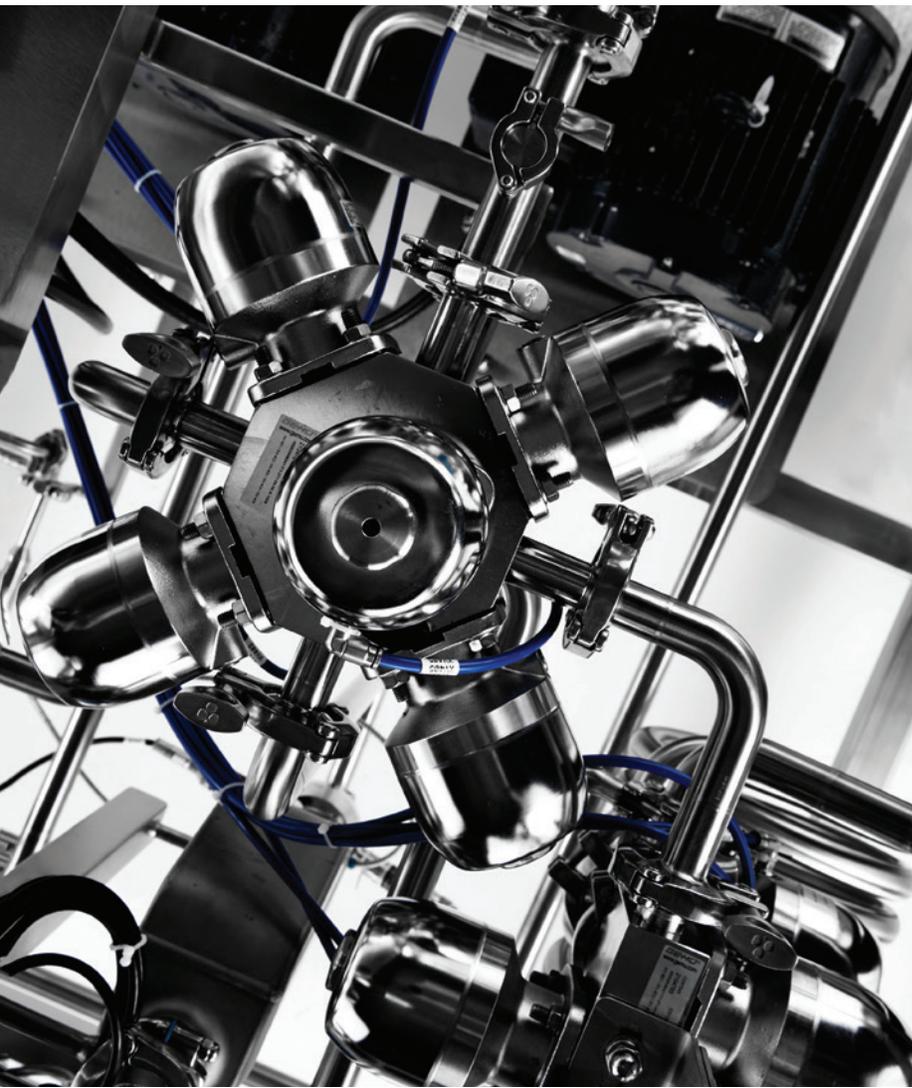


Bioprocess Chrom Systems

Combining gradient and inline buffer dilution capability with powerful software to your specifications

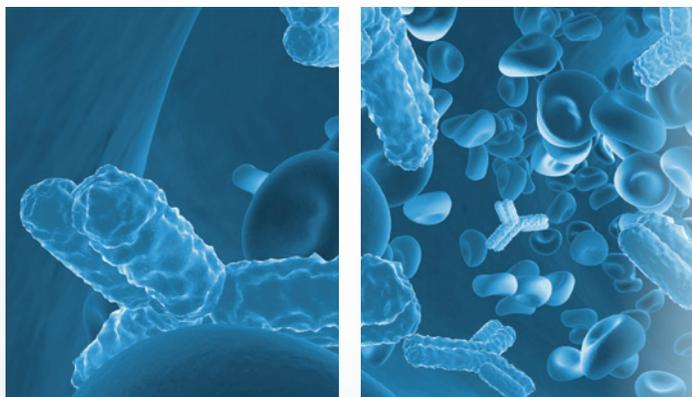




Built For You.

Asahi Kasei Bioprocess is dedicated to unlocking efficiencies and driving productivity within your biopharmaceutical and plasma derivative purification processes.

Capture and polishing remain critical steps for achieving the product purity desired in today's downstream processes for biopharmaceuticals and plasma derivatives. Drawing on our decades of experience producing custom engineered solutions, Asahi Kasei Bioprocess is pleased to offer a Bioprocess Chrom (BPC) 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, with pump turndowns up to 100X in either polymeric or stainless steel construction. All systems are available with inline buffer dilution, step gradient and linear gradient capability for maximum flexibility.



Chromatography Modes

- ① Capture chromatography
- ② Polishing chromatography
 - » Ion exchange chromatography (IEX)
 - » Hydrophobic interaction chromatography (HIC)
 - » Size exclusion chromatography (SEC)
 - » Mixed mode chromatography (MMC)

Key Features for the Chromatographer

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

- » Broad gradient operating ranges
- » Extension of the gradient during a run
- » Blend percentage hold
- » Pre- and post-column conductivity and pH sensors
- » Pressure and flow measurement
- » Dual channel variable wavelength UV detectors
- » Live and historical signal trending
- » Low pulse flow to the column
- » Fractionation by volume, column volume (CV), UV, conductivity or percentage of peak height
- » Built-in software phase for system clean-in-place (CIP)

Our Classic Bioprocess Chrom Systems: Gradient Capable. Inline Buffer Dilution Capable. You Choose.

We have been at the forefront of large-scale gradient technology for over a decade. During this time, we've accumulated a wealth of knowledge and practical expertise building BPC Systems that produce gradient blends for the purification of mammalian cell-derived antibodies, plasma derivatives, recombinant enzymes and other biomolecules with molecular weights larger than 10 kDa.

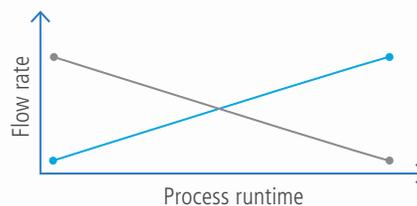
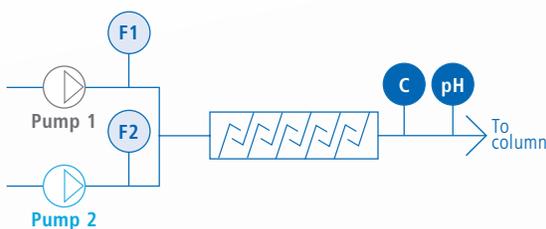
Since such diverse therapeutics have unique process requirements, our BPC Systems are engineered to be adaptable. Precise, reproducible gradient elutions enhance the resolution of product from impurities and therefore improve process economics during protein purification. The inline buffer dilution mode of these two-pump systems allows you to leverage the use of buffer concentrates to streamline your buffer formulation efforts.

Bioprocess Chrom Systems in Gradient Formation Mode (flow control or conductivity control)

Sensors: F = Flow rate C = Conductivity pH

Buffer
(pH-adjusted as needed)

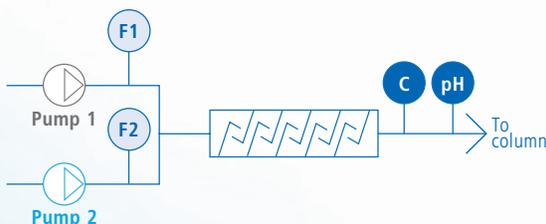
Buffer + salt
(pH-adjusted as needed)



Bioprocess Chrom Systems in Inline Buffer Dilution Mode (flow control or conductivity control)

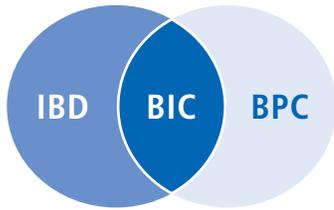
Water for injection (WFI)

Buffer or salt concentrate
(pH-adjusted as needed)



Our Next-Gen Bioprocess IBD-Chrom Systems:

Combining Inline Buffer Dilution and Gradient Formation in One System.

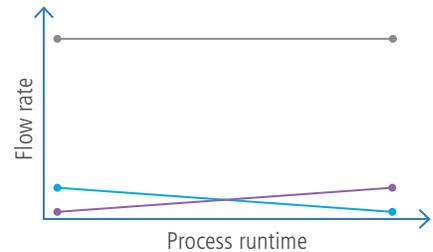
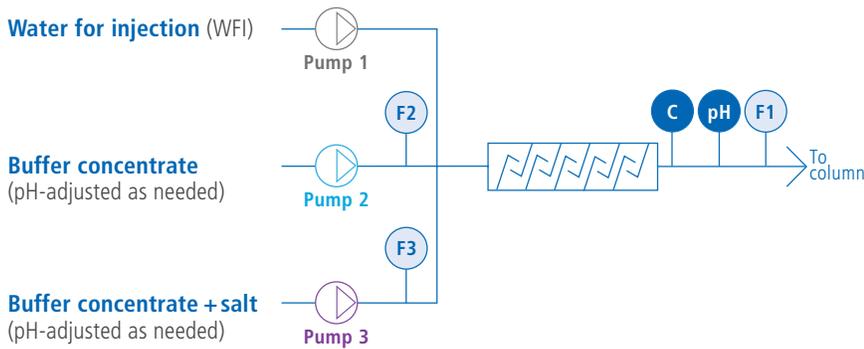


Our next-generation technology embodies our most powerful BPC System to date: combining inline buffer dilution and bioprocess chromatography. Using a Bioprocess IBD-Chrom (BIC) System, a buffer concentrate and salt concentrate are diluted with WFI while producing a linear salt gradient. By using pH-adjusted concentrates, a gradient with constant pH can be produced (see Figure 1). Buffers and salts up to 10X can easily be used.

Bioprocess IBD-Chrom Systems for Simultaneous Dilution and Gradient Formation

A novel combination of conductivity and flow control allows precise delivery of salt gradients to the column from concentrates.

Sensors: F = Flow rate C = Conductivity pH



Simultaneous dilution and gradient formation

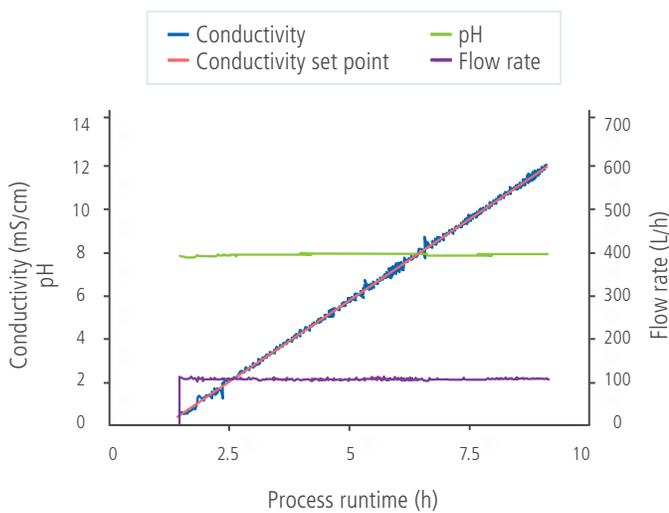
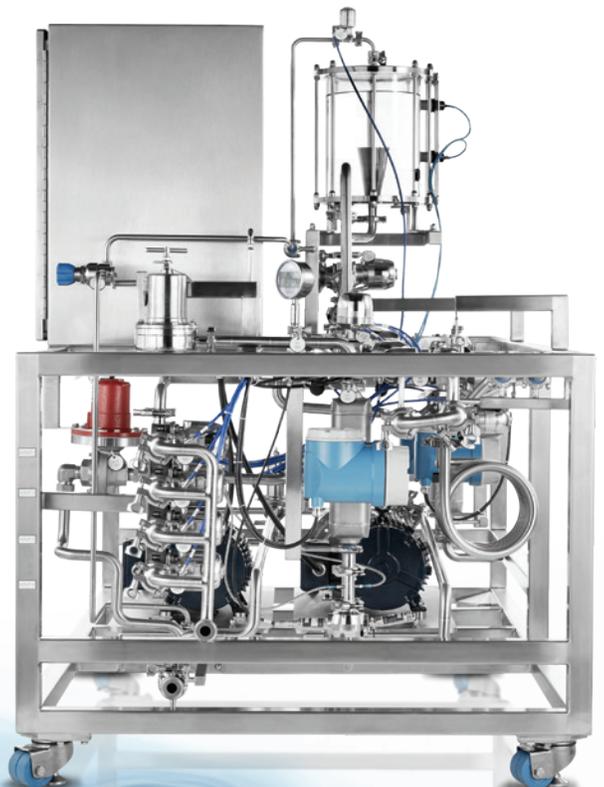


Figure 1. Example of NaCl gradient from 0.5 to 12 mS/cm in Tris buffer at pH 8.0 with concurrent inline dilution produced over 7 h at 114 L/h.

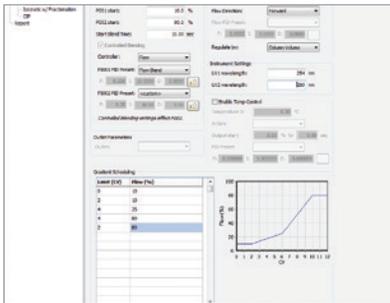


Software Designed for You

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, column management and method configuration that can be easily managed by new users but is sophisticated enough for the savviest chromatography professional.



Gradient configuration

Optimize gradient accuracy and precision by setting pump start values and selecting proportional-integral-derivative (PID) parameters.



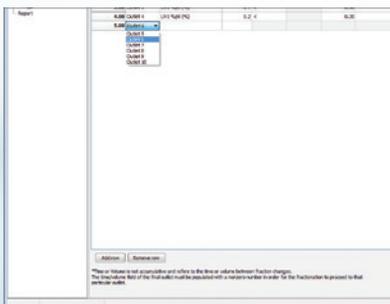
Gradient visualization

Confirm the gradient configuration profile prior to starting the method.

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.

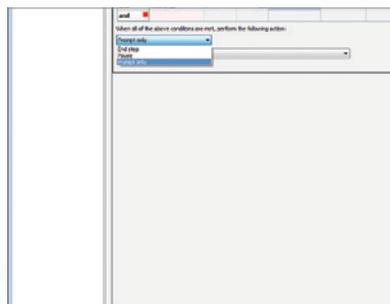
Simple, yet powerful method configurations available for the savviest chromatographer include the following:

- » Multi-step gradients programmable in one simple step
- » Sophisticated fractionation executed by time, CV, volume, UV, conductivity or percentage of peak height
- » End conditions for individual steps based on time, CV, volume, UV, conductivity or other parameter



Fractionation

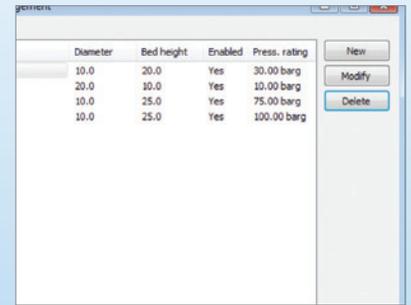
Fractionate by time, CV, volume, UV1, UV2, % of UV peak height or conductivity.



End conditions

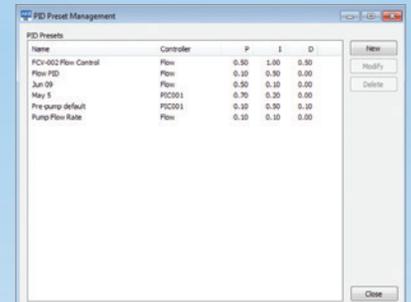
Set the end conditions for a step to display a prompt for user action, pause or end the run.

A number of effective functions for today's large-scale chromatographer.



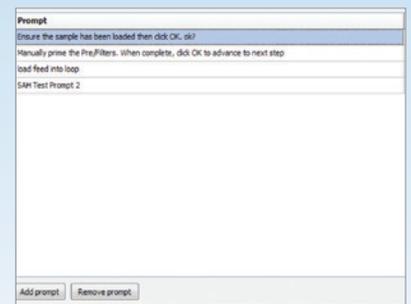
Column Management

Create and maintain a library of column diameters and bed heights for columns that will be used with your BPC System. CV will be automatically calculated.



PID Preset Management

Simplify your operation by maintaining a library of preset PID values for flow, conductivity and temperature controllers.



Batch Prompt Editor

Create custom notifications that will appear on the human machine interface (HMI) screen to prompt the operator to take a procedural action.

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
- » Height equivalent to a theoretical plate (HETP)
- » Asymmetry
- » Frontal peak analysis (FPA)

Trending

Trending of both real time and historical signals is also available through the Data Analysis Tool. Select pens from all available process values, set points and even PID outputs. Pens can be configured by the user for Y-axis association, scale and even color to enhance the visibility of your chromatographic process. Hundred of cycles of historical data can be overlaid. Typical process value pens include the following:

- » Pre-column conductivity
- » Flow 3
- » Pre-column pH
- » Post-column conductivity
- » Pre-column pressure
- » Post-column pH
- » Flow 1
- » UV1
- » Flow 2
- » UV2

Select Your Automation Platform

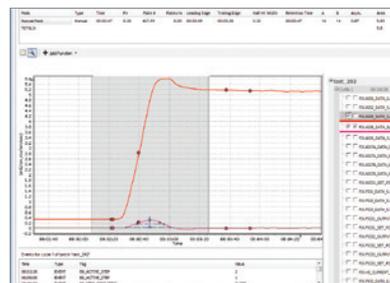
Our BPC Systems are now available on two control platforms: Allen-Bradley PLC with iFIX HMI/SCADA or Siemens S7 PLC with WinCC HMI/SCADA. Each platform is available with our flexible Method Editor and renowned Data Analysis Tool along with the following features:

- » Alarms and audit trails
- » Data export and customizable batch reports
- » 21CFR Part 11 capability with electronic signature
- » OLE (Object linking and embedding) process control (OPC) compatibility

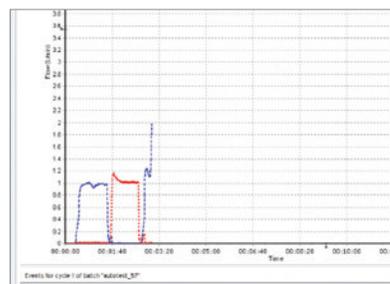
Enjoy the Freedom of Customization

Standard configuration BPC 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 a 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 BPC System platforms. Customizable options include the following:

- » Polymeric or stainless steel materials of construction
- » Locally mounted industrial PC (IPC)
- » Number of inlet ports or fractions
- » Software customization
- » End-of-stream air sensors
- » Hazardous area ratings (NFPA and ATEX)
- » Bubbletraps
- » Modified footprints to fit into tight spaces and within fume hoods
- » Pre-filters
- » IQ/OQ protocol generation and execution
- » Sample injection loops
- » GAMP-5 lifecycle documentation
- » Heat exchangers



Data Analysis Tool showing FPA



Data Analysis Tool showing trend analysis

Ordering Information

Systems with flow rates up to 15,000 L/h and custom configurations are available upon request.

Bioprocess Chrom Systems

Two-pump systems

Catalog No.	Product Specification	Pressure Rating
BPC0150P	4 – 150 L/h; polymeric	6 bar
BPC0150S	4 – 150 L/h; stainless steel	6 bar
BPC0300P	6 – 300 L/h; polymeric	6 bar
BPC0300S	6 – 300 L/h; stainless steel	6 bar
BPC0900P	50 – 900 L/h; polymeric	6 bar
BPC0900S	50 – 900 L/h; stainless steel	6 bar
BPC1800P	100 – 1800 L/h; polymeric	6 bar
BPC1800S	100 – 1800 L/h; stainless steel	6 bar

Note: All systems have gradient or inline buffer dilution capability.

Bioprocess IBD-Chrom Systems

Three-pump systems for simultaneous IBD and gradient capability

Catalog No.	Product Specification	Pressure Rating
BIC0180S	180 L/h stainless steel	6 bar
BIC0600S	600 L/h stainless steel	6 bar
BIC1200S	1200 L/h stainless steel	6 bar
BIC1800S	1800 L/h stainless steel	6 bar

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

China

Shanghai, China

Tel: +86-(0)21-6391-6111

Fax: +86-(0)21-6391-6686

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.

For more information, please visit:

www.ak-bio.com