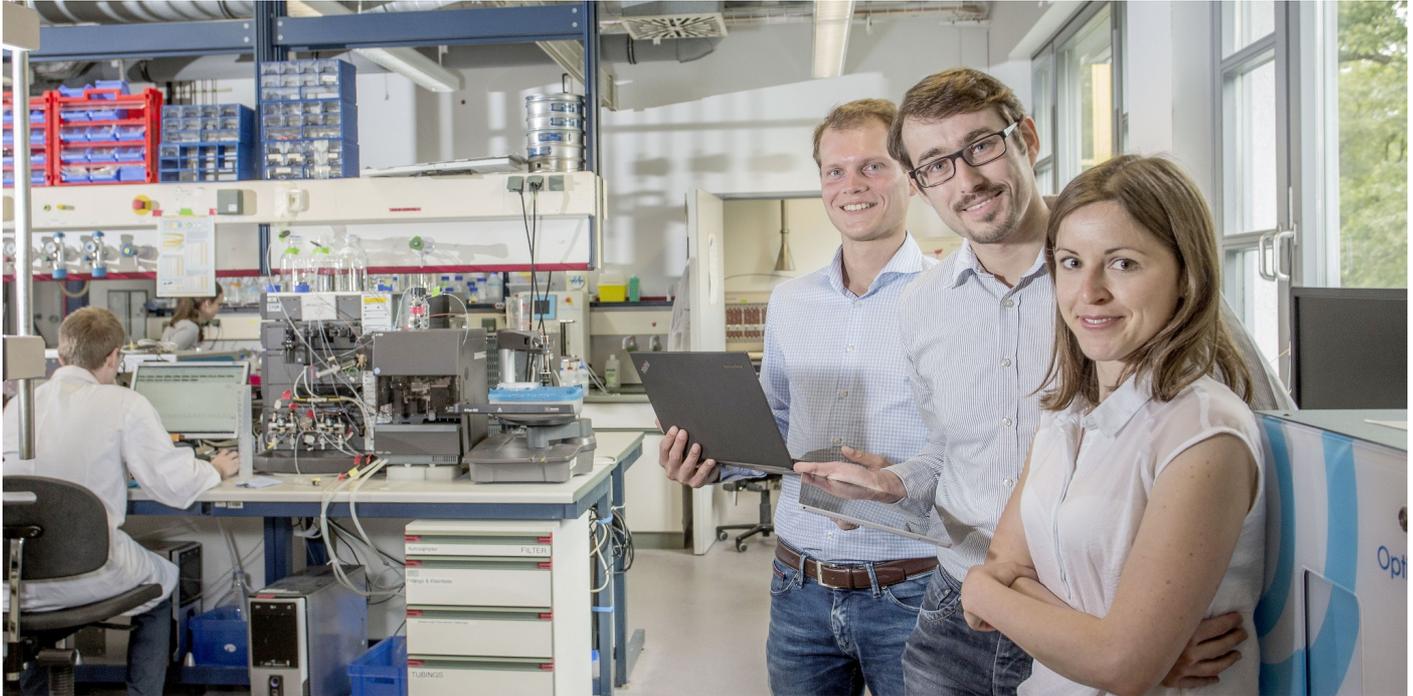


Healthcare industry BW

GoSilico: a formula for the industrial purification of biomolecules

"Stop experimenting – GoSilico" is the motto of a young start-up company from Karlsruhe. The founding team of GoSilico GmbH is causing a furore with a simulation software that would make many laboratory experiments obsolete. The chromatographic separation of biomolecules from organisms, samples and cell cultures can be reliably simulated after just a few starter experiments. This saves time, work, material and costs in pharmaceutical development.



"Stop experimenting – GoSilico" is the motto of the company founders Dr. Thimo Huuk, Dr. Tobias Hahn and Dr. Teresa Beck (from left to right).
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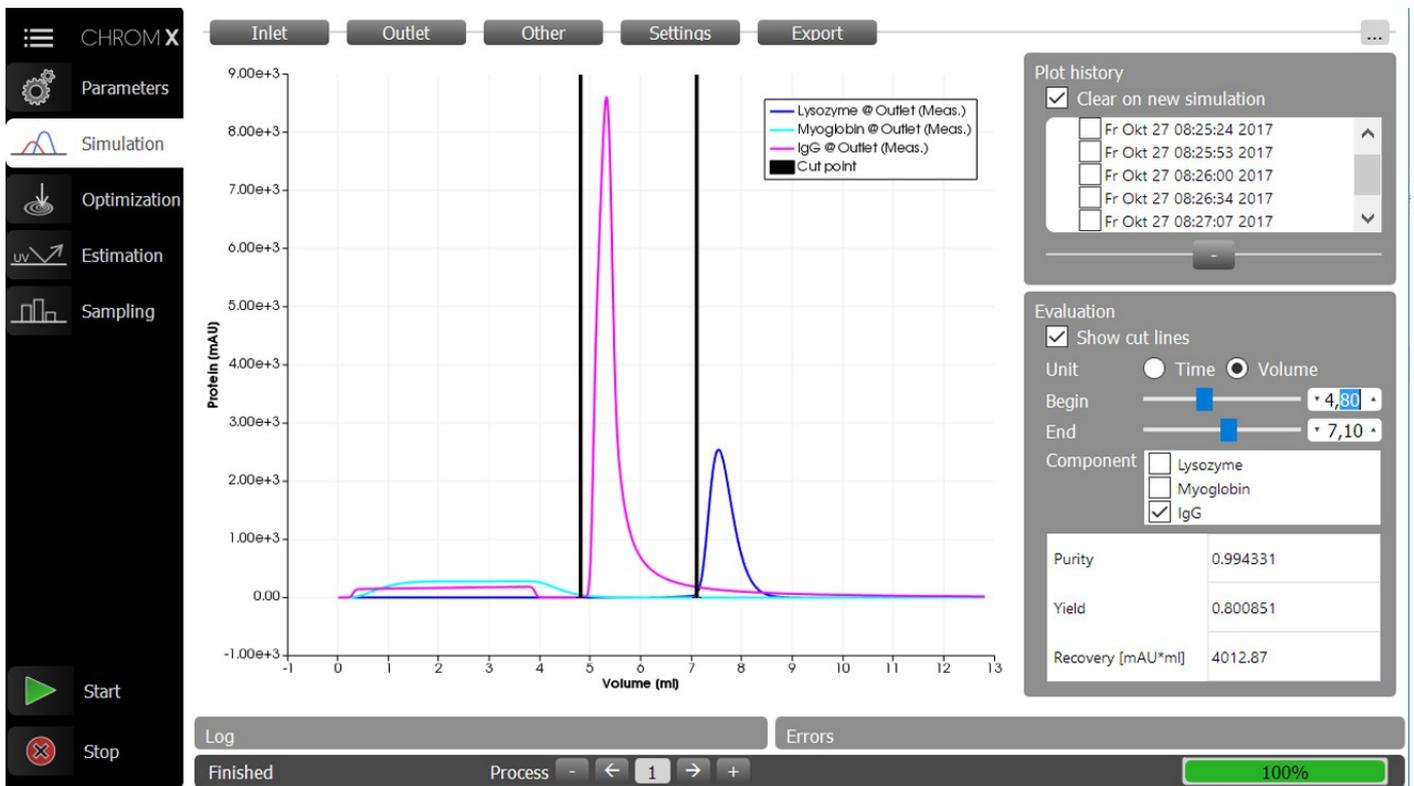
From a tool for academic applications to a top commercial product: with its simulation software for liquid chromatography, GoSilico GmbH, founded in early 2016, opens up enormous potential for savings in the development and validation of active pharmaceutical ingredients (API). Although high-throughput methods that enable the chromatographic purification of biomolecules are now well established in the pharmaceutical industry, the related technological and financial expenditures are still high – and they eat into valuable development time. This is where GoSilico's simulations come in: highly accurate and reliable simulations can be based on just a small number of laboratory experiments. "Laboratory data from conventional chromatographies are read into the software to calibrate respective models. We can then simulate the temporal and spatial changes of each component of a molecule mixture in each individual phase. In essence, our software can be used to separate all types of biomolecules," explains Dr. Teresa Beck, a founder and COO of GoSilico GmbH.

The GoSilico ChromX software is already used for the purification of antibodies, nucleic acids and insulin and supports the development of various biopharmaceuticals. According to Beck, around 95 percent of all laboratory experiments can be skipped when the GoSilico software is used. What this means exactly in euros and cents, is difficult to say. On the one hand, the technology is still too new to generate enough empirical values. On the other hand, it depends very much on the research question asked. However, Beck cites two time-saving examples: "In one case, our process characterisation software was used to obtain marketing authorisation for a new drug that would normally require around 400 experiments. Thanks to our software, it was possible to stably and robustly simulate the process and the customer saved about three months' development time. Another customer expects to be able to launch his product around six months earlier than planned thanks to the simulations."

Using simulations to bring pharmaceuticals to market more quickly and cheaply

This effectively generates tens of millions of competitive advantages, particularly when it comes to the highly competitive pharmaceutical market. This raises the question as to why nobody has come up with the idea of developing such simulation software before. One of the reasons is the expertise required for doing so. At GoSilico GmbH, the right experts in the cross-sectoral area between biotechnology and mathematics happened to come together at the right time. And all those involved were keen to start a company. The impetus for the development of the technology came from Prof. Dr. Jürgen Hubbuch from the Karlsruhe Institute of Technology (KIT), who initiated a research project to explore this issue. Dr. Tobias Hahn and Dr. Thimo Huuk are two of the founders of GoSilico who are both now CEOs of the company. Hahn began developing the technology as part of his PhD thesis in 2012, while Huuk used the simulation software in his PhD on high-throughput methods for the purification of antibodies.

The approach quickly became known in the laboratory community and the number of enquiries increased. The scientists recognised the commercial potential of the simulation software and finally made the decision to start their own business. The mathematician Beck, who boosted the capabilities of the founding team with her experience on complex weather and climate simulations, was brought on board through personal contacts. Today, the GoSilico team programmes all the software itself. The visualisation software is also developed in-house. "To our knowledge, we are the only company that offers a commercial product of this



The image shows the computer-optimised purification process of an antibody (IgG) contaminated with lysozyme and myoglobin. The simulation-based approach allows the process to be optimised to a purity of 99.4% and a yield of 80%. Only four laboratory experiments are needed to calibrate the model.
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kind - at least when it comes to separating large, complex biomolecules," says Beck.

Another unique feature of GoSilico GmbH is its comprehensive training concept. "Our customers use the software themselves. For this purpose, we grant users a one-year license and offer support for application. In addition, we offer training in the form of two to three-day courses that take place either in ours or the customer's premises," explains Beck. The company team would like to significantly reduce their training workload in the future. The software will be simplified so that it can be operated with limited prior knowledge via an intuitive, user-friendly interface. "In the medium term, we want to automate the software so that it can also be used by laboratory assistants and other laboratory staff without much training background," says Beck.

Simulated separation is expected to become standard - even in approval-relevant processes

GoSilico's overall concept has also won several awards. In 2016, the team won first place in the Baden-Württemberg-wide start-up competition "Elevator Pitch" and in 2017 it became the Karlsruhe Technology Region's "CyberChampion 2017". In addition, GoSilico, together with CEVEC Pharmaceuticals GmbH in Cologne, was able to secure EU funding: the joint project application PERMIDES that targets the development of an individualised purification process for virus-like particles was selected as the best of a total of 45 applications. CEVEC develops the cleaning process, while GoSilico contributes the simulation software and thereby considerably accelerates process development.

GoSilico also received EU support indirectly through funding in the EXIST programme run by the German Federal Ministry for Economic Affairs and Energy, which is co-financed by the European Social Fund (ESF). Later on, the company was granted funding through the Baden-Württemberg government's "Young Innovators" programme.

GoSilico's products and services are aimed primarily at pharmaceutical companies and, more generally, at laboratories involved in extensive biomolecule purification. In this context, suppliers of laboratory equipment such as absorbers are also part of the target group. At present, one third of its customers come from Germany, one third from other EU states and one third from the USA. As it expands, the young company is working hard to establish further business relationships worldwide.

Meanwhile, Beck and her colleagues continue driving forward the success of their simulation software on a completely different level. "Our goal is to establish our product as standard software in the context of approval-relevant processes in the pharmaceutical industry. In order to obtain FDA or EMA approval, pharmaceutical companies must demonstrate for many processes that they are stable and robust. Both regulatory agencies already suggest using simulations for gaining in-depth understanding of processes. However, there is still no precedent for this, everything has to be experimentally proven. We are doing our utmost to provide our customers with validation building blocks and information so that these precedent cases can be created. This also means that we will establish quality management as well as implement functionality and plausibility tests," says Beck.