

Csaba Kis CEO, Qualiskills, Hungary



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Csaba Kis, CEO of Qualiskills, shares his insights on the packaging capabilities of the company, its sustainable competitive advantage, the impact of the European serialization guidelines, and the company's strategic objectives for the future.

Can you introduce yourself and Qualiskills?

I am a physician and started working in hospitals, and then in parallel with the industry as an advisor in clinical trials. Thereafter, I transitioned fully to the industry side working in a myriad of facets such as medical affairs, business development and regulatory affairs before joining Qualiskills five years ago.

Qualiskills is a contract packaging company that focuses on solid dosage forms and has a capacity of 15 million boxes per year. It has 12 partners which vary between local and international pharmaceutical companies such as Egis, Mylan, and Valeant to whom it provides primary and secondary packaging services. Additionally, Qualiskills provides comprehensive services from importation, batch testing, batch releasing, warehousing, transportation, to acting as a distribution hub due to the favourable geographical location of Hungary. For primary and secondary packaging, the focus is on small and medium-sized batches as this is the challenge of the European demand. Cost-effective packaging is one of Qualiskills's strong suits, even though late-stage customizations

require an innovative approach and is a major cost driver.

To mediate the issue of technical change over time costs for small batches, Qualiskills developed a new solution of direct blister printing, called SilverLine. The aim is to cut the change over time, by producing ready-made blisters conventionally without country-specific information on the lidding ALU foil, which can then be quickly and cost-effectively customized to each market adapted to real market demand quantities.

How has the serialization directive affected Qualiskills?

With the Falsified Medicines Directive of February 9, almost all drugs within the EU had to be serialized to curb the sale of counterfeit drugs. Due to the new packaging guidelines, it has impacted all manufacturers and Qualiskills's productivity too, as it had to adapt and be compliant with the new production regulations. Similar to all other players, the target is to recuperate it by the beginning of 2020. Consequently, it caused shortages of drugs in the market.

Albeit a challenge, the new guidelines have re-emphasized the importance of packaging and customization capabilities. Many manufacturers were not prepared for these new regulations and hence there is a market need for offline serialization of finished products. Qualiskills can also assist clients at this stage of product survival and beyond.

In Hungary, and in many other countries, there is no mechanism in place by any regulatory or authoritative body that covers the running cost of serialization, loss of productivity and the investment.

What was Qualiskills's strategy to overcome the challenge of serialization?

Qualiskills is a small company and therefore can adapt to these changes more quickly than bigger organisations. Nevertheless, the hurdles were unexpected, but lessons were learned from this experience. Unfortunately there was no precedent in the Hungarian and European hub, so there was no experience to leverage on. Furthermore, it brought about IT challenges alongside the technical ones, which added to the complexity of the issue.

What packaging innovations can bring added value to the pharmaceutical industry?

SilverLine is an innovation that brings added value to the pharmaceutical industry by slashing a major cost contributor in the packaging cycle: minimizing the spillover cost to clients.

How is Qualiskills competing with contract development and manufacturing organisations (CDMO) that provide a 360-degree service?

A company that operates in a niche area delivers a more specialized product or service than a one-stop-shop company. Pharmaceutical packaging is a bottleneck for every service provider, as the complexity of this process increases continuously and depends on the local regulation too, country by country. Europe has stringent packaging regulations, yet 90 per cent of Qualiskills's revenue is generated from there, and 30% of that is from the domestic Hungarian market. Hence, in Hungary as

well as in Europe, the company can remain competitive as it provides a flexible service with a proven track record.

What are some of the challenges in the packaging sector?

Even though manufacturing and pharmaceutical sectors are strategic for the government, smaller companies lack visibility and support. For transnational guideline changes, such as serialization, some funds were available to lessen the impact. However, in the case of investing in the obligatory serialization technologies, the support is scarce for SMEs.

How would you assess Hungary's position as a pharmaceutical hub for the CEE region?

Hungary benefits from being a member state of the European Union and its geographical location, which gives it a distinct advantage. These attributes coupled with the competitiveness of the environment, make it an attractive destination to find potential partners that can service neighbouring eastern countries as well as even Nordic ones.

On that matter, this environment allowed Qualiskills to be present with all its products in more than 10 EU member states and in three of Commonwealth of Independent States (CIS). There is no need for further internationalization strategy, rather it follows the supply chain route requirements, fulfilling the needs of clients when they arise.

What are some of Qualiskills' objectives in the next five years?

The priority of Qualiskills is to retain its competitive advantages which are its cost-effectiveness, flexibility, and speed of adaptability. Nevertheless, one of the objectives is to increase capacity with the addition of new sites of similar capabilities within the next few years. The aim is to sustain the growth of the company while maintaining cost-effectiveness and flexibility.

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