Report

ENGEL supplies turnkey system and GMP documentation

Out with risk, in with efficiency

Systems business is on the rise: procuring injection moulding machine and automation from a single source saves costs and speeds up commissioning. Now, for the first time, ENGEL has also supplied GMP documentation as part of the turnkey package. The advantage for Helvoet, the client? Even more efficient processing of projects and a fully optimised manufacturing cell.

The market for diagnostics is changing. Rising demands on product convenience are driving a stream of new product designs and enhanced functionality while raising the efficiency of production processes. For many years Helvoet, based in Tilburg, has specialised in this dynamic market segment. Amongst other things, the Dutch company produces test cassettes via two-component injection moulding in its capacity as sole supplier to a global pharmaceutical organisation. Helvoet acts as a development partner as well as a producer. “To turn an idea into a successful product, we need to combine a wide range of technologies”, said Bas Schuurs, Managing Director of Helvoet in Tilburg. “Our expertise lies in finding the right partners and suppliers for our customers and working out the best possible manufacturing solutions in partnership.”

Reliably protecting the interior against the ingress of moisture proved the biggest challenge in the development of the test cassettes; this required a new drying agent as well as the integration of a sealing lip into the housing. The new manufacturing cell also had to offer high levels of efficiency and cost-effectiveness.

System solution speeds up time-to-market

Helvoet decided in favour of ENGEL AUSTRIA as a partner for injection moulding technology: ENGEL's ability to supply the injection moulding machines and automation from a single source tipped the balance. “From the outset, it was clear that we would be

able to cut our time-to-market", underlined Helvoet project manager Jeroen Molenschot. However, another factor – the proximity of the two companies – proved equally decisive. ENGEL AUSTRIA's branch office in the Dutch town of Houten is less than an hour's drive away and Hagen, where ENGEL Automatisierungstechnik Deutschland is based, is also within easy reach. "Our priorities are flexibility and zero risk", said Molenschot, "and that can only be assured where our partners are able to reach us quickly."

The project team from Helvoet met up with specialists from ENGEL every two weeks (in Tilburg and Hagen alternately) to develop the ideal production process for the test cassettes using injection moulding. In the end they opted for transfer technology rather than an integrated two-component injection moulding process for two reasons. Firstly, two very different shot weights were required (just 0.05g for the sealing lip), and secondly very large moulds needed to be built on account of complex slide gate systems. To be used with a turntable, the number of cavities (and thus the plant's output) would have had to be reduced. Transfer technology places particularly high demands on the automation of a manufacturing cell. Three robots – two linear robots and one multi-axis robot – perform the handling of parts between the two injection moulding machines and provide an interface to the assembly and packaging line.

In the first step, the core housing component is injection moulded out of polypropylene using an ENGEL victory machine with clamping force of 260 tons and 16 cavities. An ENGEL e-victory 180 with electric injection unit and 25mm screw are used to inject the TPE sealing lip; this ensures correct metering of the small shot volume. The machine utilises the ENGEL x-melt process, technology developed by ENGEL for the production of the smallest moulded parts on standard injection moulding machines. The finished housing components are removed by the multi-axis robot and transferred to the adjacent assembly and packaging line. The fact that the ENGEL victory and e-victory machines have no tie-bars simplifies parts handling while allowing smaller injection moulding machines to be used. Since the mould fixing platens can be used to the edge, clamping force is determined solely by the application and not the size of the mould.

The aim was to achieve very short cycle times (including handling) for the production of two-component test cassettes. “The fact that we achieved this objective was definitely a result of our close working relationship, even in the very early stages of the project”, said Bas de Bruin, account manager at ENGEL Benelux. ENGEL's scope of delivery also expanded as the project progressed – another product of the intensive planning phase. In addition, ENGEL agreed to provide all GMP documentation for the system.

GMP matters to pharmaceutical suppliers

GMP (good manufacturing practice) is designed to ensure that products are manufactured to a consistent standard of quality in accordance with their intended usage; GMP guidelines define a code of conduct and regulations that must be observed in the manufacture and utilisation of relevant products. GMP also applies to plastics processing companies that supply the sector because their clients only purchase GMP-compliant technology.

The aim of GMP is to minimise risks while ensuring observance of rules can be demonstrated at all times. For every system used to produce pharmaceutical or medical engineering products, documentation is drawn up setting out the process and the decision-making procedures that resulted in that process. Whereas GMP rules define what must be done and observed, they do not describe how this should be achieved – and therein lies the challenge.

“It's best to start on the documentation during the planning phase”, said Molenschot. “If it's compiled any later, it can be virtually impossible to reproduce decision-making processes, so they lose much of their authority. We also apply the two-man rule to GMP.” Supplying GMP documentation to the machine builder as a service is still far from common practice in the plastics processing field – but ENGEL was prepared to do so. “The Medical business unit has been very involved with the GMP issue for a long time, so for us as a systems supplier it was a logical step to include GMP documentation in our portfolio”, said Jürgen Schulze, key account manager for automation systems at ENGEL Automatisierungstechnik

in Hagen. Although the service was offered to Helvoet from the outset, the subject was originally omitted from the contract. “We were aware that this was a new venture for ENGEL so we held back, but when we realised how open and effective the dialogue was at our initial meetings, we knew we could trust ENGEL with this key part of the project as well”, admitted Schuurs. “As a plastics processing business, of course it's a lot more efficient for us to buy a system with GMP documentation included – it cuts the cost as well as the risk.”

FMEA: the backbone of process development

Failure mode and effects analysis (FMEA) is an important element of GMP documentation. According to Jeroen Molenschot, FMEA amounts to “the backbone of all process development”. Proceeding sequentially is the key: “Nothing is actually implemented until all of the risks have been evaluated and minimised”, emphasises Schulze. In this way, the intended production process is talked through step by step and individual processes are simulated. “ENGEL worked with 3D data from the start, which was a new experience for us”, reveals Molenschot. “We virtually had the system in front of us on the table at every meeting, which meant we could discuss the details much more easily.” Technological possibilities and limits, the material impact and ambient conditions were taken into account, as were the staff members who would subsequently be responsible for the process from day to day. “To maximise security, training courses are not enough”, believes Jürgen Schulze. “We also have to make sure employees see the sense in the process flows. When you cross the road you automatically look left and right, and the work steps need to be just as ingrained. That will also help to reduce the overall risk level.”

Optimising the production process at the development phase is one positive side effect of incremental risk analysis; consequently, the GMP team also succeeded in cutting rejection risk in the system from the outset. When transferring pre-moulded parts to the mould on the second injection moulding machine, the relatively large gripper head proved problematic: to

avoid damaging the sensitive parts during transfer, a kind of docking station was integrated into the mould to centre the gripper.

The transfer of finished injection moulded parts to the assembly and packaging line is equally ingenious. Whereas the injection moulding machines produce using 16 cavities, the multi-axis robot picks up nine parts to fill the trays (each of which holds 18 cassettes). FMEA analysis was instrumental here in designing a sensor system to guarantee uninterrupted placing. “Our customer processes parts without an incoming goods inspection, and they expect us to ensure error-free production”, says Schuurs.

Building on experience

Decision-making in the project team was not only based on simulation tests, but also on the experience accumulated by Helvoet staff on earlier projects. “ENGEL really stands apart from its competitors in this regard”, said Molenschot. “In every instance, the people at ENGEL listen and ask questions before deciding whether a past problem can now be resolved with new technology, or whether it would be preferable to break new ground.” The ideal balance between requirements, risk and costs is achieved by combining the user's existing expertise in product handling and documentation with ENGEL's flair for innovative technology and new possibilities. “It makes no sense to ignore the experience that a customer already has”, confirmed Jürgen Schulze. “We found it very beneficial to exchange knowledge with long-serving Helvoet staff members.”

As the project partners agreed, the keys to success were depth of expertise, experience and open communication at all times. In this way, ENGEL came through its GMP premiere with flying colours: “The system we use to make test cassettes is now the flagship plant that we always show visiting clients”, said Bas Schuurs. “Everyone is impressed by such a perfect interplay between machines and robots.”

<<Interview:>>

As a plastics processing business, what does GMP mean to you?

Jeroen Molenschot: We have to make sure our products are in perfect order and function reliably. GMP documentation reduces the risks, even at the development stage. To me, GMP documentation is like accident insurance: you might pay contributions for your whole life without once making a claim, but if you don't take out insurance at all, one serious accident could be enough to ruin you. The point is to reduce your own risk to the lowest possible level. In the event that one of our products causes a problem, we as the manufacturer must be able to verify that we did everything technically possible to prevent that problem ever arising. To do that as a plastics processing firm, we need experience and good partners. After all, the standards don't define clear guidelines.

In your view, what is the ideal procedure?

Jeroen Molenschot: In our view, it's essential that documentation is compiled in tandem with the planning and building of the system. The most important thing is to start with the risk analysis and proceed sequentially, step by step.

Pressure on costs is increasing in the pharmaceuticals industry and medical engineering sector as well. Isn't there a great temptation in these fields to work in parallel rather than sequentially?

Bas Schuurs: Many times during the period of process development, we did feel there was more talk than action. Now, though, we realise that the success of the project was actually down to this very intensive early phase. Some issues took up more time than expected, but we made up for the delays at the commissioning stage. Given the complexity of the process, the start-up time for the plant was extremely quick thanks to good preparatory work and very honest communication.

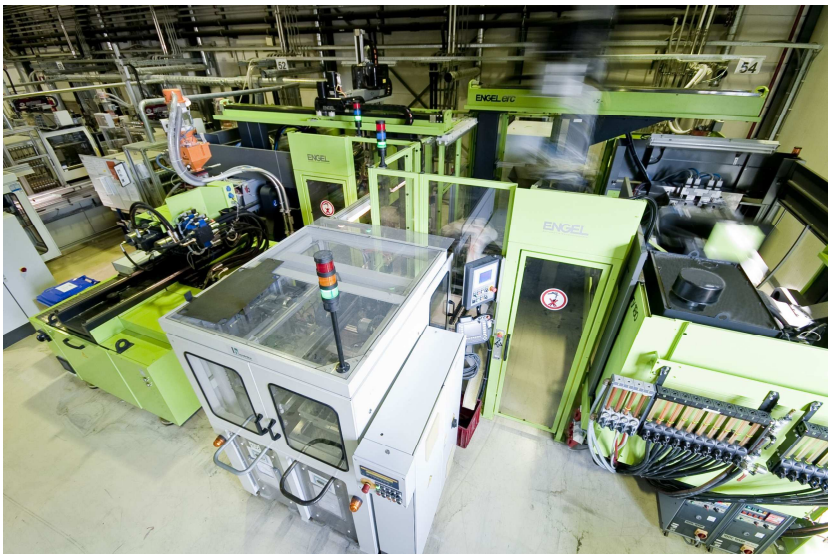
What other advice would you give to plastics processing companies addressing this area for the first time?

Bas Schuurs: The why is particularly important: you should scrutinise everything in detail, because that's the only way you'll be receptive to new solutions and means of process optimisation. Pragmatism is also needed if you want to carry on producing competitively. GMP guidelines were originally developed for the manufacture of pharmaceutical products, and the requirements of the pharmaceuticals industry cannot be compared to those of the plastics processing sector. In other words, you have to weigh up everything in the light of the practical reality of your own business and not lose sight of the product requirements. For example, not all pharmaceutical products necessarily need to be fully produced in a clean room environment. Specifications, time and costs are in a three-way relationship; if the relationship is unbalanced, the process becomes either too risky or uneconomical. Pragmatism is needed, but the number one priority is always safety and the elimination of risk.

At a glance: Helvoet

Since it was founded in 1939, Helvoet has developed and manufactured plastic and rubber products tailored to the specific needs of global clients in the automobile, food, medical engineering and pharmaceuticals sectors. Helvoet's key competitive advantages are its depth of expertise and its 70-plus years of experience in complete assemblies and functional modules. With around 600 employees and locations in the Netherlands, Belgium, India, Singapore and the United States, Helvoet can offer global support. Many of the company's clients are themselves major global players. Continual investment in know-how and production technology guarantee Helvoet customers a consistent market edge. Engineering your competitive advantage: that's the Helvoet promise.

pharmapack@helvoet.com, www.helvoet.com



The manufacturing cell comprises two injection moulding machines, two linear robots and one multi-axis robot. (Picture: Helvoet)

The multi-axis robot removes test cassettes from the mould and places them in trays for subsequent assembly and packaging. (Picture: ENGEL)

The gripper head is centred in the mould prior to the transfer of pre-moulded parts. (Picture: ENGEL)

Open communication for a successful project outcome. Left to right: Jürgen Schulze (ENGEL), Ronald van Ravenstein (Helvoet), Bas Schuurs (Helvoet), Bas de Bruin (ENGEL) and Jeroen Molenschot (Helvoet). (Picture: ENGEL)