

ZETA SOLUTION PATH

Interview

with Daniel Maier,
Business Line Director Engineering
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ZETA pools engineering services Solution path towards biopharma plants

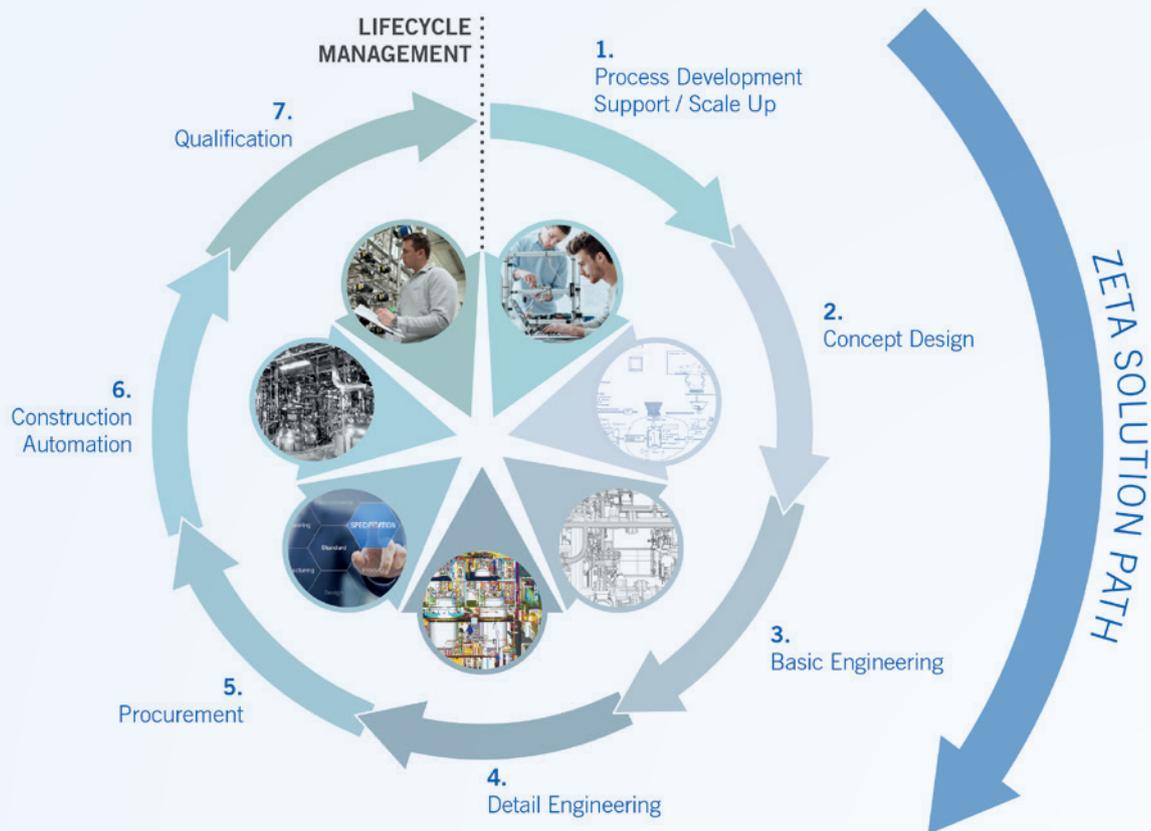
With its “Solution Path”, ZETA Biopharma accompanies customers through all stages of development of a biological medicinal product and supports them in taking the requirements of production into account at a very early stage.

As a manufacturer of biopharmaceutical plants, ZETA Biopharma is repeatedly confronted with situations where errors made during the planning phase only become apparent in the last quarter of implementation. „We are requested to accept operational guarantees but have no possibility to influence the planning process“, says Daniel Maier, Business Line Director Engineering at ZETA. This is why the company is very interested in contributing its expert knowledge more efficiently; even more so after an in-house knowledge management process showed that the know-how is far broader than realised. „ZETA has grown quickly over the past few years. With the significant growth in headcount, the engineering expertise of our company is now much larger than we had assumed“, says Maier. The specific environment of some projects makes it necessary to consider all the steps of the development process and analyse production as early as from laboratory scale.

Consequently, ZETA decided to assign the individual elements of the range of services that it offers to the biopharmaceutical industry to the individual development stages of a medicinal product. By this means, the foundation is laid for discussions with customers about their actual requirements. A vital issue in many of these meetings is the often-invoked time-to-market. Maier: „The whole industry is talking about fast-track projects. They will only work if you develop the process together with a company that is able to build plants.“

Industrial-scale manufacture in mind

The earliest point in time where ZETA can dock on to the life cycle of a biopharmaceutical agent is when the customer has mastered its production process at lab scale – i.e. during preclinical development. From this early phase on, it is possible to analyse the process with a view to industrial-scale production and develop a concept for a pilot plant. „People who develop a medicinal agent often tend to ignore aspects in this early phase that will be important at a later stage“, explains Maier. This is where ZETA comes in and accompanies customers through the entire process of clinical studies, supports the parallel scale-up to industrial scale and takes the appropriate plant engineering measures to assist a professional product launch.



This service is particularly interesting for start-up companies, many of which deal with the development of pharmaceutically active biomolecules. „Start-up companies often shy away from large contract manufacturers who are, after all, quite expensive“ according to Maier. What ZETA can offer in such cases are workshops. „We meet with the customer for one or two days and raise issues that need to be addressed“, Maier says. Consulting services of this kind are not only a form of order initiation but also a service that is paid as such; this is not least necessary due to the high risk involved in such early project phases and because the project outcome is not foreseeable at this stage. The high demand for such consulting services surprised Maier: „We are currently working on three projects where we came on board in phase II; in two other projects we have even been involved since phase I.“

While this offer of involvement in the very early stages of development is mainly geared to small and medium-sized companies, large biopharmaceutical companies can also profit from the ZETA engineering know-how to scrutinise their workflows or optimise the technology employed. This is the other end of the development process where the production of agents is analysed that are already on the market (phase IV). Maier concludes: „Our advantage is that the ZETA Group can also draw on expertise in all matters of automation.“

written by Georg Sachs,
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