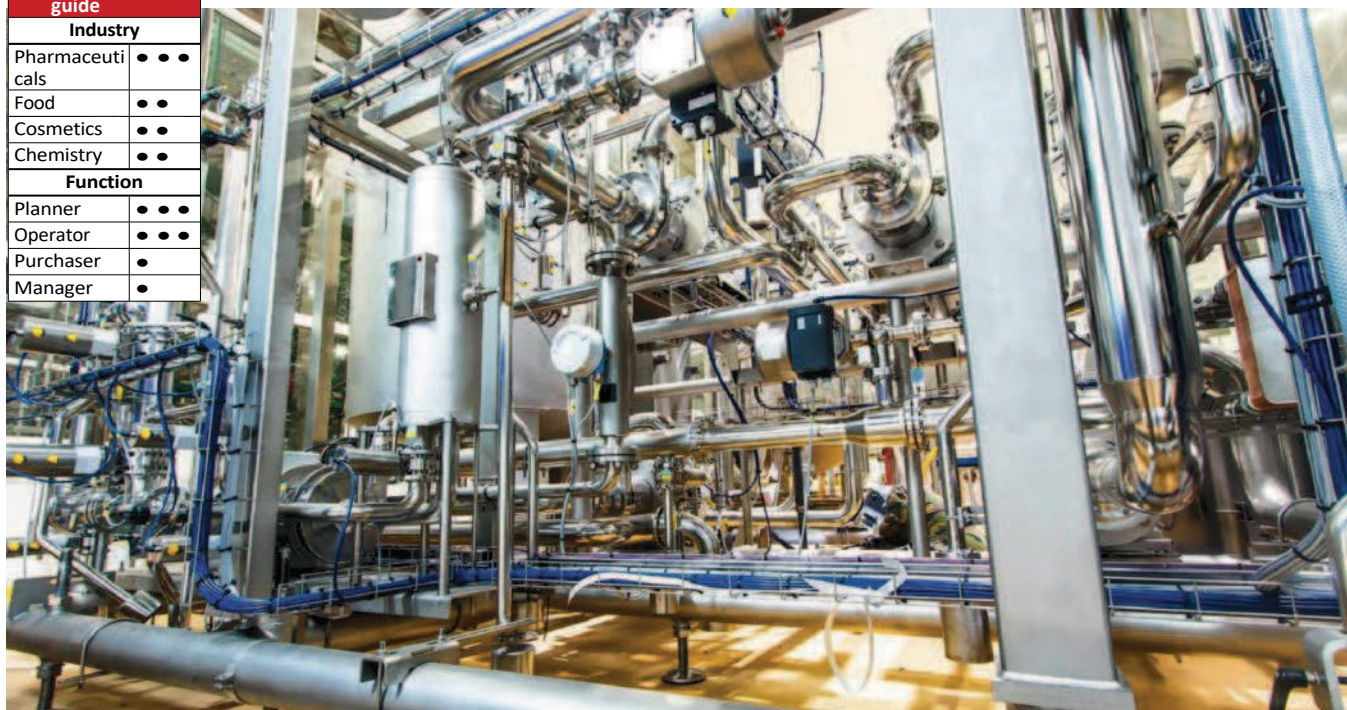


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Complex production plant
Image: Shutterstock

Complex cleaning in complex systems

Clean new systems - efficient existing systems

Pharmaceutical companies place very high demands on the cleanliness of their production facilities. This begins with the planning and construction of new production facilities and applies in particular to the operation of new and existing plants.

The commissioning of newly constructed production plants can be delayed, for example, if foreign bodies are introduced into the plant during construction or conversion. reach the pipes and equipment. The effort required to bring the non-accessible parts of the system in particular into a wall-free state is often enormous. The highly branched piping system with numerous installations can be a real challenge. In addition, there are few options for flushing in and out without having to disconnect the pipes again.

Intensive cleaning measures are necessary to meet the high cleanliness requirements. Chemical cleaning agents are often used. These must be removed completely from the piping system after the exposure time. However, this does not allow foreign bodies such as chips that have entered the pipelines as a result of conversion work to be removed. This requires intensive mechanical cleaning.

Complex cleaning is a powerful mechanical solution for complex systems: The way the cleaning principle works generates high abrasive forces to remove foreign bodies and contaminants.

and also completely discharge them. The process uses only purified water in demineralized or WFI quality and filtered compressed air. If the production plant requires it, inert gas such as nitrogen can also be used. In many places, drinking water or another aqueous medium is also suitable instead of purified water.

Component groups before assembly

Pipelines and equipment in pharmaceutical plants are made of high-quality materials, in particular stainless steels. Before assembly, it is essential to store and handle the components properly. However, as this is not always guaranteed everywhere, some assembly companies have started to have components and pre-assembled component groups cleaned in advance. They are increasingly using Complex technology for this task. It not only enables the components to be cleaned reliably, but also to be dried afterwards.

Newly built plants

During plant construction, auxiliary materials such as lubricants and unintentional contamination such as dust get into the

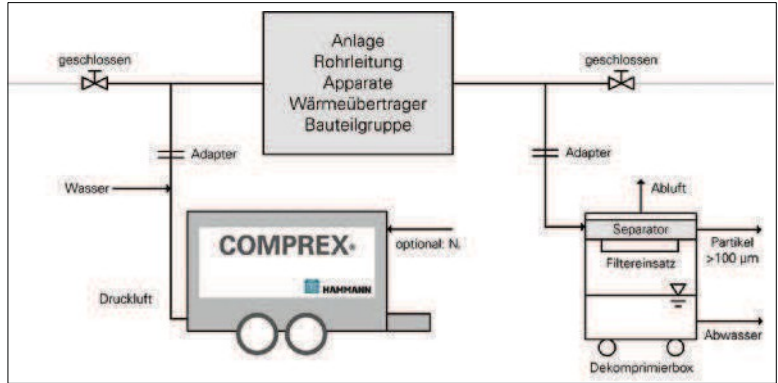
Authors

Sebastian Zimmermann, Hammann Dr. Norbert Klein, Hammann



Pipes and appliances. Foreign bodies such as sawdust can also get in when cutting pipes to length or during conversion work. They must be removed before commissioning, but can remain in the production system in places with low flow velocities due to improper cleaning or inadequate water rinsing. If steam sterilization is subsequently carried out, assembly residues that are not very heat-resistant may cake in the piping.

During the commissioning phase, it often turns out that changes need to be made to the piping system. Reasons for this include improper installation of components and process optimization,



new safety regulations or expansion of the system. During such subsequent construction measures, pipelines are disconnected again and then reconnected. Again, it cannot be ruled out that foreign bodies will get into the pipes again. In complex and highly branched systems, conventional water flushing (e.g. as part of CIP) is not sufficient to completely remove the foreign bodies. The reason for this is flow-calmed or geometrically complicated areas, such as those found in fittings or branches.

workplaces.

Foreign bodies and impurities in production systems directly or indirectly impair the quality of the product and therefore potentially jeopardize the quality of the product.

Figure 2: Discharge of foreign bodies on the filter fleece of the decompression box.

Figure 3: Scheme of Complex cleaning in the industry.



Complex cleaning in the pharmaceutical industry

	Occasion	System components	Remarks
Component groups	Before assembly	Pipes, appliances, fixtures	Discharge foreign bodies and impurities
Newly built plant	Before and during commissioning	Installed pipes and appliances	Discharge construction-related substances
Existing system	In cleaning phase in production times	Selected pipelines	Remove deposits
	System downtime	All pipes divided into cleaning sections and component groups	Remove deposits and coverings

Source: Hammann

health of consumers/patients. They can provide microorganisms with nesting opportunities and thus protect them from cleaning agents and disinfectants. Corrosion can also occur as a result of foreign bodies entering the system. DIN EN 12502-4 refers to the likelihood of corrosion due to impurities in stainless steel pipes.

After commissioning, localizing the contamination in the system can be a major challenge if foreign bodies are introduced and water flushing is inadequate. Targeted local cleaning measures are not possible. It is therefore advisable to intensively clean specific sections of the system using suitable methods during the construction phase, before commissioning the system or immediately after necessary conversion measures.

Cleaning using an air/water mixture is described in several standards and worksheets. It represents a significant improvement on conventional water flushing. The impulse flushing process increases this effectiveness even further. It is therefore frequently used for cleaning fluid-carrying systems, e.g. when cleaning drinking water distribution systems and is explicitly recommended in regulations, e.g. DVGW W 557 (A). The Complex process is an optimized pulse flushing process. Several research projects have led to a significant improvement in cleaning performance with the lowest possible water consumption. The economical use of water not only plays a role in drinking water systems, but can also be a decisive cost factor in pharmaceutical systems due to the use of deionized or WFI water.

Cleaning during production times

During cleaning phases, individual sections of the system are temporarily out of operation. This allows product lines to be cleaned while pipelines with ultrapure water, acetic acid, caustic soda or ultrapure steam are available for CIP or SIP. Complex technology can assist with free rinsing. It enables cleaning residues to be removed from areas with poor flow and edge zones.

Effect of pulse d air and water blocks in pipelines.

Picture: Hammann



In contrast to newly built systems, the task of existing systems is to mobilize and remove operational deposits. Aqueous solutions of acids or bases are often used to mobilize adhering deposits. Ultrapure water and steam are then used to condition the system components. They alone are not always sufficient to completely remove all residues and particles due to insufficient drag forces in critical areas.

If it is possible to remove operational deposits in good time, i.e. before they harden, Complex cleaning can be a cost-effective and effective solution. Stationary Complex technology offers advantages for frequent cleaning. It enables cleaning in short cycles in the event of heavy deposit build-up.

The Complex technology for the applications mentioned must be integrated into the production process and, as an extension of CIP, requires corresponding validation.

Cleaning during system downtimes System downtimes enable thorough cleaning measures. If necessary, individual assemblies can be removed for maintenance. The Complex process allows pipelines to be cleaned in sections, also in combination with other, e.g. chemical cleaning processes. The downtime-related time window allows the condition of the system to be checked and the reliability of the system to be ensured.

Decision-maker facts

- Complex cleaning technology is beneficial for the pharmaceutical industry in several areas.
- It enables the economical cleaning of pipelines and appliances and thus also helps to ensure the quality of the products produced.
- Food-producing companies place similar demands on cleanliness. Here, too, the cleaning method is proving its worth more and more.