

One supplier makes cleaning into a business

Since this summer, Cellpack AG in Villmergen has been operating a clean room with ultramodern technical infrastructure in its Cellpack Medical business unit. It meets the highest standards. An important integral part is an ultrasonic cleaning system from Elma. In addition to the parts production for medical technology customers Cellpack has created additional core business. The TR ("Technische Rundschau") asked what should be considered for such an investment.



(As soon as its code has been read in, the batch passes through the Elma ultrasonic cleaning system.)

The subject of parts cleaning is omnipresent. Every parts manufacturer must somehow clean or arrange cleaning of his products before delivery. The only problem is: whoever, like Cellpack, manufactures parts for the medical sector is already subject to particularly strict regulations during their manufacture, but loses control over the process as soon as the part is passed on externally for final cleaning and packaging. The process chain becomes more complex and the cycle times increase.

These thoughts were considered from the beginning to the end one and a half years ago when Cellpack really studied the subject: as many manufacturers in the medical technology sector show great respect for the entire cleaning / packaging process, Cellpack was convinced it could also provide this service to external interested parties. It was decided to create an as versatile as possible clean room facility.

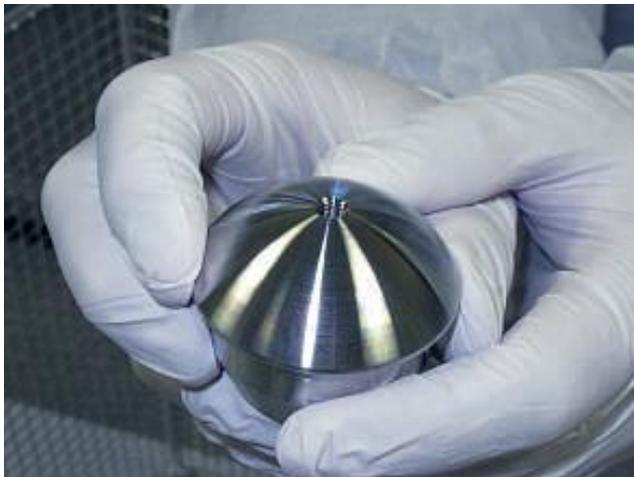
With this, Cellpack is significantly enhancing its own added value chain which previously comprised the manufacture of plastic parts including their finishing in the medical technology sector. With immediate effect, the products can be packaged ready to use and, if required, also supplied sterile to the customer. Thereby the quality control is kept in Cellpack's own hands and the customer has a single contact for all processes.

Andreas Binkert, responsible for the complete project at Cellpack during the project phase, defines the current situation on the Swiss market as follows: "There are some contract packers from the final rinsing stage onwards. But in Switzerland, we only provide this

interface to a few medical technology suppliers, in which the parts from the oil dripping stage to the final rinsing can be cleaned and packaged with very little germ content. There are of course contract packagers for industrial applications, but this sector is not at the same level as regards the cleanliness requirements".

What sounds trivial is a challenge with pitfalls and snares in reality. This is far from the case with the procurement and installation of the clean room facility. In order to achieve the required versatility of the system which occupies just under 400 m² in the production halls of Cellpack, it was necessary to demarcate a second clean room compliant with Class ISO 7 inside the outer clean room which complies with the requirements of clean room Class ISO 8 according to ISO 146441 and in which the Elma ultrasonic cleaning system is located. This only permits one tenth of the particles of Class 8. In this room, the finally cleaned parts are assembled if necessary and finally packaged and labelled.

Air locks between the two rooms for the products and the personnel are integrated in these. As the packaged parts have to carry a label for identification, a printer must also be available



The system with the Elma ultrasonic cleaning system has been certified and validated using such part dummies. (Images: TR)

This is also in a separate room with air lock as laser printers present a contamination risk with their toner cartridges. There was also a separate material air lock to the room with the stricter ISO class with an integrated final cleaning washing machine for purely aqueous spaying final rinsing with water from a complex ultra pure water purification system. "We take over the parts with a defined cleanliness", explains Andreas Binkert. "They come on to the existing Elma cleaning system consisting of nine modules. They pass through there to the fine cleaning of the ultrasonic bath and then to three rinsing baths and the drying tub. This is followed by the final rinsing in the washing system and the packaging with very little germ content in the ISO 7 clean room in blister packs or bags with many different specifications.

Technical Installation

- Outer clean room Class ISO 8
- Inner clean room Class ISO 7
- Water treatment hot water for ultrasonic cleaning system, cold water for final rinsing machine
- Two material feed air locks from ISO 8 to ISO 7
- Separate air lock from the printer room between ISO 8 / ISO 7
- Discharge air lock for packaged material from ISO 7 to ISO 8
- Final rinsing machine
- Diverse systems (packaging etc.) Elma ultrasonic cleaning system with nine modules, consisting of:
 - Station 1: cleaning bath for metal
 - Station 2: cleaning bath for plastic
 - Station 3: rinsing bath 1
 - Station 4: paaivation bath
 - Station 5: rinsing bath 2
 - Station 6: rinsing bath 3
 - Station 7: rinsing bath 4
 - Station 8: drying tank
 - Station 9: free for option
- Transport robot
- Control concept according to FDA CFR Part 11



The modular Elma bath line established according to requirement.)

If required, the products are sterilised externally afterwards." However, it is a condition for reliable processes to have total control of the incoming goods inspection and the definition of specifications and their compliance. Product families were set up for the ultrasonic system and material classes with surface classes and preliminary processes for these defined. The dummy parts with many different complexities to be cleaned were then produced. "We combined these with the most severe preliminary processes" says Binkert. "We left the polishing paste on and bathed them in emulsion and oil until we could not get them any dirtier. We then tried to meet the defined specifications using the defined cleaning processes for these parts. If our family validation is sufficient for the customer as performance verification, he saves money and time in the product launch. If not, the parts are cleaned according to his expectations, validated and passed on to the laboratory for checking.

In the project and implementation phase, the processes were first applied internally for dummies. Because, according to Andreas Binkert: "No orders can be generated before the machines have been qualified and the processes have been validated. The complete system must also be completely installed and ready to start. Before that is completed, nothing at all happens commercially. In the last step, the system must still also pass the audit for the ISO 13485 certificate for management standards in medical technology. Binkert adds: "This is the basic prerequisite to be able to obtain orders and participate in the market at all. The preliminary work is enormous both financially and as regards personnel". Part of the investment was made in the Elma ultrasonic cleaning system which was procured via Walter Meier AG. The decision for this provider was made early. "Of the three providers who made a quotation, Walter Meier with Elma showed the best cost/benefit ratio", explains the project manager. "We are very satisfied with this to date. It was only when experimentally going to the limits of the machine that the timing and coordination of the processes sometime no longer functioned optimally. That is due to the modularity and versatility of the system which has a relatively complex control system. We were at the limits and had to adjust the control system. The service was always outstanding when we contacted Walter Meier or the manufacturer about such problems. The technicians dealt with everything via remote access in a very short time. The communication was perfect."

Cellpack

Cellpack AG is a company of the Behr Bicher Cellpack BBC Group with headquarters in Villmergen. It generates sales of approx. CHF 300 million and provides around 1,200 full-time jobs, of which approx. 70 are for trainees. In the Cellpack Medical division, many different types of implants, inlays, manipulation parts, cassettes and instruments, among other things, are manufactured and new cleaning and clean room activities which are described in this article are



Clean room ISO 7: in the centre of the packaging system with assembly table, material air locks at the rear, washing machine on the left, labels air lock on the right.)

The ultrasonic system today is functioning without any error messages. Binkert would still like to retrofit the time-intensive parts drying with a second drying bath. The bottleneck was at least already recognised in the project phase and empty spaces were planned as reserve in the system. "As soon as we can no longer get by in two-shift operation, the second dryer will be there. The system will then be twice as fast. The costs are relatively low. And I would order the baths with covers as the open ones emit a bit too much heat over night; however that can be retrofitted easily"

When asked afterwards what he would advise to companies considering a comparable investment, he said: "First, the customer requirements, relevant standards, regulations and legal provisions must be known and certainly talk with as many providers as possible in advance so that the requirements can be precisely defined matched to the systems available on the market. Both hardware and service competence must be correct for the systems. Trade fairs and exhibitions such as CleanDays and parts2clean are also very useful". And the most important tip from Andreas Binkert: "Do not underestimate the task; it requires respect because the subject includes extremely sensitive areas! Procuring and making such a system profitable needs staying power, a lot of expertise and the correct specialists. It is feasible, but must never be rushed through. The knowledge must be acquired step by step".

Markus Schmid

Cellpack AG Medical
5612 Villmergen, Tel. 056 618 12 14
medical@cellpack.com,
<http://medical.cellpack.com>

Elma:
Walter Meier (Fertigungslösungen)
AG 8603 Schwerzenbach,
Tel. 044 806 46 46 www.waltermeier.com