



# Engineering the future of life-saving drugs.

Taking a state-of-the-art facility from concept to market in just over two years.

*The pandemic might be winding down in Austria, but efforts by one biotech player to expand production of key protein- and DNA-based ingredients for tomorrow's drugs are moving into high gear. In just 25 months from initial concept development, Biomay has started up its new, state-of-the-art CDMO plant in Vienna. Thanks to all engineering partners, and the innovative design of the 4,000 m<sup>2</sup> high-tech facility, biomay now operates a flexible manufacturing platform for a wide range of bioproducts of virtually any batch size.*



“Every day, when I walk into this building, I feel so proud to see how we are scaling up and making a difference for so many people – enabling innovative and truly life-saving medicines for our customers’ patients all over the world,” says Dr. Hans Huber, Chief Executive Officer at Biomay.

“With our new facility, we can massively increase production volume while responding much faster to changing market demands – so we can make an even bigger impact.”

“Life-saving medicine” is certainly no exaggeration. In 2021, for example, the company announced its partnership with BioNTech SE to support the supply chain for manufacturing of the Pfizer-BioNTech COVID-19 mRNA vaccine.

### Overcoming early growing pains

Hans Huber may be feeling relaxed and confident these days, but life hasn’t always been so easy. A few years ago, the company began to hit some growth constraints. To begin with, requests for batch sizes and types were increasingly varied and frequent – sometimes even requests for personalized products. Some larger customers also wanted more plasmid DNA as starting material for mRNA, since the production of COVID vaccines simply couldn’t wait.

As a biopharmaceutical contract development and manufacturing organization (CDMO), the customers include a diverse mix of international biotech companies. However, with a maximum bioreactor capacity of just 40 liters, there were limits to what could be delivered from the older facility.

“The volume of requests was just crazy,” recalls Hans Huber.

*Biomay is a world-leading, one-stop supplier of GMP services, providing DNA plasmids, messenger RNA and other cellular materials for demanding international customers.*



“We reached a stage where we had to make a critical decision about what kind of a company we wanted to be in the future. It became clear that we needed to rethink, reimagine, and reinvest to move to the next level as a CDMO,” he recalls. “Our ambition is to be a leading one-stop supplier of GMP services with a unique position of providing DNA plasmids, messenger RNA and recombinant proteins for breakthrough drugs.”

### Growing together with VTU Engineering

In 2018, finding themselves at a crossroads, Hans Huber and his team decided that Biomay needed to scale up and build a larger facility to support their ambitious plans. To help guide them on this journey, they turned to VTU Engineering, an international technology group with extensive experience in executing large CAPEX projects in the life science industry in Europe.

*“I feel so proud to see us making a difference.”*

DR. HANS HUBER, CEO, BIOMAY AG

“I remember our initial meeting vividly,” recalls Alexander Asbäck, Managing Director and Chief Operating Officer of VTU Group GmbH. “We met up in a residential neighborhood of Vienna where their technicians were huddled in a lab doing magical things with molecules. It was so obvious to me that they really needed and deserved a new, state-of-the-art manufacturing facility.”

“We chose VTU not only because of their experience in EPCMV projects but also because of their willingness to work on flexible design solutions within a very tight budget frame,” said Hans Huber. “They listened, worked closely with our team to develop innovative solutions, and were flexible enough to accommodate our needs and collaborate with other partners.”

In its role as EPCMV contractor, VTU was responsible for bringing the project together, gathering all the necessary expertise for the required speed of execution. The next question was where to build, what to build and how fast?

### A holistic, sustainable approach

Biomay secured a site and building permits in Aspern Seestadt, a northeastern suburb of Vienna. Aspern Seestadt is one of Europe's largest urban development projects, known for its "green", eco-friendly profile. In addition to providing cutting-edge technology, sustainable design is a key part of the district's profile. And indeed, the facility is equipped with a groundwater heat pump for cooling and heating the entire building as well as solar panels for fossil-free electricity supply.



Upstream production in the GMP clean room area.

### Building a future-proof CDMO facility

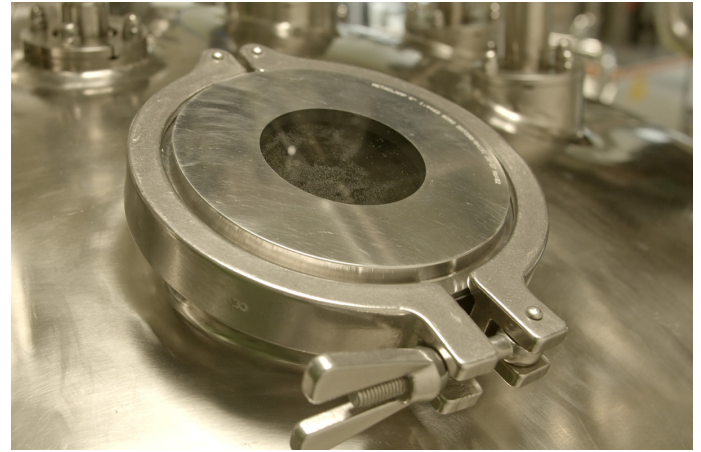
"One early engineering challenge was defining the specifications to be flexible enough to handle multiple process steps, support a future-proof design, be GMP compliant and meet a tight budget – all at once," says Alexander Asbäck. "Flexibility was our guiding star for everything."

The two-storey, multi-purpose facility is deceptively simple, stylish and has everything required for being a next-generation manufacturing plant. The classic GMP production setup follows an "upstream-downstream" seed-train flow with one key difference – there is a dedicated area for innovative, personalized (patient-specific) batches.

**"Flexibility was our guiding star for everything."**

ALEXANDER ASBÄCK, CHIEF OPERATING OFFICER, VTU ENGINEERING

Upstream, by starting with a 750-liter stainless steel fermentation tank, Biomay boosted its capacity by a factor of ten with respect to batch size and volume.



Quality in the details.

Gross bioreactor sizes are now 5L, 50L, 150L and 750L. The upstream layout, which is divided into multiple clean room areas, includes a central media supply as well as separation, cell disruption via homogenization or chemical lysis and sedimentation.

Downstream, purification steps include chromatography followed by ultrafiltration skids that can be flexibly configured via panels and mobile tanks. The aseptic filling section is designed as its own separate clean room. VTU was involved in everything from feasibility to design, procurement, and construction, including documentation and validation.

### Patient-specific treatments

One unique aspect of the design is Biomay's ability to supply personalized batches for patient-specific drugs. "Imagine creating personalized medicine for cancer patients in GMP quality within just a few weeks," Hans Huber says. Together with its customers, Biomay is now providing DNA plasmids for patient-specific tumor antigens, known as "neoantigens," as a promising new solution to cure cancer patients. "This places tough challenges on us to be innovative and creative, to meet short time frames while remaining cost-effective," he says.

### Building during a pandemic

The construction and planning of the plant, which took 25 months and began in end 2019, was finalized in January of 2022. One of the big challenges was that planning and construction took place during waves of the covid pandemic, requiring Biomay, VTU and the other partners to meet up virtually for much of the development work.

"On top of everything else, securing a safe and healthy workplace and adhering to a Zero Accidents policy for all parties was our highest priority," says Thomas Miklautsch, Managing Director of VTU Engineering who was deeply involved in the project. Since the project was crucial to



*Modern bioreactor with real-time digital monitoring.*

overall public health, vaccinations were administered early on, and physical meetings kept to a minimum. "It's ironic that we were constructing a factory for covid vaccines in the middle of the pandemic," says Thomas Miklautsch.

"In the end, we provided the complete package from A to Z – guiding them from initial concept to final certification," says Miklautsch. "We did this on time, on budget and by applying the most modern planning tools." He notes that key success factors included bringing in a wide range of competencies, using advanced engineering planning tools, and thinking out of the box.

### **Digital engineering platform**

Another process expert who was involved in the project was Gloria Galindo-Peitbuchner, Senior Process Engineer at VTU. For her, working virtually was a novel twist that took some getting used to. Equally challenging was "working smart" to set efficient engineering standards that did not yet exist at Biomay due to its rapid growth and mid-tier size. "The digital engineering platform we used was also helpful in keeping everything on track," she says. "This was critical since it provided the structure needed to move quickly and get GMP and other key certifications."

***"The digital engineering platform we used was crucial to keeping everything on track."***

GLORIA GALINDO-PEITBUCHNER, SENIOR PROCESS ENGINEER,  
VTU ENGINEERING

### **Using standardized manufacturing processes**

To avoid "overdesigning" and waiting for approvals for every small process design modification, Biomay adhered to standardized biotech manufacturing processes. This also meant sticking to standard stainless-steel equipment, versus single-use equipment with disposables, which the staff was familiar with in terms of cleaning-in-place (CIP) and steaming-in-place (SIP) sterilization. Also, instead of using a "ballroom concept" the facility was divided into smaller rooms to keep production changeover times to a minimum.

"There are always tradeoffs," says Hans Huber, "but I now feel we've got a next-generation facility that that will allow for strategic growth and offer our customers attractive manufacturing capabilities." Looking ahead and considering ongoing waves of the pandemic globally, he expects that some higher production scale will be required, even for Phase 3 clinical studies or for bringing new products to market. Not only can Biomay meet this need by also implementing single-use equipment, if required, but it also owns a plot of land behind the facility for potential future expansion.

### **Success through teamwork**

"To sum up, what made this project a success is the very good teamwork and communication with VTU and all the other contractors who brought their experience and tools to the table. Thanks to the efforts of many, we now have a sustainable and cost-optimized process facility that offers a higher degree of flexibility and can be quickly adapted to new market requirements," concludes Hans Huber.



*Bioreactors and other equipment are placed on wheels to allow for flexible batch configurations and cleaning.*

### **Biomay in brief**

- *Location: Aspern Seestadt, Vienna, Austria*
- *Ownership: Privately held company, founded 1984*
- *Multi-production GMP facility for active ingredients based on proteins, DNA and mRNA*
- *Startup: January 2022; 100 staff members*
- *GMP manufacturing: 1,000 square meters (1st floor)*

### **Capacity and products**

- *4-5 production lines*
- *Three key molecules: plasmid DNA, mRNA and recombinant proteins*
- *Gross reactor batch size: 5L, 50L, 150L and 750L*
- *Includes personalized manufacturing of tailored drugs*

### **Key EPCMV success factors**

*Strong teamwork – together with customer and partners*  
*Digital engineering platform – 3D modeling, COMOS, etc.*  
*Deep project experience – of VTU project team and partners*  
*Good communication – using remote tools in-person*

### **Five key engineering challenges**

- 1. DEFINING THE SPECIFICATIONS** of this scaleup to get it right from the start.
- 2. DESIGNING FOR FLEXIBILITY** making it future-proof for single-use buildout, etc.
- 3. SETTING ALTERNATIVE ENGINEERING STANDARDS** to tailor setup within GMP regulations.
- 4. MEETING A TIGHT BUDGET** respecting the client's budget scope.
- 5. COMPACT BUT COMPLETE** all under one roof, no compromises.

### **Main engineering partners**

**Architects:** Delta Podsedensek Architekten ZT GmbH  
**HVAC / Building Service:** TECH.CON GmbH  
**Plant and Process Engineering:** VTU Engineering GmbH  
**Process Automation:** WK-Tech GmbH