“We are growing with PVC-free medical compounds”

Why alternatives are in demand in the pharmaceutical, medical and food industries and how Melitek manufactures them

“What we have achieved in the last ten years, we can happily repeat in the next five,” smiles Kim Laursen, who, together with his brother Jesper Laursen, is managing partner of the Danish company Melitek A/S in Alslev. What he means is the doubling of turnover that his company has achieved with the production and sale of PVC-free speciality compounds. The market for thermoplastic elastomers in the medical and pharmaceutical sectors is booming, he explains in an interview with K-PROFI, attributing this to the desire of many companies to offer phthalate-free products and specialities. Kim Laursen explains in more detail why this is the case, exactly which raw materials the company offers and on which compounding lines they are produced in an interview with K-PROFI.

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Melitek Managing Director Kim Laursen (left) relies on the compounding expertise of KraussMaffei, represented here by Managing Director Ralf Benack.

All photos: KraussMaffei

Melitek began producing its own compounds for medical and pharmaceutical products in 1998 and has gradually expanded this to five compounding lines over the last 27 years.

During the tour of the plant, Kim Laursen explains exactly what is important in compounding systems so that he and his team can produce high-quality PVC-free special compounds for customers in the medical sector.

For many years now, there has been discussion about the use of PVC compounds in the manufacture of pharmaceutical and food packaging as well as medical products such as bags for intravenous fluids, connecting tubes, catheter tubes and the like. The reason for this is the plasticisers used, in particular phthalates, which ensure that the rather brittle PVC plastic retains its flexibility and soft feel. Since phthalates are not firmly bound in the plastic, they can diffuse out of food packaging, for example, and be ingested by humans or enter the bloodstream directly from medical products. Even though the carcinogenic effect on humans has been relativised in recent years, the question of developmental and reproductive toxicity effects still remains. This is one of the reasons why many companies are looking for PVC-free alternatives and one of the reasons for Melitek's growth.

Wide range of products for many applications

Kim Laursen reports: "After initially trading in compounds for medical and pharmaceutical products, we started our own production in 1998 and have gradually expanded it over the last 27 years." Today, Melitek employs more than 60 people and operates a total of five compounding lines, including a laboratory facility for development projects and small orders. The maximum production capacity is 50,000 tonnes per annum, with orders between 1 and 2,000 tonnes of compound being fulfilled for mainly European customers according to recipes developed in-house.

The company manufactures modified PP compounds that are flexible even without plasticisers, do not absorb medicines due to their chemical resistance, are sterilisable, sealable, transparent and easy to process into films. "One advantage of PP film products made from our compounds is that they provide a good water vapour barrier and high strength, which allows the film thickness to be reduced to 200 µm instead of 350 µm for PVC," says the managing director, highlighting a sustainable advantage. The PP compounds are used for films for IV bags, food bags and dialysis bags, with one or more chambers as required.

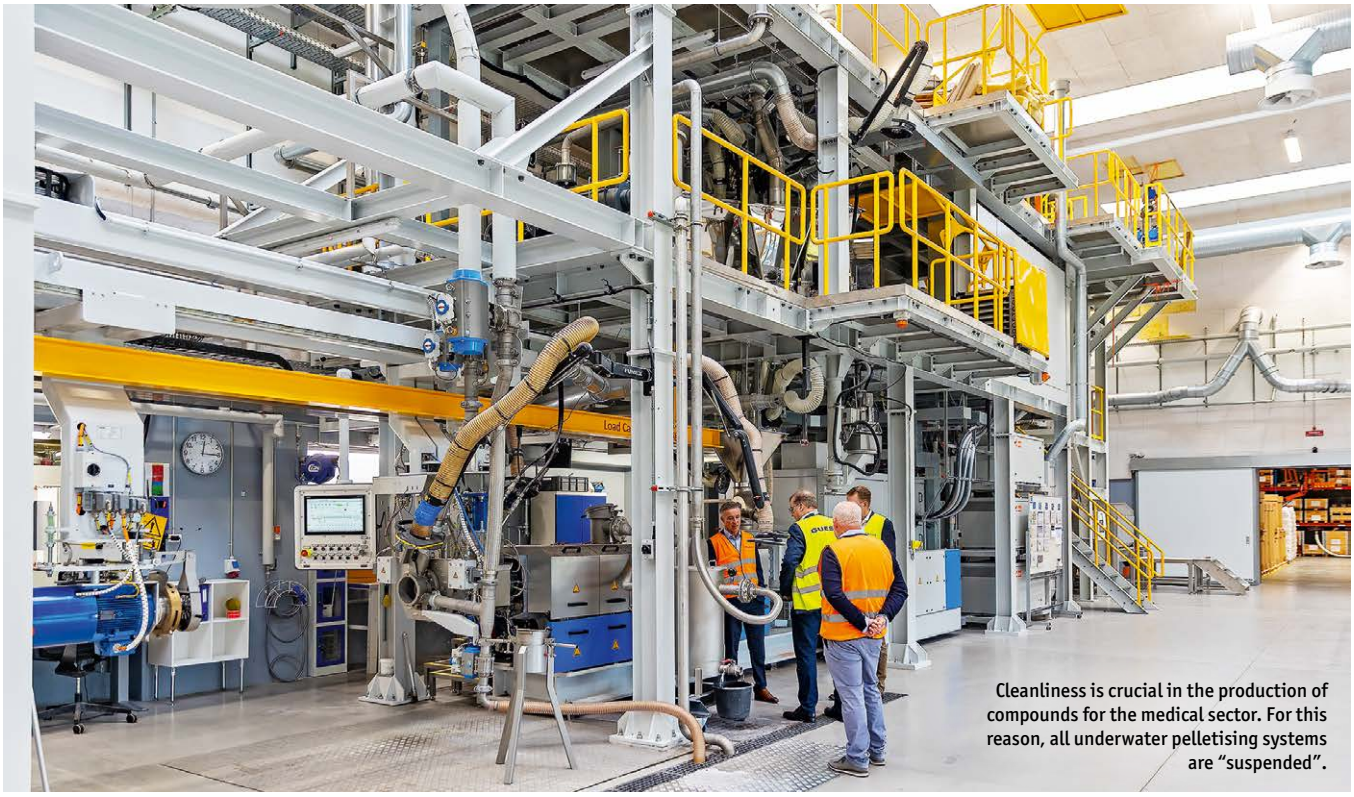
Polyolefin-based TPE and TPO compounds are also part of the Melitek range. These are used, for example, in the manufacture of medical tubing, where they score highly thanks to their durability, pressure resistance and kink resistance, combined with flexibility and softness. If medical plugs, connectors, shut-off connections or drip chambers are produced, Melitek recommends its unfilled TPE/TPO elastomers with Shore hardnesses from 10 A to 65 D. Like all compounds, they can be sterilised and exhibit good chemical resistance in use, are transparent, have good processing properties and are suitable for both overmoulding and coextrusion. "We are very pleased that our innovative raw materials have enabled us to win many customers, including some of the largest manufacturers of medical devices in Europe," says Kim Laursen proudly. Of course, this high level of acceptance did not come about by itself; after all, companies that had previously worked with PVC raw materials had to adapt their moulding and welding machinery to the new materials.

Extrusion systems in the test centre proved convincing

For its compounding systems, Melitek relies heavily on the extrusion system manufacturer KraussMaffei Extrusion from Laatzen (formerly Berstorff from Hanover). "Before purchasing our first compounding system in 1998, we ran a few test runs, back then still in Hanover. This was very important and informative for us, as we had little experience of compounding at that time." Kim Laursen purchased a compounding line with a ZE 75A UT twin-screw extruder and a laboratory system with a ZE 25A UT. He opted for complete solutions in which all components came from a single source and were coordinated with each other.

A lot has happened since then. Today, Melitek knows exactly how to manufacture its products and what is important to the company when it comes to extrusion systems. "After our business developed well, we purchased a third compounding line with a ZE 75A UTX in modular design in 2012," reports the managing director. The modular design was chosen not only because it is a particularly compact solution, but also because of its clarity and cleanliness. The entire compounding system is housed in several containers that already have a media supply and only need to be connected to each other on site.

Even though Melitek does not manufacture in a certified clean room, cleanliness is naturally essential when producing compounds for the medical sector. For this reason, all underwater pelletising systems



Cleanliness is crucial in the production of compounds for the medical sector. For this reason, all underwater pelletising systems are "suspended".

are "suspended". This means easy accessibility, flexibility and good cleanability. Next, in 2014, Melitek purchased another small system with a ZE 30A UTX.

The latest system, which was installed in 2021, is also a complete system, as before, this time with a ZE 98 from the new Blue Power series. "With an output of 3,000 kg/h, the latest system not only doubles the output of the system with ZE 75A UTX, it was also custom designed for Melitek," says Ralf Benack, Managing Director of KraussMaffei Extrusion GmbH. "Melitek attaches great importance to the protection of its employees, which is why the motor and gear block is enclosed for sound insulation," Ralf Benack continues. And Kim Laursen adds: "We are also very satisfied with the new ZE Blue Power extruder because of its low energy consumption."

For quality control, Melitek operates an FTIR spectrometer in its laboratory, which is used to regularly examine production samples.

Safety is paramount

"If we make a mistake in the production of our compounds, in extreme cases it could cost a human life," says Kim Laursen, who is well aware of the importance of accuracy and reproducibility. That is why he values the systematic approach of KraussMaffei Extrusion's systems, which enable consistent results to be achieved. "We take responsibility for quality assurance for all orders. After developing the formula, we first produce a test quantity of compound, which is checked by the customer and approved for their application before we start production." For quality control within its own company, Melitek operates an FTIR spectrometer in its laboratory, among other things, which is used to regularly examine production samples. The managing director is convinced that the journey of PVC replacement in the medical, pharmaceutical and food industries is far from over and that his company will continue to grow in the coming years.

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