



Pioneering Biologics Safety and Manufacturing Efficiency

FLUID MANAGEMENT SOLUTIONS. BUILT FOR YOU.





The Fluid Management business unit of Asahi Kasei Bioprocess is a boutique engineering group devoted to solving therapeutic product safety, efficiency and purity challenges within the pharmaceutical and bioprocess industries. By focusing our expertise on fluid management technology, we have developed a portfolio of artisanal equipment solutions. Our 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.

# Asahi Kasei Bioprocess is dedicated to unlocking efficiencies and driving productivity within your drug substance manufacturing process.

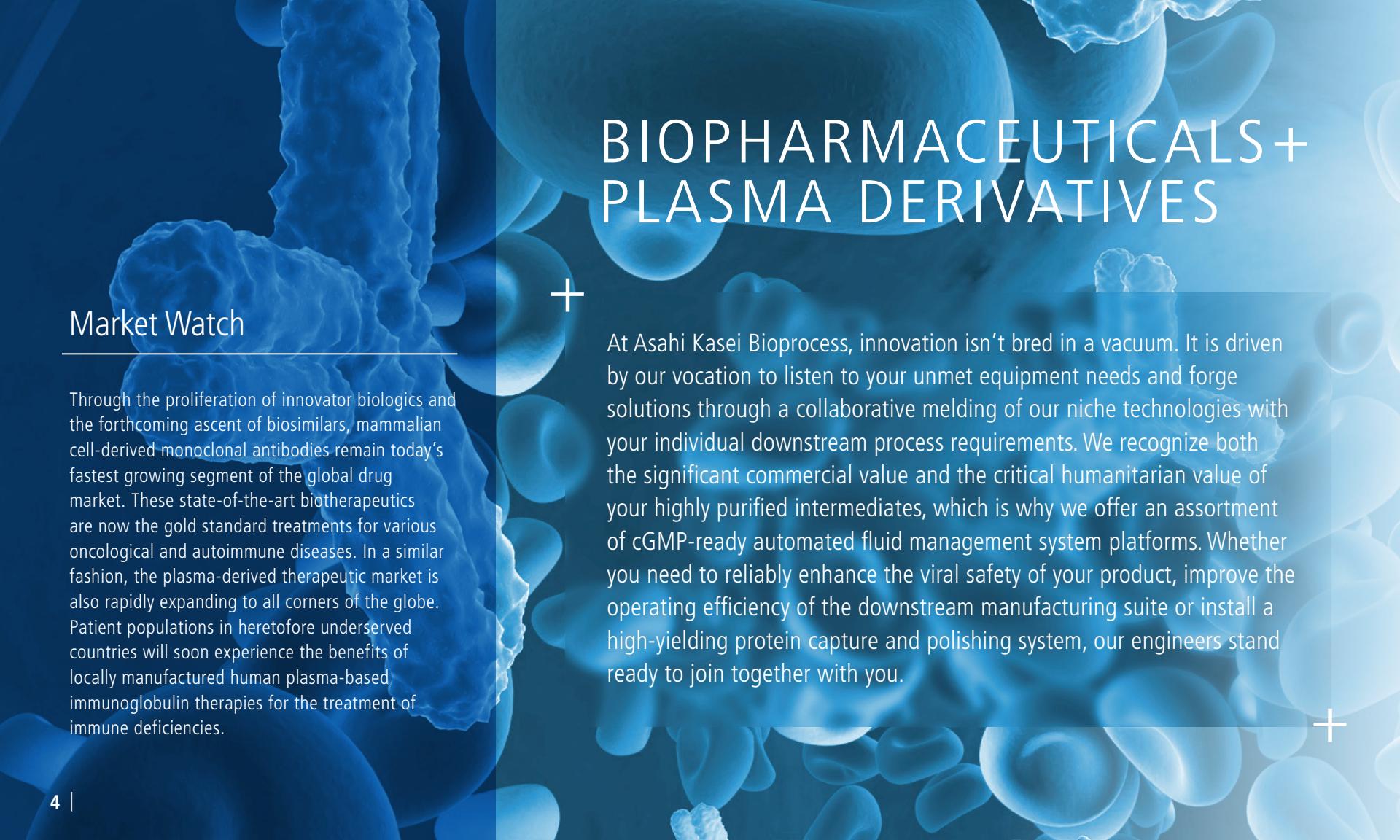


Our Fluid Management business unit combines its extensive knowledge of fluid management technology with passion for downstream processing and dedication to craftsmanship. Building on decades of engineering experience with fluid management systems, we take pride in providing equipment with the lowest possible total cost of ownership for your downstream manufacturing process. Drawing on our repertoire of custom engineered solutions, we are pleased to offer a growing suite of standard bioprocess equipment options that fit our technology into a smaller footprint for greater flexibility in "manufacturing facilities of the future". Our commitment to the quality of our manufactured equipment is rooted in the following tenet: **expectations of our customers and the expectations of our society shape the quality that we aim to create.**

Our customers engage in a myriad of sophisticated and unique manufacturing processes from the generic API manufacturer in India, to the plasma derivatives supplier in Europe, to the RNAi developer in the USA, to the multinational company with antibody manufacturing plants in the USA, Germany and China. Each has a particular set of chemical or biological manufacturing specifications. Asahi Kasei Bioprocess can provide you with an equipment solution for your particular process, as we have for hundreds of specialized installations throughout the world.

As part of the Asahi Kasei Group, we stand ready to support our customers in the United States, Europe and Asia. Our representatives are ready to serve your individual needs.

Solutions that are Built For You.



# BIOPHARMACEUTICALS + PLASMA DERIVATIVES

## Market Watch

Through the proliferation of innovator biologics and the forthcoming ascent of biosimilars, mammalian cell-derived monoclonal antibodies remain today's fastest growing segment of the global drug market. These state-of-the-art biotherapeutics are now the gold standard treatments for various oncological and autoimmune diseases. In a similar fashion, the plasma-derived therapeutic market is also rapidly expanding to all corners of the globe. Patient populations in heretofore underserved countries will soon experience the benefits of locally manufactured human plasma-based immunoglobulin therapies for the treatment of immune deficiencies.



At Asahi Kasei Bioprocess, innovation isn't bred in a vacuum. It is driven by our vocation to listen to your unmet equipment needs and forge solutions through a collaborative melding of our niche technologies with your individual downstream process requirements. We recognize both the significant commercial value and the critical humanitarian value of your highly purified intermediates, which is why we offer an assortment of cGMP-ready automated fluid management system platforms. Whether you need to reliably enhance the viral safety of your product, improve the operating efficiency of the downstream manufacturing suite or install a high-yielding protein capture and polishing system, our engineers stand ready to join together with you.



# Fluid management solutions for virus filtration



Asahi Kasei Bioprocess offers a range of multi-use and single-use systems to help you perform clinical-through commercial-scale virus filtration with Planova™ 15N, 20N, 35N or BioEX filters.



## Multi-Use Systems For stainless steel facilities

**Planova Virus Filtration Rack (VFR)**  
Ergonomic filter holder

**Planova Virus Filtration Controller (VFC)**  
Fully automated for 1.0 to 8.0 m<sup>2</sup> filter area

**Planova Virus Filtration System (VFS)**  
Custom solutions for large-scale manufacturing

## Single-Use (SU) Systems For single-use facilities

**Planova SU-VFR**  
Semi-automated system

**Planova SU-VFC**  
Fully automated for 1.0 to 4.0 m<sup>2</sup> filter area

**Planova SU-VFS**  
Custom solutions for large-scale manufacturing

## Convenient integrity testing



The Asahi Gold Particle Test System-II (AGPTS-II) automates the post-use integrity testing of Planova filters. By filtering a proprietary solution of colloidal gold particles matched to Planova filter type, the pore size distribution of the filter can be assessed. The AGPTS-II completes this gold particle test on 4.0 and 1.0 m<sup>2</sup> Planova 15N and 20N filters in less than 25 minutes and returns both an empirical value and a pass/fail reading.

Asahi Kasei Bioprocess offers a palette of specialized fluid management systems to improve safety, efficiency and purity in both mammalian cell-derived and plasma-derived biotherapeutic downstream processes.



### Asahi Gold Particle Test System-II Single and multi-filter configurations

- Reduce sample handling and offline spectrometer analysis
- Minimize manufacturing and QC labor
- Shorten product hold times based on the quick, validated QC result

# Inline buffer dilution and conditioning



Our award-winning inline buffer dilution (IBD™) fluid management platform is producing millions of liters of buffers annually in cGMP manufacturing plants throughout the world. Patented process analytical technology enables the production of reproducible diluted buffers on demand from stock solutions with up to 20X concentration. This results in a significant reduction of both capital investment and operating costs on the manufacturing floor.

## 3-Pump IBD™ Systems Cost-effective and reliable



- Available flow rates: 1000, 5000, 10,000 and 15,000 L/h
- Produce buffers constructed from up to 3 streams
- Dilution and conditioning
- Economical solution

## 5-Pump IBD™ Systems Advanced and highly flexible

- Available flow rates: 200, 1200 and 2000 L/h
- Produce complex buffers constructed from up to 5 streams
- Dilution, conditioning, mixing
- Maximum flexibility



# Contemporary biochromatography systems



Capture and polishing remain critical steps for achieving the protein purity desired in today's downstream processes. Innovative, easy-to-use Bioprocess Chrom Systems are the backbone of purification unit operations. Our bioprocess engineers can design an elegant solution based on your individual process requirements.

Equipment designed  
to respect your  
individual needs.



## Bioprocess Chrom Systems (BPC) Greater customization for capture and polishing

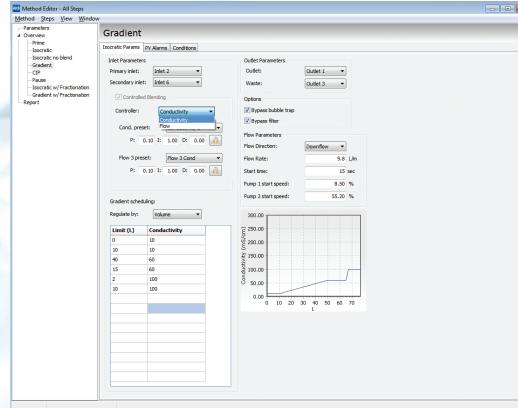
- Gain flexibility with broad gradient operating range
- Leverage modern Data Analysis Tool software for powerful post-run analysis
- Utilize inline dilution capability
- Available flow rates: 150 to 1800 L/h

## Method Editor | Data Analysis Tool

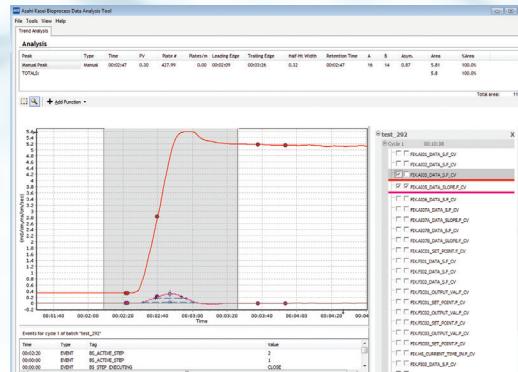
### Modern chromatography system software

Off-the-shelf chromatography systems provide familiar software, but have rigid hardware constraints; conversely, systems with customized hardware are typically burdened with cumbersome and dated software. You no longer have to compromise. With our novel Method Editor and Data Analysis Tool combined with our custom engineering prowess, you can attain a configured mechanical system design coupled with feature-rich chromatography software for the automated purification of your biotherapeutic.

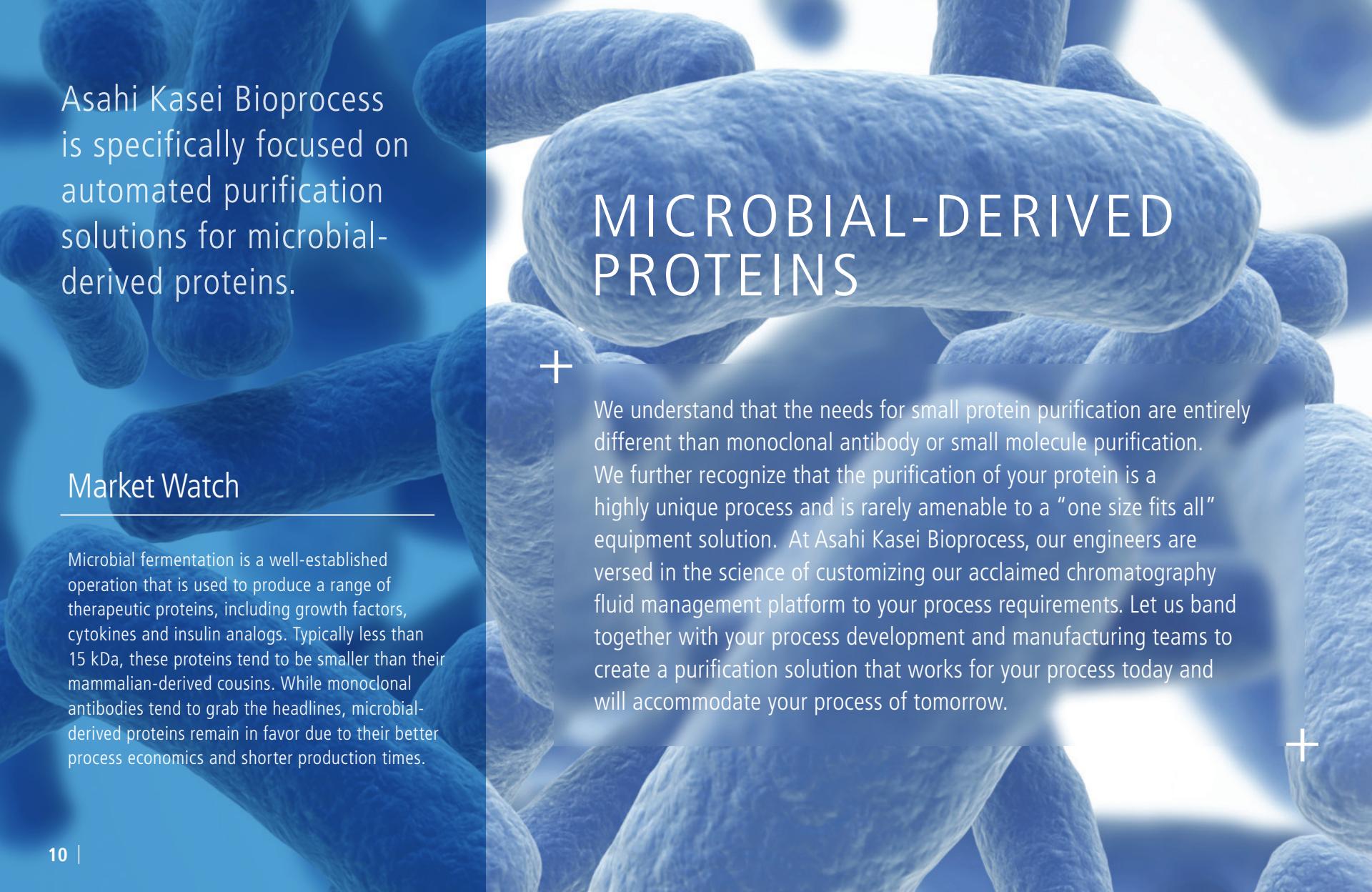
- Program sophisticated multi-step gradient elutions and fractionation routines
- Analyze chromatography peaks for HETP and asymmetry, or leverage frontal peak analysis
- Overlay up to hundreds of multiple historical trends



Method Editor



Data Analysis Tool



Asahi Kasei Bioprocess is specifically focused on automated purification solutions for microbial-derived proteins.

## MICROBIAL-DERIVED PROTEINS



We understand that the needs for small protein purification are entirely different than monoclonal antibody or small molecule purification. We further recognize that the purification of your protein is a highly unique process and is rarely amenable to a "one size fits all" equipment solution. At Asahi Kasei Bioprocess, our engineers are versed in the science of customizing our acclaimed chromatography fluid management platform to your process requirements. Let us band together with your process development and manufacturing teams to create a purification solution that works for your process today and will accommodate your process of tomorrow.

### Market Watch

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Microbial fermentation is a well-established operation that is used to produce a range of therapeutic proteins, including growth factors, cytokines and insulin analogs. Typically less than 15 kDa, these proteins tend to be smaller than their mammalian-derived cousins. While monoclonal antibodies tend to grab the headlines, microbial-derived proteins remain in favor due to their better process economics and shorter production times.

# Specialized chromatography equipment for small proteins



Purification of microbial-derived proteins often involves ion exchange chromatography in aqueous eluents and reverse-phase chromatography in a combination of aqueous/organic eluents; in either case, the risk of microbial contamination is real. With this in mind, Asahi Kasei Bioprocess supplies sanitary dynamic axial compression (DAC) medium-pressure liquid chromatography (MPLC) and high performance liquid chromatography (HPLC) columns and systems to carry out ion exchange and reverse-phase gradient separations.



## DAC MPLC and DAC HPLC Columns Sanitary design

- MPLC columns for applications that generate back pressure of <20 bar
- HPLC columns for 70 to 100 bar applications
- Interior electropolishing and sanitary connections
- Available in diameters from 6 to 160 cm i.d.
- DAC Ergo option for safe column handling



## MPLC and HPLC Systems Reproducible gradient formation

- Reverse phase and ion exchange gradient systems
- Sanitary eluent pumps, sensors and piping to maintain quality standards
- Compatible with organic solvents for use in hazardous areas
- Available in flow rates from 60 to 2400 L/h

# OLIGONUCLEOTIDES

## Market Watch

The relatively young therapeutic oligonucleotides industry is rapidly approaching an inflection point. Promising signs include an uptick in financial valuations of nucleic acid drug developers and recent technical triumphs achieved by oligonucleotides scientists, such as overcoming drug delivery issues. Further, sponsors may achieve success with their strategy to pursue targeted orphan drugs. Taken together, we now see dozens of therapeutic oligonucleotide programs advancing through late-phase clinical trials, perhaps a leading indicator of the fulfillment of the momentous potential of gene-silencing technology.

The book is still being written on the scale-up of oligosynthesis and purification processes. At Asahi Kasei Bioprocess, we bring a decade of experience to every oligonucleotide synthesis and purification equipment project that we undertake, continually improving our platform as we gain valuable feedback from both sponsors and contract manufacturers. This wealth of knowledge allows us to understand that oligonucleotides are a rather unique breed of therapeutic—chemically synthesized, yet much larger in size than classic small molecules. Hence, our engineers employ a hybrid approach when designing manufacturing-scale equipment for oligonucleotides, blending the best of antibody equipment and small molecule equipment design principles together to generate the ideal solution specifically for your oligonucleotide.

# Efficient large-scale synthesis of oligonucleotides



The increasing number of antisense oligonucleotides, aptamers and RNAi-based drugs entering Phase II or Phase III clinical trials highlights the need for rapid, economical process scale-up. By pairing Asahi Oligosynthesizer™ and Asahi SCS Columns™ with sanitary MPLC or HPLC Columns and Systems, process engineers can increase throughput and drive down costs during late-stage manufacturing.

Asahi Kasei Bioprocess is your partner for oligosynthesis and purification process equipment.



## Asahi Oligosynthesizer™ Solid-phase flow-through oligosynthesis

- Leverage the throughput of a patented, two-pump system with the highest coupling efficiency
- Minimize reagent carryover and maintain quality with ultra-hygienic pumps and patented valve manifolds
- Available in capacities from 30 mmol to 2.5 mol

## Scalable flow-through oligosynthesis columns



Mid- to large-scale oligosynthesis has moved from using legacy mixed bed reactors to more efficient flow-through column formats. Whether using a swellable solid support or a more rigid support, Asahi Kasei Bioprocess offers a synthesis column to meet your scale-up needs.

### Asahi SCS Column™

Leading synthesis column for scale-up



- Manually adjust bed heights between 2 and 15 cm for packing swellable or rigid supports
- Accommodate linear velocities used for oligosynthesis
- Maximize coupling efficiency using CAD-modeled “active” flow distributors
- Available in diameters from 10 to 100 cm i.d.

### Asahi ACS Column™

Advanced design for rigid supports



- Leverage simplified packing and unpacking
- Accommodate linear velocities used for oligosynthesis
- Maximize coupling efficiency using CAD-modeled “active” flow distributors

# Advanced oligonucleotides purification equipment



The purification of oligonucleotides can require reverse-phase or ion exchange chromatography operating at higher pressure than bioprocess chromatography. Additional special requirements may include operating at high temperatures or over a broad range of gradient conditions. Asahi Kasei Bioprocess is a proven leader in the supply of purification equipment that solves these challenges and more.



## DAC MPLC and DAC HPLC Columns Leading oligo purification column

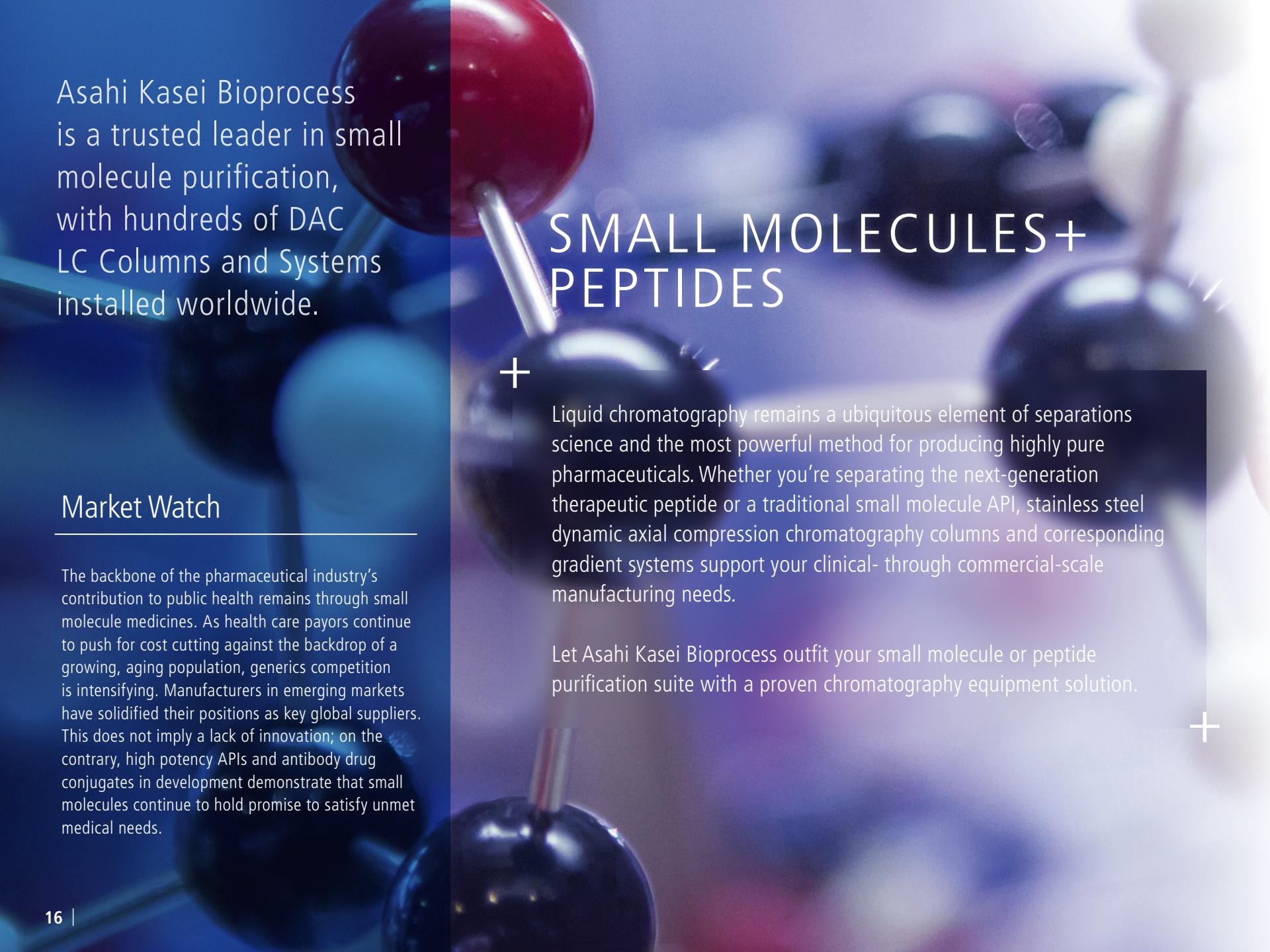
- Accommodate most processes with 20 bar MPLC columns and 70 to 100 bar HPLC columns
- Control column temperature with jacketing and/or sheathing
- Leverage electropolishing and sanitary connections
- Maximize oligonucleotide yields with operating temperatures up to 80 °C
- Available in diameters from 6 to 160 cm i.d.



## MPLC and HPLC Systems Reproducible and precise gradients

- Easily perform both ion exchange and reverse phase gradients for oligonucleotide elutions
- Leverage electropolished surfaces, Tri-Clamp® connections and sanitary-grade components
- Compatible with organic solvents for use in hazardous area
- Available in flow rates from 60 to 2400 L/h

Tri-Clamp is a registered trademark of Alfa Laval, Inc.



Asahi Kasei Bioprocess  
is a trusted leader in small  
molecule purification,  
with hundreds of DAC  
LC Columns and Systems  
installed worldwide.

## SMALL MOLECULES + PEPTIDES

### Market Watch

The backbone of the pharmaceutical industry's contribution to public health remains through small molecule medicines. As health care payors continue to push for cost cutting against the backdrop of a growing, aging population, generics competition is intensifying. Manufacturers in emerging markets have solidified their positions as key global suppliers. This does not imply a lack of innovation; on the contrary, high potency APIs and antibody drug conjugates in development demonstrate that small molecules continue to hold promise to satisfy unmet medical needs.

Liquid chromatography remains a ubiquitous element of separations science and the most powerful method for producing highly pure pharmaceuticals. Whether you're separating the next-generation therapeutic peptide or a traditional small molecule API, stainless steel dynamic axial compression chromatography columns and corresponding gradient systems support your clinical- through commercial-scale manufacturing needs.

Let Asahi Kasei Bioprocess outfit your small molecule or peptide purification suite with a proven chromatography equipment solution.

# Trusted small molecule purification columns



We understand that different small molecule and peptide purification applications require different grades of chromatography media for optimized economics. Asahi Kasei Bioprocess offers a range of DAC column pressure ratings from Flash to HPLC, to our new ultra high performance liquid chromatography (UHPLC) columns. Pair your column with a suitably pressure-rated industrial chromatography system, available in isocratic or gradient configurations.



## DAC Flash LC Columns

Applications up to 10 bar

- Purify small molecule APIs with irregular silica in organic environments
- Accommodate longer packed bed heights between 35 and 70 cm
- Implement pneumatically or hydraulically driven operation with a maximum column diameter of 160 cm i.d.

## DAC HPLC Columns

Applications between 70 and 100 bar

- Purify peptides, enantiomers and APIs
- Employ the lowest height requirement of any DAC column
- Suitable for organic environments
- Available in diameters from 6 cm to 100 cm i.d.

## DAC UHPLC Columns

Applications up to 200 bar

- Purify difficult peptides using reverse-phase chromatography with maximum resolution
- Tolerate higher pressure than conventional prep HPLC
- Utilize silica gels as small as 5 µm in columns with diameters from 10 and 60 cm i.d.

# Industrial liquid chromatography systems



For process engineers performing reverse-phase peptide separations or normal-phase chromatography involving small-molecule APIs in organic eluents, industrial Flash, HPLC and UHPLC Systems offer a broad gradient operating range. These systems include our renowned Method Editor and Data Analysis Tool software and are available at flow rates from 1 to 60 L/min.



**Flash LC Systems**  
Applications up to 10 bar

- Economical large-scale purification systems
- Include automated fractionation and UV detection
- Electrical protection for installation in hazardous areas

**HPLC Systems**  
Applications between 70 and 100 bar

- Advanced gradient capability for either normal phase or reverse-phase gradient elutions
- 21CFR Part 11 compliant software
- Compatible with organic solvents

**UHPLC Systems**  
Applications up to 200 bar

- Purify the most challenging peptides with maximum resolution
- Tolerate higher pressure than conventional preparative HPLC
- Deliver consistent gradients to UHPLC columns

## Quality Policy

Asahi Kasei Bioprocess America, Inc. is committed to providing high quality and innovative equipment and filtration solutions within the bioprocess and pharmaceutical industries. This commitment is driven by



### QUALITY

Sustaining an effective Quality Management System in conformance with ISO 9001:2015

### SATISFACTION

Meeting customer needs and requirements with high levels of customer satisfaction

### IMPROVEMENT

Continually improving our quality systems and products

### VALUES

Encouraging and empowering our employees to embody the company values of Sincerity, Challenge, Creativity, Wisdom, Curiosity, Growth, Passion and Responsibility

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