process parameters were defined for this system. The basic concept: In the first cleaning chamber, solvent-based cleaning is used for degreasing of springs that are later integrated into the autoinjectors. In the second chamber, water-based cleaning is performed on springs that have undergone mechanical processing, forming, and heat treatment — and which therefore also exhibit inorganic contamination.

Reliable Removal of Organic and Inorganic Contaminants

With its unique combination of aqueous and solvent-based cleaning processes, all carried out under vacuum, the MODULAR Multichamber is considered a benchmark in precision cleaning.
“This system type combines the advantages of both the water-based and solvent cleaning worlds. In the aqueous stage, both an alkaline and a neutral cleaner are used — i.e., media from two different chemical classes. This allows each type of contamination to be individually ‘targeted,’ effectively loosened, and then removed from the process.”

The result: exceptional cleaning performance for both nonpolar (organic) and polar (inorganic) contaminants. Two solvent stages for pre- and fine cleaning, along with a total of five aqueous cleaning stages, further ensure that the process meets the highest standards for residual contamination.

The two separate cleaning systems and processing chambers prevent cross-contamination. Operating the entire solvent-handling system under vacuum or reduced pressure allows cleaning to be performed both via immersion and vapor degreasing above the flash point. Certainly, all structural requirements for particle-free cleaning have been implemented — from polished cleaning chambers and low-dead-space piping to stainless-steel valves without flanges.

The use of ultrasound and pressure flooding further supports particle-free cleaning. Cleaning media are circulated continuously and maintained through a robust triple-filtration system, ensuring consistently high cleanliness levels throughout the process.

Smart and Demand-Oriented Automation – Including Customized Solutions

In addition to sizing the system and adapting the cleaning process, the project team also focused intensively on automating the MODULAR system for autoinjector production.
“Extensive automation is not only efficient — it also contributes to the cleanliness of the process. This allows us to achieve two goals at once. That is why we have largely automated the loading, feeding, and removal of the cleaning baskets.”

Automatic handling of cleaning baskets in the processing chambers is a standard for HEMO systems. This surely includes the automatic locking of the baskets inside the chamber, preventing parts from falling out during the cleaning process.

Comprehensive Measurement Technology, Control Integration, and End-to-End Documentation

The dosing of the aqueous cleaning chemicals is also fully automated. One of the key control parameters is the conductivity measurement in the aqueous rinse tank. To meet documentation requirements, the team developed a comprehensive tracking concept. “Before cleaning, the operator scans the cleaning basket number, the article number, and the corresponding batch number with a handheld scanner. These data are fully traceable at every station — from the loading area to the basket removal point.”

After the cleaning process is completed, the corresponding process data are assigned to each basket and can be provided to the customer’s IT interface, such as an OPC/UA server. Additionally, the automation system offers, if needed, the capability for measurement and calibration of the sensors.

From Trials and Testing to Commissioning and Validation

Before delivery of the hybrid cleaning system, a Factory Acceptance Test (FAT) was conducted, as is standard in medical device manufacturing and routine practice for HEMO. During this test, the system was first checked for completeness of scope, followed by a quality inspection and functional testing.

After commissioning on site in Taiwan, a Site Acceptance Test (SAT) was carried out. Only then did the extensive validation process begin, with all procedures defined and the corresponding results documented. The system is now operating to the complete satisfaction of the user, with all specifications and cleanliness requirements for the components reliably met.

Andreas Fritz comments:

> „This project demonstrates once again how a collaborative partnership between manufacturer and system supplier can produce excellent solutions that reliably and sustainably meet the stringent requirements of medical device production. When cleaning and degreasing systems are planned for the new production facilities in the United States and Europe, we will benefit significantly from the experience gained in this first project. “

Text: Ralf Högel