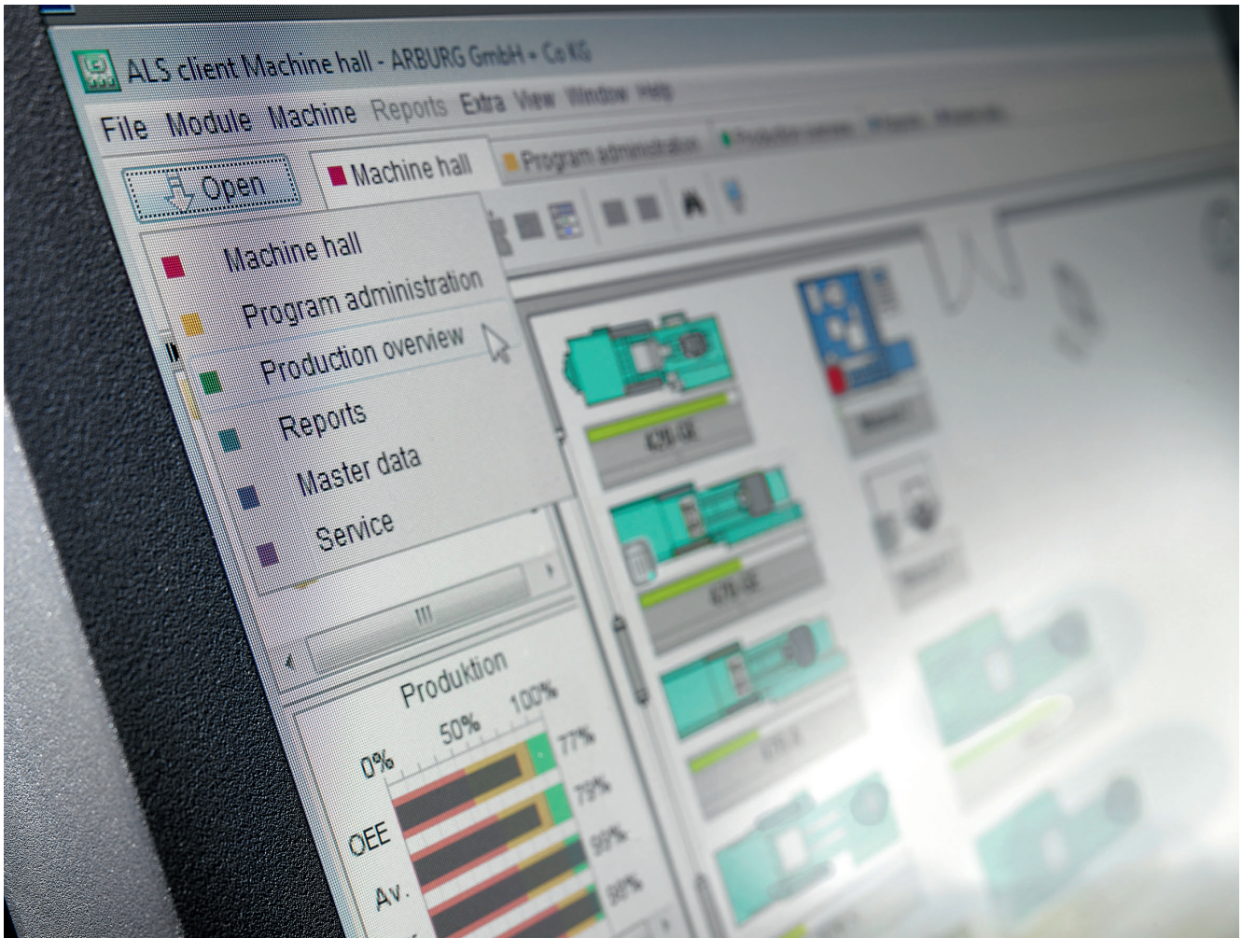
The Arburg Host Computer System as a Basis of Higher Productivity and Product Quality

Case Files for Patient Safety

How do you bring 65 injection molding machines and various assembly lines – most of the manufacturing cells in the cleanroom – as well as, soon, a large number of ancillary equipment under one digital roof? A field report about the highly complex project for introducing a host computer system, which was performed in a very grounded way and has helped Röchling Medical boost its performance on several levels.



The Arburg host computer system ALS is the link between the shop floor and ERP system and connects order management with process and quality monitoring. © Arburg

We are one of the few customers in medical technology who use the ALS host computer system." Daniel Tobin, Head of Production at Röchling Medical Waldachtal AG establishes the benchmark at the very beginning of the discussion, which ***Kunststoffe*** holds with him via a video link. When, in the course of the following hour, we hear from him that they have succeeded in not only increasing the company's own plastics processing productivity, but also patient safety, this finding may seem astonishing at first.

ALS is the German abbreviation for the Arburg host computer system, the production management tool of the injection molding machine manufacturer from the Black Forest, Germany, which, with its modular design, can be adapted to the manufacturing plant's needs and can grow along with the production size and its requirements. ALS can be used to manage the entire

Daniel Tobien, Head of Production at Röchling Medical in Waldachtal, Germany, is key-user for ALS. © Röchling Medical

production – to achieve a high product quality and as little machine downtime as possible. Indicators that are available at all times, about current orders, processes or the overall production effectiveness put users in a position to identify weaknesses and achieve lasting improvements in processes and work flows.

High Requirements, Strict Documentation Obligations

The medical branch, with sales of EUR 164 million, is the smallest of the Röchling Group's three divisions, whose overall revenue, with the two strong pillars of automotive and industrial, was just over EUR 2 billion in 2020. Medical products are produced at a total of six sites in Germany, the USA and China. In 2018, the site in Waldachtal, Germany, was added, which Röchling took over from Frank plastic AG and where Daniel Tobien coordinated all phases of the ALS roll-out.

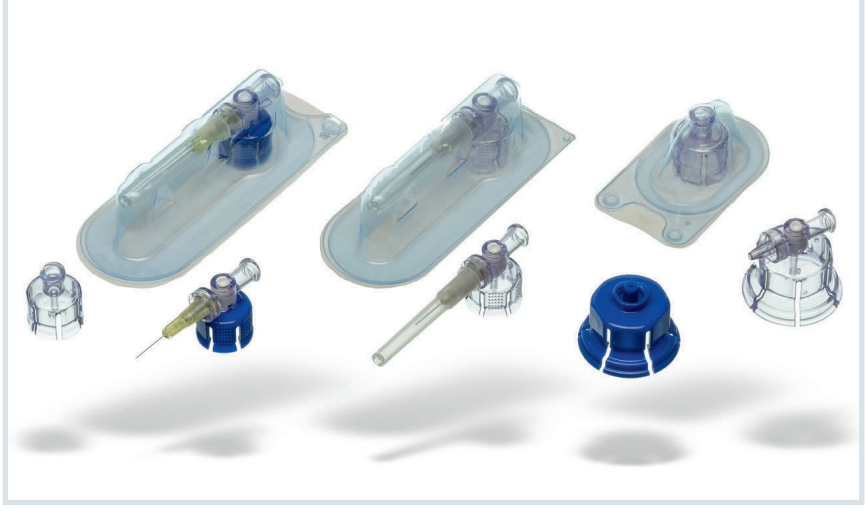
It is well known that the requirements and documentation obligations for manufacturing medical products are particularly high and strict. Why that is – or better said, must be – the case becomes immediately clear if we look at Röchling Medical's product range. The company acts predominantly in three market segments (medical technology, diagnostics and pharmaceuticals), the arc stretches from crystal-clear parts for oxygenators, which filter and oxygenate the patient's blood outside the body during heart operations, through Petri dishes for diagnostics, as well as different pharmaceutical primary packaging and administration systems, to ophthalmological instruments for eye surgery or endoscopic solutions for minimally invasive surgery.

"Some 85 percent of the parts that we manufacture in Waldachtal are highly complex applications," says Tobien. This requires a precision that is often not apparent at first sight, if at all. The trained mechanical engineer refers to geometrical and dimensional requirements on one hand and dimensional requirements, for example in 0.2 mm diameter needle guides or in blood-carrying components, which must be flash-free with their edges and orifices rounded, so as not to damage the blood corpuscles as they pass through. On the other hand, he mentions the high optical requirements: "How are doctors and nurses expected to distinguish whether the black specks in crystal-clear parts are uncritical inclusions in the material or loose foreign matter? "In addition, the proportion of assemblies and ready-assembled, packaged and sterilized single-use products has been growing for years.

Cleanroom with 43 Injection Molding Machines

The Waldachtal site has resources such as product development, an own mold making shop (including design), an automation department, as well as product validation specialists, and mainly produces in a 2500 m^2, class ISO 8 cleanroom. It contains 43 injection-molding machines, 22 are outside the cleanroom and are partly equipped with laminar flow boxes – these machines are to be primarily connected to the ALS.

The machines process all conventional thermoplastics, including high-performance polymers such as PEEK or PEI with shot weights from 0.1 to 1800 g and processes such as insert and multi-component technology, micro and endless injection molding. "In the cleanroom, we produce quantities from 10,000 to 24 million units per year, from customized components and assemblies to complete OEM products," says Tobien. One of the best sellers is a Luer Lock cone for prefilled syringes with injection port. All injection-molding machines are connected to a com- »



"Mixject" mixing and injection system for autonomous mixing and administering of medication by the patient (left) and cardiotomy reservoir (right) as part of an oxygenator, which filters and oxygenates the patient's blood outside the body. © Röchling Medical

puter-aided, fully automated pellet drying and feed system.

Why Use a Host Computer System …

When you realize that production also includes ten assembly units and four assembly lines, which are also to be connected to the ALS without exception, and such different processes as laser marking, pad and screen printing, hot embossing and various welding techniques, such as ultrasonic welding, you get at least an idea of the complexity of the project. But the question remains, why use a host computer system at all?

Of course, Röchling Medical has thought carefully about the answer, "We essentially wanted to increase the transparency in production. Likewise, we wanted to perform better process analyses and make our problems, which we knew more by feeling in the past, visible and to gain an understanding of them. The crucial point was that we wanted to control production with a KPI and needed a tool for this in order to introduce the OEE as an indicator and represent it rationally," explains Tobien in retrospect.

The overall equipment effectiveness (OEE) is defined as the product of the factors availability, performance and quality. In principle, it is an indicator for unplanned losses of a plant due to shutdown or producing rejects. The OEE thus indicates for how much of the planned running time a machine has actually generated products corresponding to the quality criteria. Based on the mathematical formula, the value generally lies well below 100 percent, with the limiting factors revealing the weaknesses.

… and Why this One?

A second important point, but one which only indirectly concerns production, is that of traceability. "The requirements with regard to patient safety and customer requirements are growing continually. We must continuously document that we manufacture using reproducible, validated processes: what product, with which material, on which machine and with which production parameters. That used to be done manually and is now largely automated," according

In ALS, both Arburg and third-party machines are connected. © Röchling Medical

to Tobien. There is no chance of typing errors and non-GMP-compliant documentation; the time gain is considerable.

As the head of production continued, at the project start in spring 2018, four suppliers were shortlisted for implementing an MES (manufacturing execution system), two – Arburg and Gewatec BDE – already had installations in house. In the end effect, the decision was made pragmatically: "Because of the large number of Arburg machines in our manufacturing base, we decided it would make most sense to go with ALS throughout," says Tobien summing up the initial situation. In fact, at Röchling in Waldachtal, 60 injection molding machines originate from Arburg, the others are distributed among three manufacturers. Engel, KraussMaffei and Dr. Boy.

Here, according to Tobien, one advantage is decisive: machines from third-party manufacturers can very easily be integrated into the ALS via OPC US according to Euromap 77. The 40-year-old says: "We can read most of the information from the third-party machines, though not in as much depth as with the Arburg machines." No additional terminals are needed; communication between the machine control and the ALS is performed on the machine display. Tobien adds: "With other suppliers, we would have to additionally mount a tablet on the machine."

From the Test Phase to Roll-Out

After opting for Arburg, Röchling Medical set about preparing the infrastructure; this means: "Retrofitting the machines with the necessary host computer interfaces as appropriate, laying data cables, building up server capacities," as Tobien explains. Some weeks later, the ALS was started up in predefined areas and, after commissioning, tested for one month – in particular for whether the ALS receives the responses from the machines and the communication with our ERP system is working," says Tobien.

After a successful test phase, the ALS was quickly rolled out in the manufacturing areas: first on the injection-molding machines at the end of 2018, since the biggest effect and most synergies were to be expected here due to the high requirements, then on the assembly units by the middle of the following year. Röchling opted for the full expansion of the ALS – at a cost of EUR 150,000. The names of its modules are almost entirely self-explanatory: MDE & BDE, Reports, Setting Data, Mobile Production, Orders and Progression. The last two describe the possibility of posting orders from SAP to ALS and clearly presenting the data gathered during manufacturing.

In parallel with the second roll-out phase, Daniel Tobien and his team began setting up the setting-data management, i.e. "Transferring all programs that we used to have on memory cards or diskettes to ALS and linking up the order management – so that the setter receives the right setting data record for an order." The biggest challenge was specifying and assigning the names of the individual programs so that the MES and ERP system can work together smoothly thanks to a clear assignment. We currently have about 1800 active molds and

about 3000 data records. That was a huge amount of work," says Tobien about the dimension.

How Does ALS Help Increase Productivity?

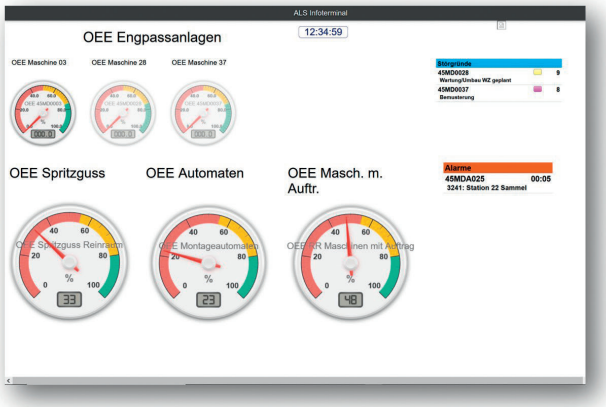
In the next step, the production hall was built up in the ALS, so that in the monitor display, the machines are at the same places as in the real manufacturing shop. And the number of fault reasons that the setter can select was reduced from the original 30 to the 13 most common (**see Info Box**).

In the meantime, the company has trained all the employees that the OEE will in future be the only indicator for productivity. Displays in production are used to distribute current information, for example: What is the current state of orders and sales? How are the reject costs developing? Since the introduction of the ALS in 2019, we have been able demonstrably to increase our OEE by 20 percent. The leap was essentially the result of the fact that, today, we register the fault reasons far more accurately than before and consequently improve the production planning by evaluating process data and downtimes, and were able to increase the process stability," summed up Tobien.

It is remarkable that on two so-called OEE days, Röchling was able to increase the OEE in cleanroom manufacturing by as much as over 70 percent in the short term. "On these days, we oriented the complete company toward achieving a best value. Seen realistically, the maximum is 80 percent in view of the complexity of our products. We can't achieve any more, as has been shown by these trials. Our goal is of course to be able to maintain these values continuously," says Tobien.

And How Does ALS Increase Patient Safety?

The learning curve can be raised almost indefinitely. "In 2020, we had a special report generated for us by Arburg. In this, each individual part was evaluated according to what fault reasons were present for how long in period X. That gives us insights into our own systems, for example what molds we will have to take care of in the near future, but it also serves the goal of improving the master data in the SAP system," says Tobien, naming an example.



Transparency in production: the OEE is the sole and definitive indicator for the company's own productivity.

© Röchling Medical

Not only Röchling benefits from ALS but also the patients who come into contact with the company's medical products. Daniel Tobien enumerates them: "Our injection molding expertise is now securely archived. There is no diskette to fail, no data record can be lost, obsolete setting records are proverbially a thing of the past. Now there is only a controlled and approved data record and each change can be traced because the machines are now equipped with access cards. All important process parameters are monitored, more effectively than the machine can, so that the setter can intervene as necessary before the machine produces reject parts. For each order, all the parameter settings used are saved. And we can even generate and compare parameter lists from archived setting data – though only with Arburg machines.

But how does this gain in reproducible product quality become measurable? Tobien replies immediately, "Our ALS shows us our higher quality rate each day." Together with the higher OEE, this leads overall to a higher capacity offering, which is available for the customers and possible new projects.

Marrying the Machines with the Ancillary Equipment

In a brief outlook, Tobien reveals that all ancillary equipment are equipped with a barcode or UDI (unique device identification) code, The setter can register these with a hand scanner and store them directly in the ALS. This ensures that the machine-side dryers, temperature-control equipment or hot-runner controllers, which are validated, can be used for each order. In addition, we want to equip all machines with electricity meters to analyze our electricity consumption according ISO 50001 and make corresponding efficiency investments, with the aim of permanently reducing the electricity consumption," adds the plastics specialist. Even after the successful ALS launch, Daniel Tobien's team will not be short of work. ■

Dr. Clemens Doriat, editor

13 Principal Fault Reasons

These factors are OEE relevant:

- No order
- No operator
- No setter
- No material
- Tooling
- Maintaining the system
- System defective
- Sample examination
- Maintenance/conversion of mold planned
- Repair/cleaning of mold unplanned
- Start-up
- Unstable process
- No QA-clearance

Service

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