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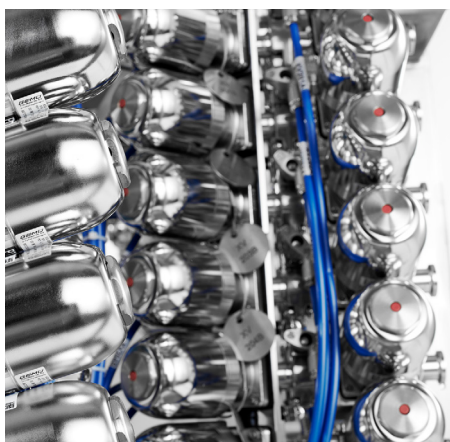
Steve received his Bachelor of Arts (B.A.) in Advertising from Marquette University and Master of Science (M.S.) in Integrated Marketing Communications from Northwestern University.

Meeting Oligo System Development Challenges Head-On

Customer-driven equipment developer leverages a longstanding, trusted partnership with supplier to redefine what is possible in oligonucleotide manufacturing.

Asahi Kasei Bioprocess America (AKBA) is devoted to solving therapeutic product safety, efficiency and purity challenges within the pharmaceutical and bioprocessing industries.

By focusing our expertise on fluid management technology, our portfolio of market-driven equipment and cutting-edge technology touches unit operations across a wide range of therapeutic modalities, including classical small molecule pharmaceuticals, current-generation antibodies, plasma derivatives and next-generation oligonucleotide therapeutics.



The GEMÜ Group is a family-owned, leading manufacturer of valves, measurement and control systems for liquids, vapors and gases – as well as a global market leader in sterile application solutions.

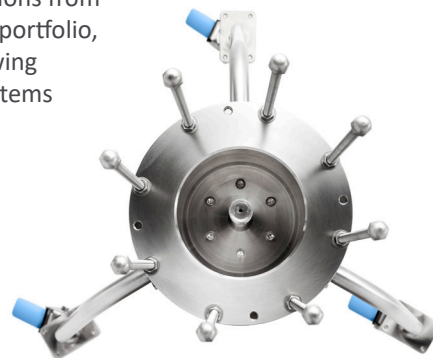
GEMÜ is committed to the pursuit of quality and excellence in the development, production and manufacturing of engineered diaphragm valves. Guided by their philosophy to consistently exceed expectations, all customer needs and technical requirements are carefully considered so only the most suitable solutions are brought forth to meet each bioprocessing challenge.

AKBA and GEMÜ align on values – particularly when it comes to putting the customer first – and use an open exchange of ideas to develop systems that push the limits of responsiveness.

MEETING THE NEEDS OF OLIGO

For decades, Asahi Kasei Bioprocess has supported oligonucleotide developers and manufacturers with novel equipment solutions from synthesis to purification. With an industry-leading product portfolio, we are helping manufacturers around the world meet growing demand through the supply of highly efficient columns, systems and automation solutions.

Prioritizing system responsiveness, AKBA builds every oligo system to be space-efficient with strong consideration placed on cleaning, drain-ability and eliminating hold-up volumes. Building skids around advanced GEMÜ valve assemblies allows Asahi Kasei Bioprocess to achieve its goals while dependably meeting customer requirements.



Questions?

Email me at steve.foy@ak-bio.com



Meeting Oligo System Development Challenges Head-On

PARTNERS IN PRODUCTIVITY

For nearly a decade, we have relied on GEMÜ's component expertise to help create equipment solutions for the pharma and bioprocess industries. Every AKBA system is painstakingly developed to meet the exact requirements of customers, no matter how unique their needs may be. And that has been the primary driver behind our continued use of specialized GEMÜ diaphragm valves. They provide a unique level of hands-on service along with an industry-leading range of valves – and can always customize exactly what we need.

AKBA and GEMÜ also align on values – particularly when it comes to putting the customer first – and use an open exchange of ideas to develop systems that push the limits of responsiveness.

It is a very rare thing that all parameters would be defined upfront in a project, so communication during development is key. As requirements evolve, AKBA and GEMÜ must remain agile – exploring different solutions while staying focused in on a singular end goal: a high-quality system with performance that will drive efficiency and productivity. With one point of contact on either side of the valve assembly process, miscommunication is mitigated, allowing projects to maintain crucial momentum.

GEMÜ's flexibility and knack for cleverly packaging together assemblies allows AKBA to create well-designed, sanitary systems built to customer-defined parameters and always with a minimal footprint.

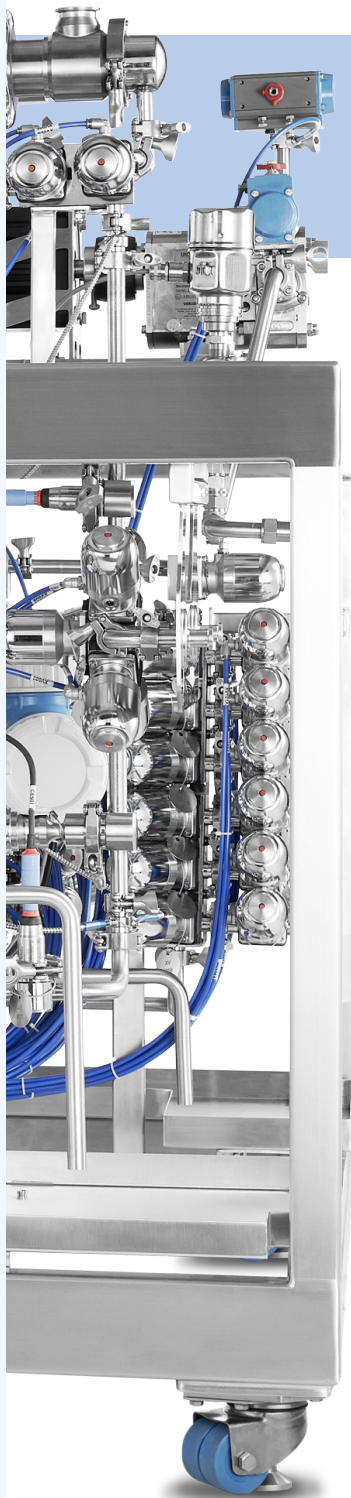
While some of the same challenges may arise for every project, each new build is an opportunity to explore and push the limits of what may be ultimately achievable. With this in mind, AKBA offers both standard and fully customizable systems. GEMÜ, fortunately, operates in much the same way – and two of our more recent projects exemplify this shared mindset:

1. Using challenging materials to create a custom Cleavage & Deprotection (C&D) system

- Machines used for oligonucleotide development must be built resilient enough to withstand the acid concentration of the fluids involved. While 316 stainless steel is the go-to for most systems across bioprocessing, in these cases other materials must be considered – namely polymer or Hastelloy.
- Utilizing different materials along the flow path – in piping or with other components – can present difficulties; but requiring Hastelloy for a valve assembly is an exceptional challenge that not every supplier can handle.
- Hastelloy is a more trying material to work with, as compared to stainless steel, with a higher price point and much more labor involvement. The added time and cost mean the valve build carries higher risk, leaving very little margin for error and must be built right the first time.



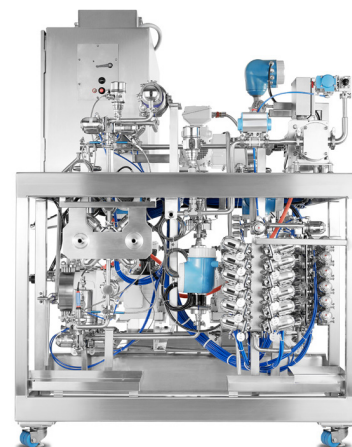
Meeting Oligo System Development Challenges Head-On



- For AKBA to develop what the customer needed, we had to trust our partners to deliver on requirements with efficiency – and this is where our longstanding relationship with GEMÜ paid off. We knew we could rely on them to give us exactly what we needed while we tackled other key project milestones along the way.
- AKBA has confidence that GEMÜ can deal uniquely well with tricky applications, and this project was no different. Our collective solution resulted in a system that met all requirements while exceeding expectations – a platform that became truly greater than the sum of its parts.

2. Developing a state-of-the-art, large-scale oligosynthesizer to achieve high performance with minimal hold-up

- We knew at the outset of this project that one of the customer's primary concerns was minimizing hold-up volumes. To address these concerns, AKBA incrementally improved its own system by 'compressing' a standard design – which was only achievable with a new GEMÜ multiport stainless-steel assembly that could facilitate compact and secure amidite delivery.
- GEMÜ's custom design drastically reduced the number of separate pieces involved in the assembly and reduced the length of pipe necessary to maintain an optimized level of production capability.
- Ultimately, AKBA was able to craft a beautifully packaged, large-scale system that radically reduced hold-up volumes while increasing process efficiency and performance.



OLIGONUCLEOTIDES ON THE HORIZON

Oligonucleotides are one of the most promising therapeutic modalities for today and the future. As more investment flows into development in this space, the push for greater safety, productivity and efficiency will become even more crucial. Advancements in metallic assemblies, single-use products and even inventory management present opportunities for suppliers to make inroads – all of which AKBA can achieve with the help of strong partnerships, as with GEMÜ.

As Asahi Kasei Bioprocess looks to the future of oligonucleotide development, we are actively pursuing incremental product/service improvements to better meet evolving needs. It is our job to set customers up for success over the long-term – to help them deliver life-saving and trusted medications to those that need them most. This is what drives us. And this is what we take into very serious consideration when it comes time to choose our own suppliers. GEMÜ has time and again come through for us, enabling a strong, trusted partnership we can count on as we continue to push boundaries, creating systems that are truly *Built For You*.

Questions?

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