GE Healthcare Life Sciences

## ÄKTA™avant

Inspi*red* to Äccelerate your process development







# ÄKTA avant

## Inspi*red* to be the icon of process development

In today's challenging environment, the issue is how to make sure the competitive advantage is on your side of the bench. Unquestionably, the challenges within biopharmaceutical process development are both real and escalating. And there are mounting pressures to constrain costs and expenditure while overcoming increasingly tough competition, regulations, and guidelines. These pressures do not take away from the fact that your overriding goal is to achieve swift and secure handover of robust processes.

#### Introducing the next generation of ÄKTA

ÄKTA is the Swedish word for true or real. And it is the name for GE Healthcare systems that have enabled over 100,000 users to achieve breakthroughs and advances within protein purification and separation. This proud lineage now sky rockets into the next generation with ÄKTA avant.

ÄKTA avant is the result of research and close dialog with you. Your realities and needs have been the source of our inspiration. We have listened, learned, and developed one platform encapsulating features and functions that work smoothly together to allow you to achieve your goals.

ÄKTA avant is available in two versions. ÄKTA avant 25 is optimized for media screening and method optimization using small columns. ÄKTA avant 150 is designed for scaling up to larger columns, as well as fine-tuning and robustness testing of the optimized process. ÄKTA avant systems allow fast and secure development of scalable chromatographic processes for biopharmaceutical production.





**Speed:** Achieving robust, well characterized processes consumes time. ÄKTA avant overcomes this, enabling quicker insight and allowing you to get more done in the same time frame.



**Scalability:** ÄKTA avant enables you to achieve direct, dependable scalability while systematically anticipating errors so that they are not passed on to impact safety, consistency, or economy of the full-scale separation.



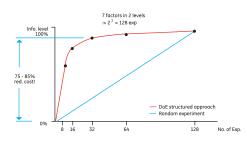
**Security:** ÄKTA avant allows you to obtain reliable results while working in a compliant, error-free manner with complete sample security.



## Inspi*red* with the speed to confirm a winning idea



Ultimately it all boils down to the strategic value of getting new products to market faster. This means translating your ideas effectively to the experimental arena, and being able to gain quicker insight and input into your process. It also means that you have to eliminate manually intensive steps that consume time and creative energy. The innovative technology embodied in ÄKTA avant will enable you to get more things right the first time around. It eliminates guesswork so that you can utilize precise, educated input that delivers spot on results. All in all, ÄKTA avant has the capacity to shorten the process development time by a number of days or even years.



## Maximum information, minimum experiments with DoE

Design of Experiments (DoE) is a powerful software tool integrated in UNICORN<sup>™</sup> 6 that allows you to obtain the maximum amount of information from a minimum number of experiments.

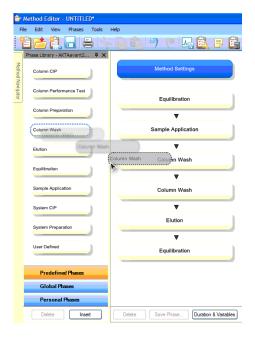
- Leads the way to automated process development.
- An organized, statistical approach that varies all factors simultaneously to significantly reduce the number of required experiments.
- Because variability, noise, and interaction effects between factors are analyzed, more precise information is obtained.
- Significantly reduces process development costs.

#### Automation with BufferPro

BufferPro is an automated on-line buffer preparation function that will increase your throughput by speeding up the development process.

- Facilitates preparation of single buffers as well as screening for optimal buffer compositions.
- Enables true buffer mixing with corresponding acid or base, and automatically compensates for changes in temperature and salt concentration.
- Delivers quick and easy pH scouting.
- Save up to 30 minutes per buffer and pH value.





#### Ease-of-use with Method Editor

Method Editor incorporates an approach to method programming that is simple, highly intuitive, and yet flexible enough to be used by both beginners and experienced users.

- Methods are built up using phases, where each phase corresponds to a step in a chromatography run.
- Methods are created simply by dragging-and-dropping predefined phases from the Phase Library.
- UNICORN 6 automatically generates the programming code, but also offers flexibility by allowing advanced users to retain full programming control.

## Inspi*red* to succeed in smooth scale-up

Your ultimate goal is to ensure smooth transition from product discovery to economical GMP-conforming production. Consider achieving direct, reliable scalability using the same chromatography media and column formats. From a production perspective, this means cost effective processing using smaller unit operations as well as avoiding last-minute surprises.

ÄKTA avant and UNICORN have built-in scalability that enable fast and predictable scale-up. Optimize your process with ÄKTA avant 25, and then easily scale-up your methods in ÄKTA avant 150 using UNICORN 6. Dedicated columns formats for ÄKTA avant enable you to work with modern BioProcess<sup>™</sup> media in smallscale and ensure seamless scalability to production.

### A higher standard of intelligence with UNICORN 6

UNICORN 6 saves time by automatically converting methods between the two ÄKTA avant systems. Method conversion and rescaling are simple, with automatic adjustment of system settings.

#### Scalability from start to finish

BioProcess chromatography media are specifically designed to meet the demands of today's industrial biomanufacturing, and are available in a range of column formats and sizes. ÄKTA avant, together with BioProcess media, reduce process time with high volume throughput and transparent scale-up.

### PreDictor™ 96-well filter plates for high throughput process development (HTPD)

Prefilled PreDictor plates allow rapid, parallel screening of chromatographic conditions in a 96-well format. Results obtained using PreDictor plates correlate well with column data and lay the foundation for the development of robust manufacturing processes.



### HiScreen™ prepacked columns for method optimization

Prepacked HiScreen columns are ideal for fast method optimization and parameter screening, and are easily connected in series. The columns have a 10 cm bed height, giving reliable results that serve as a basis for linear process scale-up.

#### HiScale<sup>™</sup> columns for easy scale-up

Pressure stable HiScale columns are available in i.d. 16, 26, and 50 mm. HiScale columns are user friendly and allow reproducible column packing.

## AxiChrom™ columns for predictable scale-up to production scale

AxiChrom columns with Intelligent Packing simplify column handling at scales from process development to full-scale production. ÄKTA avant 150 and UNICORN 6 support AxiChrom 50 and 70 columns. UNICORN guides the user through column packing, reducing operator dependence and ensuring optimally-packed beds.



## Inspired to secure operation within tight time frames

You work to win against the clock. You also have to work in a compliant, quality-assured manner even when the experiments and documentation are tedious and time consuming. These pressures are reinforced by the fact that the methods you develop will be transferred to an environment that cannot compromise safety, reliability, and product quality. When pressures are great, mistakes can occur. Being able to gather reliable data within tight time constraints is the key to acheiving a deeper understanding of the process and controlling risks when it is transferred into the production hall.

One of the most important things in biopharmaceutical process development is safety: operational safety and process safety. But the faster you go, the more exposed to risk you are—so we developed an instrument that is as safe as it is fast.

Inspired by your need to fulfill quality by design, ÄKTA avant incorporates cutting-edge functionality critical to achieving real security throughout the development process.



### UniTag scanning for complete traceability

It stands to reason that the more information at your disposal, the more likely you are to come to accurate conclusions. UniTag scanning allows you to easily track column and run data, empowering you with the right input to be precise in your conclusions.

- Individual columns are identified using a matrix code, and key column performance parameters are automatically saved in the column's history.
- Notification limits can be set, for instance, to define the number of times the column may be run between cleanings.
- The user is notified when it is time for column maintenance.

### Reliable column protection with differential pressure measurement

It is to your advantage to run the system at optimum levels of productivity. At the same time, it is vital to ensure the safety of the system.

- Two pressure sensors protect the column hardware and the chromatography media from overpressure.
- The sensors are integrated into the column valve to deliver true pressure measurements.
- Differential pressure measurements are performed in a manner that corresponds to instruments utilized in large-scale manufacturing processes.

### Built-in fraction collector for true sample integrity

The integrated fraction collector ensures that samples are as secure as possible.

- Temperature control (6°C to 20°C) allows samples to be cooled and protected.
- Load up to six cassettes in any combination that suits your needs. Racks are also available for large tubes and bottles.
- Tube types are automatically detected and the user is alerted when the tubes do not match the method.

#### Working faster while being compliant

UNICORN 6 is FDA 21 CFR Part 11 compliant and features a system audit trail, electronic signatures, and electronic records.

- Results are stored in a single, unalterable database.
- Individual user access permissions can be set and individual users are password protected. Active processes can be locked for unattended operation without risk of unauthorized interference.
- Validation support documentation is available to you through audited and accredited software from Regulatory Support Services.



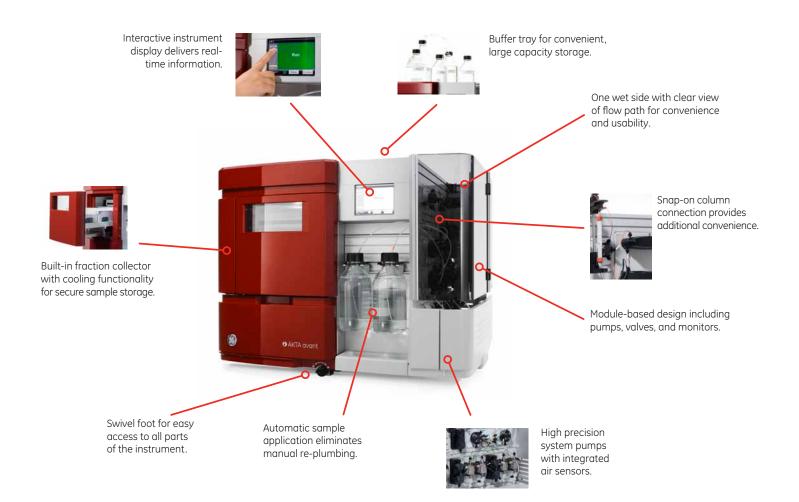
Inspired technology

## When inspi*red* technology meets reality

ÄKTA avant comprises innovative features and functions for delivering recognizable benefits like increased flexibility, ease-of-use, and throughput. It is built to work seamlessly with UNICORN control software enabling real time control of chromatography from method development to full-scale production.

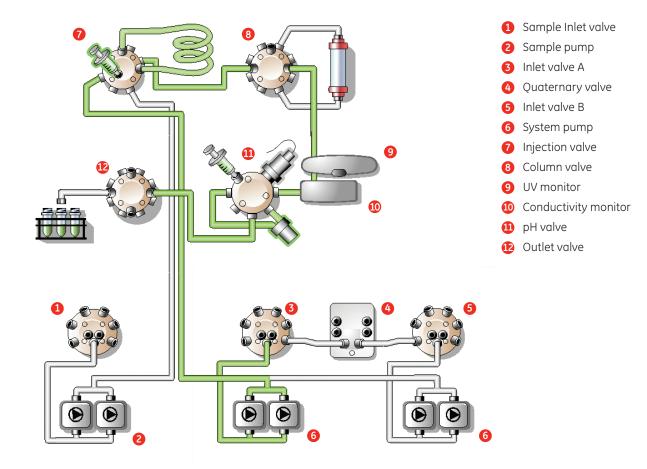
#### Support and service all the way

Downtime is kept to an absolute minimum during service thanks to the easily accessible front-mounted units. Our Service Agreements can help you decrease your downtime further with priority response from our Labcrew Field Engineers.



## An overview of the system flow path

The ÄKTA avant flow path is designed to optimize chromatographic performance and minimize band-broadening effects. All wetted materials used in the flow path are biocompatible and resistant to commonly used solvents.



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