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# Ex-Roche Executive Mahler On Past, Present And Future Of Swiss CDMOs

by Ayisha Sharma

With ten years of experience at Roche under his belt, ten23 CEO and co-founder talked to *Scrip* about trends in the Swiss manufacturing landscape, from pandemic-related capacity growth to increased demand for small-batch production and sustainability efforts.

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Before Switzerland became a hotbed for biopharma start-ups, the country was known for its strengths in manufacturing. In fact, there are currently 59 CDMOs with operations in Switzerland, according to the Swiss Biotech Association (SBA) directory.

One of these is ten23, a self-described "human-centric and sustainable" firm focused on producing sterile dosage forms. Its CEO and founder, Hanns-Christian Mahler, previously headed up pharmaceutical development and supplies at pharma major *Roche Holding AG* for ten years. Mahler sat down with *Scrip* at the SBA annual meeting in April to discuss all things manufacturing.

Unsurprisingly, the Swiss manufacturing sector saw a major surge in demand during the COVID-19 pandemic. "The filling of COVID-19 products was pretty much absorbing vital capacity, especially in the sterile dosage space, which led companies to increase their building capacity," Mahler said.

For instance, manufacturing major *Lonza Group AG*, which is Swiss in origin, was selected by *Moderna, Inc.* to produce the drug substance for its mRNA vaccine during the pandemic. In 2020,

the firms entered a ten-year-long strategic collaboration to this end, prompting Lonza to install additional production lines in Switzerland and the US.

While the end of the pandemic saw demand subside, "I think we're still far from a situation where there's excess capacity over demand," Mahler said. "With the general trend in healthcare towards more personalized medicines, encompassing a diversity of therapeutic modalities and patient stratification requiring separate batches, demand is still present."

However, the increasing complexity of personalized medicines has impacted manufacturing trends. "The days of just scaling up and working on single batches of a gigantic scale are probably coming to an end," Mahler said. Personalized medicines instead require production in smaller batches which must be matched to groups of patients with certain attributes, often genetic.

"At ten23, we've been manufacturing products for commercial use in the amount of 10,000 units, which 10 years ago would have may only sufficed for a clinical Phase I trial," the CEO revealed.

Many personalized medicines must be made on demand within a certain timeframe so if production falls behind schedule, or is inadequately audited, whole batches can be rendered useless. Manufacturers are thus having to utilize more detailed scenario planning and work harder against the clock.

ten23 can produce any sterile therapeutic (except for steroid hormones, beta lactam antibiotics and cytotoxics) but Mahler said there had been a recent downtick in demand for certain modalities. "Five years ago, everything was about monoclonal antibodies but now, we are working with very few monoclonal antibody programs," he said. "The standard monoclonal IgG1 has become so commoditized, and it may no longer be the most desirable option for start-ups from a mode of action standpoint."

Instead, Mahler said he had observed greater diversification within the recombinant protein and antibody space, with more firms requesting CDMO services for bispecific and multi-specific approaches or completely novel recombinant approaches. "This means it's even more important for manufacturers to understand the critical quality attributes of these products and critical process parameters," he explained.

Elsewhere, there has been a boom in the manufacturing of cell and marrow therapies but relatively little focus on enhancing related production processes. "I think cell therapies today are where antibodies were in the 80s – everyone is happy to make the cells, but often people don't really worry about formulation, stability or dosing methods, and just focus on standard infusion," Mahler said.

"We see few formulation requests for viral or cell therapy products at ten23 because most

companies and start-ups believe that any base formulation and just freezing the therapy is good enough," the CEO continued. Cryopreservation of cell and marrow therapies is most commonly done using dimethylsulfoxide, but alternative cryoprotectants are being investigated, such as sugars, sugar-alcohols and naturally occurring anti-freeze proteins.

Alternatives to cryopreservation being explored include alginate hydrogel encapsulation for short-term storage and lyophilization, better known as freeze-drying. "I hope that in the next decade, there will be a little bit more maturity in the cell and marrow therapy spaces in the form of more innovation," Mahler said.

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Another improvement Mahler said he hoped to see was enhanced sustainability in both biopharmaceutical R&D and manufacturing. "Almost 5% of greenhouse gas emissions are caused by the pharmaceutical sector which is, per revenue, more than the automotive sector," he explained.

ten23 is leading by example and started with switching to renewable energy sources back in 2021, the year it was founded, rendering the firm carbon neutral. "We implemented composting at our sites, so we have a full circular chain for organic waste, and we implemented separate plastic waste collection," Mahler said, adding that the latter is not implemented in Switzerland more broadly.

The firm is also part of the UN Global Compact program and the Pharmaceutical Supply Chain Initiative. However, "we've received questions from some individuals asking, 'How much could we save [on your services] if you weren't offsetting or didn't have these measures in place?' and that's very disappointing," Mahler said, concluding the industry needed to undergo a broader shift in mindset.