

Future trends in modular pharmaceutical plants.

Herman Bottenberg, Marketing and Sales Manager at Zeton B.V.
is in conversation with Esther Schröder



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Esther: “In this feature we’d like to give Zeton’s perspective on the future of the pharmaceutical industry. Is there a specific trend that is driving change in this industry?”

Herman: “In the past year especially, the pharmaceutical industry has proven to be a crucial factor in the everyday life we all enjoy. In less than a year, vaccines had to be developed, and the technologies for this had to be rolled out globally to multiple locations and production facilities. Speed of execution and flexibility are key, and more important than ever.

“Along with this we recognise a trend towards independency, and local production in smaller quantities. More and more, continuous manufacturing will be chosen as the preferred route.

“Looking ahead, wouldn’t it be great to develop a new technology which is better suited for future products, their control and required quality, independent of location, and one that is quickly scalable at the right moment?”

Esther: “What is the current status of this change in operation in the pharmaceutical industry?”

Herman: “The trend towards continuous, smaller production, and unknown future products, requires flexible solutions. And for rapid deployment, bottlenecks have to be removed. There are various initiatives, like

Namur and VDI in Germany, acting on this, developing guidelines and standardisation on new modularisation technologies in anticipation of this.”

Esther: “Does this future outlook influence how an engineering firm has to act? What is expected by our customers?”

Herman: “We have identified a focus on modularisation of production, to develop standardised functional process modules, which can be used for multipurpose processing. The overall process is divided into smaller process sections, with each operating as its own process unit. A selection of these modules together will form a complete process plant. By including automation in each module, we create predefined and pre-validated systems, eliminating a significant amount of validation when introducing new process modules for the next product or production run.

“The challenge is to understand the overall process required to produce this future product in such a newly configured system, and this goes beyond the process hardware to include a robust automation solution. Future industry developments can use Module Type Packages (MTP) to achieve fast integration of process modules. And we believe module-to-module communication will also be required to achieve maximum advantage in speed and flexibility. Zeton has successfully applied this latter functionality to several recent projects.

“An engineering firm realizing these processes should have excellent knowledge on the individual unit operations/functional modules, understand overall process design/operation and provide a modular automation solution.”

Esther: “How did Zeton approach this?”

Herman: “When designing and building modular plants for various pharmaceutical customers in the last decade, standardization towards a modular concept has always been a key topic. We have developed a suite of standard process modules, ranging from simple pump and flow modules up to highly complex reaction and separation modules. These modules were delivered as single module assemblies and combined to form small molecules pharmaceutical and biopharma processing lines.

“A key philosophy is not changing process technologies between pilot and production scale. The modular design can then minimise

time loss between those phases. Furthermore, being standalone systems, these process modules can easily be exchanged to facilitate maintenance while the production plant remains in operation.”

Esther: “What is the pharma industry’s benefit of embracing this modular concept?”

Herman: “As the modular concept is flexible and, to a degree, independent of the process, it will be a primary tool for any future product to be developed and produced. Working with standardized process modules also ensures industry-wide alignment between production sites; the scale-up and technology transfer challenges associated with traditional processing methods are largely avoided.

“Furthermore, a backbone can be integrated into Zeton’s modular plant concept, to simplify integration at site. Feeds and utilities are run in advance to the edge of the backbone, and connected to each module through a standardized connection system, saving significant time and effort. The modular automation will also reduce the time required for process and automation validation.

“Overall, this approach offers the flexibility and speed required by our customers.”

Esther: “How does someone start implementing the modular concept? Can you start small?”

Herman: “Yes, one approach is to start small; this is the beauty of the modular concept. The process modules can be combined in the lab in a simple configuration to start with. We have had customers buying two pump modules and a reactor module, for example. Then they expand later by adding additional downstream processing modules, or parallel reaction modules. The backbone grows with the future expansion, since it is designed in a modular fashion as well.

“As an alternative to a simple starter set, we can also integrate new systems into existing facilities, and deliver complete, multi-step GMP/GAMP facilities for dedicated processes. They are fully-integrated with the site and the customer’s process control system, also referred to as Process Orchestration Layer (POL). Although we standardise the process modules, the requirements of the process, together with our customer’s specifications, defines the project scope. Zeton then tailors the modular plant solution for each customer using our established project-oriented approach.” ■