



Protecting patients and operators

Faced with new regulations aimed at greater patient safety; alongside increasing demand, the protection of operators from an active agent and strict travel restrictions – how did Orion manage to be successful under these conditions?

With Uhlmann, a partner who provides security.

At the end of 2023, the EMA regulation EMA/587673/2019 will enter into force. It is intended to prevent serious errors in the dosing of the drug Methotrexate. That's good news for Marja, a fictional patient from Finland who serves in this report as an example for the at least 100 million people worldwide affected by psoriasis.

This young woman lives in southern Finland with her two children. She has her illness well under control thanks to taking Methotrexate Orion. So, how will Marja benefit as a result of regulation EMA/587673/2019? In future, she will receive the drug in a package size that better suits her application situation. Instead of a bottle containing 100 tablets, her doctor will be able to prescribe four or eight tablets, packed in a childproof manner in a blister with a folding box. This will increase patient safety because Methotrexate Disodium is also used as a cancer drug and is a highly active ingredient.

While Marja continued to struggle with her psoriasis, it was quite different challenges that faced Juha-Pekka Koskela in early 2020. This tall, calmly charismatic engineer is a project manager at Orion, the Finnish market leader in human and veterinary

medicine. Koskela needed to procure a new blister line to enable Orion to implement regulation EMA/587673/2019 in time for the cut-off date at the end of 2023 – all against the backdrop of sharply rising demand for Methotrexate. With an additional packaging line, Orion will be in a position to secure further growth and this is why it's part of a 17 million Euro project to expand Orion's plant in Turku, Finland.

Highly-active ingredients, safely packaged

In the search for a partner to implement the blister line, Koskela was guided by Orion's strategic priorities. "For us, high quality, product safety and compliance are paramount. On this basis, we maintain a competitive product portfolio, which we constantly update. In order to be able to meet these demands, we need partner companies that operate at the same high



Marja is a fictional patient who exemplifies the at least 100 million people worldwide who suffer from the skin disease Psoriasis.

Orion received an overall concept from blister machine to palletizer. When feeding the BEC 300 blister line, the contaminated filling line with vacuum unit protects the operating personnel from the active ingredient.

level of efficiency, reliability and excellence as we do – and which can supply the corresponding equipment,” he states.

Given the special circumstances in the spring of 2020, Juha-Pekka Koskela and his team had no difficulty in choosing a partner. “Orion and Uhlmann have been working together for decades. We have had very good experiences in past projects and knew that we wouldn’t have to worry about anything. I was sure the

collaboration would work online,” he says, adding mischievously, “and we couldn’t fly anywhere to look at any other line anyway because of the travel ban. So, things were clear and we signed the contract in September 2020.”

Another decisive factor was the fact that Orion and project manager Koskela were already familiar with the planned line. Orion already has two identical BEC 300 blister lines – high-performance combina-

From the standard blister machine to the customized line concept

tions of a blister machine and cartoning module – in operation. The company therefore commissioned Uhlmann to tailor a BEC 300 line to meet the following specifications:

- Overall line concept from the blister machine to the palletizer.
- Containment filling line with negative pressure to protect the operators from the active ingredient.
- Integration of a cover foil printer which, due to its size of 1.5 by 1.5 meters, had to be placed next to the line rather than on it.
- L-shaped installation with extended airgate and air extraction in addition to the pharmaceutical wall.
- Integration of the “Track & Trace” system used at Orion including the installation of the corresponding cameras.





Orion is a global Finnish pharmaceutical company that focuses on the health of its patients. Orion develops, manufactures and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. The Finnish market leader sells its products in over 100 countries, either through its numerous sales offices or through collaboration partners. Its subsidiary, Fermion, offers comprehensive CDMO services for active pharmaceutical ingredients and drugs: from development to production, packaging and marketing. Orion's headquarters are located in Espoo, with another large production facility being based in Turku. In 2021, the group of companies and its approximately 3,400 employees achieved sales of 1.041 billion Euro.

www.orion.fi

The Uhlmann team implemented this catalog of requirements in close collaboration with Orion. "For example, the contamination protection was developed in a joint, agile sub-project to which Orion contributed its experience with a similar protection solution for a tablet counter. This all worked out very well," reports Volker Rafensteiner, who managed the Orion project from Uhlmann's side.

A little over a year later, in October 2021, Juha-Pekka Koskela travelled to Laupheim with a team of technicians and operators for the Factory Acceptance Test. There, the following blister line was ready for acceptance.

- A B 1330 blister machine with SimTap infeed, which was equipped with the faster C 2305 cartoner at Orion's request,
- An Uhlmann Serialisation Platform,
- An ES 60 stretch bander
- AN ECP 12 case packer with integrated palletizer.

"The team gained a very positive impression of the line. In particular, the fact that the entire line could be monitored and operated via uniform HMI was very well received. This makes work easier and we were able

to optimally integrate the line into our network," reports Rafensteiner. "The other advantages of the BEC 300, such as the small format parts and the uncomplicated format changeover in less than 30 minutes, were already known to the operators from their own experience."

During the visit, the operational team performed several test runs themselves, with the goal being a quick ramp-up. And this what happened following the delivery in December and commissioning in March 2022. The line became productive by summer 2022.

Excellent overall package

Currently running a batch of Methotrexate Orion 2.5 mg, the BEC 300 packs two blisters with ten oblongs each into a folding box at a uniformly high speed. Juha-Pekka Koskela stands next to the line, whose compact dimensions make it a perfect fit in the existing production

environment. He seems pleased. “Today, more than a year before the directive comes into force, Orion can already deliver optimal packaging sizes and thus contribute to greater patient safety. The performance of the line also meets all expectations and we received an excellent

overall package from Uhlmann,” he says, taking stock of the situation.

Just as before, his team is in almost daily contact with Uhlmann Nordiska, the branch responsible for Finland. Although Orion carries out routine maintenance

itself, the Uhlmann experts are always available for maintenance work or repairs.

Orion plans to continue its collaboration with Uhlmann beyond this. “The collaboration between Orion and Uhlmann is to both companies’ benefit”, explains Marcus Lagestrand, Sales Manager at Uhlmann and main contact person for Juha-Pekka Koskela. “That has a lot to do with the fact that it’s not just a supplier relationship, but rather a trusting partnership of equals.”

close-up online

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“ Together with Uhlmann, we had defined key figures that we wanted to achieve as a minimum with the new equipment. Today, several weeks after the ramp-up, it is clear that we will have a better performance on a permanent basis. The total costs are also as economical as we expected

Juha-Pekka Koskela, Project Manager at Orion

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blister lines >>

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