Liquid Chromatography Systems

Reproducible gradient formation and cutting-edge software for today’s purifications

AsahiKASEI BIOPROCESS

FLASH | MPLC | HPLC | UHPLC
Built For You.

Asahi Kasei Bioprocess is dedicated to unlocking efficiencies and driving productivity within your small molecule, peptide, oligonucleotide and microbial-derived protein purification processes.

At Asahi Kasei Bioprocess, our engineers understand that there is no “one size fits all” chromatography system in the world of large-scale purification. We know that small molecule manufacturing facilities may require a cost-effective flash chromatography system for normal phase purification. Meanwhile, the oligonucleotide clinical-scale facility may need a sanitary Medium Pressure Liquid Chromatography (MPLC) System equipped for ion exchange gradient elutions. And the insulin purification facility may need a sanitary High Performance Liquid Chromatography (HPLC) System to generate accurate solvent gradients for reverse-phase elution.

Drawing on our decades of experience of custom engineered solutions, Asahi Kasei Bioprocess is pleased to offer a Liquid Chromatography (LC) System platform that is configurable to the unique purification requirements of your molecule. Systems are available in capacities suitable for process development/scale-up, clinical manufacturing and commercial manufacturing.

To learn more about antibodies and other bioprocess chromatography applications, refer to our Bioprocess Chrom Systems Brochure.
Streamline Your Purification Process

Preparative- to production-scale LC remains one of the most powerful separation processes in the production of pharmaceuticals. Motivated by a passion for downstream processing and a desire to foster your purification of therapeutic small molecules, Asahi Kasei Bioprocess integrates flexible functionality and advanced automation into a range of scalable LC Systems to reduce operating costs and minimize downtime.

A Family of Systems for Your Unique Application

**HPLC Systems**

Classic small molecule and small protein purification processes utilizing 10 to 15 µm chromatography media will generate backpressures of 70 to 100 bar. Such applications typically require linear gradients to achieve the desired product purity. Our HPLC Systems meet the required pressure rating while offering an array of flexible gradient technology options to fit your needs—whether it is normal phase, reverse-phase or chiral chromatography. Industrial configurations are available for small molecule and peptide applications, while sanitary configurations can be applied to microbial-derived protein applications.

**UHPLC Systems**

With the ongoing trend toward the use of chromatography media with smaller particle sizes in analytical chromatography, new impurities are being identified that cannot be separated at preparative scale by conventional HPLC. Asahi Kasei Bioprocess has acknowledged this trend by launching a line of large-scale gradient Ultra High Performance Liquid Chromatography (UHPLC) Systems which operate at pressures up to 200 bar. Now, challenging peptide separations which require the use of 5 µm reverse-phase silica gel can be separated with consistent linear gradient formation and shorter run times.

**MPLC Systems**

Many mid-sized therapeutics in the 4 to 15 kDa range, such as microbial-derived proteins and oligonucleotides, are purified using 15 to 40 µm chromatography media. Such processes generate higher backpressures than can be accommodated by a typical 6 or 10 bar system but don’t require the pressure rating and upfront capital cost of traditional preparative HPLC. For over a decade, Asahi Kasei Bioprocess has been a leader in 20 bar MPLC Systems for these applications. Both ion exchange and reverse-phase gradient elutions can be accommodated.
Flash Systems

For rapid cleanup of small molecules using 40 to 63 µm or for larger irregular silica gels, Asahi Kasei Bioprocess offers industrial Flash Chromatography Systems. These economical large-scale purification systems are designed for both normal-phase and reverse-phase applications that are operated at pressures up to 10 bar with optional UV detection and automated fractionation to maximize yields and decrease costs.

Table 1. LC System recommendations based on the type of molecule being purified.

<table>
<thead>
<tr>
<th>End Product</th>
<th>Chromatography Mode</th>
<th>Recommended LC System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oligonucleotides</td>
<td>Ion exchange</td>
<td>Reverse-phase</td>
</tr>
<tr>
<td>Peptides</td>
<td>Reverse-phase</td>
<td>HPLC</td>
</tr>
<tr>
<td>Microbial-derived proteins</td>
<td>Ion exchange</td>
<td>Reverse-phase</td>
</tr>
<tr>
<td>Enantiomers</td>
<td>Normal-phase</td>
<td>HPLC</td>
</tr>
<tr>
<td>Small molecules</td>
<td>Normal-phase</td>
<td>HPLC</td>
</tr>
<tr>
<td>Small molecules (rapid cleanup)</td>
<td>Normal-phase</td>
<td>Flash</td>
</tr>
</tbody>
</table>

Key Features for the Chromatographer

Borne from two decades of providing LC Systems for GMP production around the globe, our LC Systems include various standard features that will improve the efficiency of your process. Features include the following:

- Broad gradient operating ranges
- Low pulse flow to the column
- Dual channel variable wavelength UV detectors
- Pressure and flow measurement
- Fractionation by volume, CV, UV or percentage of peak height
- Live and historical signal trending
- Extension of the gradient during a run
- Blend percentage hold
- Built-in software phase for system clean-in-place (CIP)
- Alarms and audit trails
Explore the Benefits of Gradient Accuracy

Precise, reproducible step or linear gradient elutions help maximize process economics and peak separations during LC applications. We have been at the forefront of large-scale gradient mixing technology for over a decade. During this time, we’ve accumulated a wealth of knowledge and practical expertise building a variety of LC Systems to create binary and ternary gradient blends for process engineers seeking to purify oligonucleotides, adjuvants, peptides, interleukins and insulin.

Each of these therapeutics has unique process requirements, and our LC Systems are engineered with this flexibility in mind. Choose from our renowned, best-in-class adaptive process analytical technology (PAT) configuration with conductivity or near-infrared (NIR) feedback control, or our flow control configuration for multi-purpose gradient blending. Alternatively, we can design high turndown configurations or customize a solution to accommodate your purification needs.

Gradient Mixing Technologies

1. Low Pressure Gradient Mixing
   - Control valves proportion eluents
   - Mixing is on low pressure side of pumps

A. Classic Low Pressure Gradient Mixing

B. Enhanced Low Pressure Gradient Mixing

Controller type: Adaptive PAT control or flow control
Eluent supply: Pressurized
Turndown: Up to 30X
Accuracy: ± 2%
Availability: Flash, MPLC, HPLC, UHPLC

Controller type: Adaptive PAT control or flow control
Eluent supply: Unpressurized/minimally pressurized
Turndown: Up to 90X
Accuracy: ± 2%
Availability: Flash, MPLC, HPLC, UHPLC
2. High Pressure Gradient Mixing

» Pumps proportion eluents
» Mixing is on high pressure side of pumps

3. Ternary Low Pressure Gradient Mixing

» Three control valves proportion eluents
» Mixing is on low pressure side of pumps
» Ideal for combination aqueous/organic elutions

Controller type: Flow control
Eluent supply: Unpressurized/minimally pressurized
Turndown: Up to 90X
Accuracy: ± 2%
Availability: Flash, MPLC, HPLC

Controller type: Adaptive PAT control or flow control
Eluent supply: Pressurized
Turndown: Up to 30X
Accuracy: ± 2%
Availability: MPLC, HPLC

Choose from Industrial and Sanitary Flow Paths

For small molecule and peptide chromatography processes run in organic mobile phases, our industrial flow path option is a cost-effective solution. Rugged stainless steel construction is augmented with threaded connections and compression fittings for leak-tight connections.

For oligonucleotide or microbial-derived protein purifications that mainly utilize aqueous mobile phases with limited use of organics, or for highly potent active pharmaceutical ingredient (HP-API) purifications where minimized system hold-up is desired, our sanitary flow path option is an attractive feature. Sanitary eluent pumps, electropolished 316L stainless steel piping, high purity ball valves and zero-static diaphragm valve manifolds for fractionation reduce carryover and support good system cleanability. All wetted parts are fully traceable, and material certificates are available.

Sanitary triple-head eluent pump

Table 2. Flow path based on the type of molecule being purified.

<table>
<thead>
<tr>
<th>End Product</th>
<th>Recommended Flow Path Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small molecules</td>
<td>Industrial</td>
</tr>
<tr>
<td>Small molecules (HP-API)</td>
<td>Industrial</td>
</tr>
<tr>
<td>Enantiomers</td>
<td>Industrial</td>
</tr>
<tr>
<td>Peptides</td>
<td>Industrial</td>
</tr>
<tr>
<td>Oligonucleotides</td>
<td>Sanitary</td>
</tr>
<tr>
<td>Microbial-derived proteins</td>
<td>Sanitary</td>
</tr>
</tbody>
</table>
Software Designed for You

Method Editor

Off-the-shelf chromatography systems may 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.

Our batch engine is a feature-rich program called the Method Editor. Developed and enhanced over the past decade, the Method Editor includes advanced recipe management and method configuration that can be easily managed by new users, but is sophisticated enough for the savviest chromatography professional.

At its core, the Method Editor permits quick and simplified configuration of methods by linking together preset step types, such as Equilibration, Sample Loading, Gradient, Fractionation and CIP.

Simple, yet powerful method configuration for the savviest chromatographer.

» Multi-step gradients can be programmed in one simple step
» Sophisticated fractionation can be executed by time, volume, column volume, UV, conductivity or percentage of peak height
» End Conditions for a step are based on time, UV, volume, column volume, conductivity or other parameters

Data Analysis Tool

The Data Analysis Tool (DAT) software alleviates the need for offline data manipulation by automating many of the key analytical chromatography functions. Available post-run calculations include the following:

» Area under the curve
» Asymmetry
» Height equivalent to a theoretical plate (HETP)
» Frontal peak analysis (FPA)
» Overlay of hundreds of historical trend data
(UV, conductivity, pH, pressure, flow, temperature, etc.)

A number of effective functions for today’s large-scale chromatographer.
Automation Features

» Manual or automated control
» Flexible programming of isocratic, gradient and sample loading steps
» Step regulation by time, volume or column volume
» Sophisticated fractionation routines ideal for both process development and production runs
» 21CFR Part 11 capability with electronic signature and audit trail
» Data export
» OLE (Object linking and embedding) process control (OPC) compatibility
» Customizable batch reports
» Optional GAMP-5 lifecycle documentation

LC Systems can be operated with either a local system-mounted Industrial PC (IPC) or a remote desktop PC.

Enjoy the Freedom of Customization

Standard configuration LC Systems suitable for typical applications are available with short lead times. However, we recognize that your unique purification processes or multi-product applications may require an LC System that is different than the standard offerings. In keeping with our focus on artisanal fluid management, Asahi Kasei Bioprocess has an experienced staff of engineers and designers who will craft you a customized solution based on our standard LC System platforms. Customizable options include the following:

» Number of inlet ports or fractions
» Spill-free connections
» Sample pumps
» End-of-stream air sensors
» Prefilters
» Sample injection loops
» Heat exchangers
» Software customization
» Hazardous area ratings (NFPA and ATEX)
» Modified footprints to fit into tight spaces and within fume hoods

We are dedicated to driving productivity within your drug substance purification process.
## Ordering Information

### HPLC Systems

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Typical Flow Rate Range</th>
<th>Pressure Rating</th>
<th>Typical Column Pairing</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPC060</td>
<td>6 – 60 L/h</td>
<td>100 bar</td>
<td>6 – 15 cm i.d.</td>
</tr>
<tr>
<td>HPC120</td>
<td>12 – 120 L/h</td>
<td>100 bar</td>
<td>7.5 – 20 cm i.d.</td>
</tr>
<tr>
<td>HPC180</td>
<td>18 – 180 L/h</td>
<td>70 bar</td>
<td>10 – 20 cm i.d.</td>
</tr>
<tr>
<td>HPC240</td>
<td>24 – 240 L/h</td>
<td>70 bar</td>
<td>10 – 30 cm i.d.</td>
</tr>
<tr>
<td>HPC360</td>
<td>36 – 360 L/h</td>
<td>70 bar</td>
<td>15 – 40 cm i.d.</td>
</tr>
<tr>
<td>HPC600</td>
<td>60 – 600 L/h</td>
<td>70 bar</td>
<td>20 – 45 cm i.d.</td>
</tr>
<tr>
<td>HPC900</td>
<td>90 – 900 L/h</td>
<td>70 bar</td>
<td>30 – 60 cm i.d.</td>
</tr>
<tr>
<td>HPC1K2</td>
<td>120 – 1200 L/h</td>
<td>70 bar</td>
<td>30 – 80 cm i.d.</td>
</tr>
<tr>
<td>HPC2K4</td>
<td>240 – 2400 L/h</td>
<td>70 bar</td>
<td>40 – 100 cm i.d.</td>
</tr>
</tbody>
</table>

### UHPLC Systems

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Typical Flow Rate Range</th>
<th>Pressure Rating</th>
<th>Typical Column Pairing</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPC060</td>
<td>6 – 60 L/h</td>
<td>200 bar</td>
<td>6 – 15 cm i.d.</td>
</tr>
<tr>
<td>UPC120</td>
<td>12 – 120 L/h</td>
<td>200 bar</td>
<td>7.5 – 20 cm i.d.</td>
</tr>
<tr>
<td>UPC180</td>
<td>18 – 180 L/h</td>
<td>200 bar</td>
<td>10 – 20 cm i.d.</td>
</tr>
<tr>
<td>UPC240</td>
<td>24 – 240 L/h</td>
<td>200 bar</td>
<td>10 – 30 cm i.d.</td>
</tr>
<tr>
<td>UPC360</td>
<td>36 – 360 L/h</td>
<td>200 bar</td>
<td>15 – 35 cm i.d.</td>
</tr>
<tr>
<td>UPC600</td>
<td>60 – 600 L/h</td>
<td>200 bar</td>
<td>20 – 45 cm i.d.</td>
</tr>
<tr>
<td>UPC900</td>
<td>90 – 900 L/h</td>
<td>200 bar</td>
<td>30 – 60 cm i.d.</td>
</tr>
</tbody>
</table>

### MPLC Systems

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Typical Flow Rate Range</th>
<th>Pressure Rating</th>
<th>Typical Column Pairing</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPC240</td>
<td>24 – 240 L/h</td>
<td>20 bar</td>
<td>15 – 30 cm i.d.</td>
</tr>
<tr>
<td>MPC360</td>
<td>36 – 360 L/h</td>
<td>20 bar</td>
<td>15 – 40 cm i.d.</td>
</tr>
<tr>
<td>MPC600</td>
<td>60 – 600 L/h</td>
<td>20 bar</td>
<td>20 – 45 cm i.d.</td>
</tr>
<tr>
<td>MPC900</td>
<td>90 – 900 L/h</td>
<td>20 bar</td>
<td>30 – 60 cm i.d.</td>
</tr>
<tr>
<td>MPC1K2</td>
<td>120 – 1200 L/h</td>
<td>20 bar</td>
<td>30 – 80 cm i.d.</td>
</tr>
<tr>
<td>MPC2K4</td>
<td>240 – 2400 L/h</td>
<td>20 bar</td>
<td>40 – 100 cm i.d.</td>
</tr>
</tbody>
</table>

### Flash LC Systems

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Typical Flow Rate Range</th>
<th>Pressure Rating</th>
<th>Typical Column Pairing</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPC360</td>
<td>36 – 360 L/h</td>
<td>10 bar</td>
<td>30 – 45 cm i.d.</td>
</tr>
<tr>
<td>LPC600</td>
<td>60 – 600 L/h</td>
<td>7.5 bar</td>
<td>40 – 60 cm i.d.</td>
</tr>
<tr>
<td>LPC900</td>
<td>90 – 900 L/h</td>
<td>7.5 bar</td>
<td>60 – 100 cm i.d.</td>
</tr>
</tbody>
</table>

Note: LC Systems with flow rates and configurations matched to your needs are available upon request. Please contact us to configure your LC System.
Artisanal Fluid Management

The Equipment Division of Asahi Kasei Bioprocess combines its extensive knowledge of fluid management technology with passion for downstream processing and dedication to craftsmanship.

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.

Artisanal Fluid Management reflects this passion and commitment.

Pair your LC System with one of our industry-leading Dynamic Axial Compression (DAC) LC columns for a proven, turnkey purification solution. With hundreds of DAC columns and LC Systems installed across Europe, the US, India, Korea, and Southeast Asia, we invite you to join our growing list of satisfied customers who have enjoyed the benefits of Artisanal Fluid Management.

Equipment designed to respect your individual needs.
Contact Information

North and South America
Glenview, IL, USA
Tel: +1-847-556-9700
Fax: +1-847-556-9701
Email: info.us@ak-bio.com

Europe
Cologne, Germany
Tel: +49-221-995007-59
Fax: +49-221-9950077-59
Email: info.eu@ak-bio.com

India and Southeast Asia
Mumbai, India
Tel: +91-22-6710-3962
Fax: +91-22-6710-3979
Email: info.jp@ak-bio.com

East Asia and Oceania
Glenview, IL, USA
Tel: +1-847-556-9700
Fax: +1-847-556-9701
Email: info.jp@ak-bio.com

Technical Support and Warranty Information

A reliable technical support network is available throughout the United States, Europe and Asia.

We offer an extendable 1-year warranty, service contracts and a personalized level of service for peace of mind and timely support when you need it.