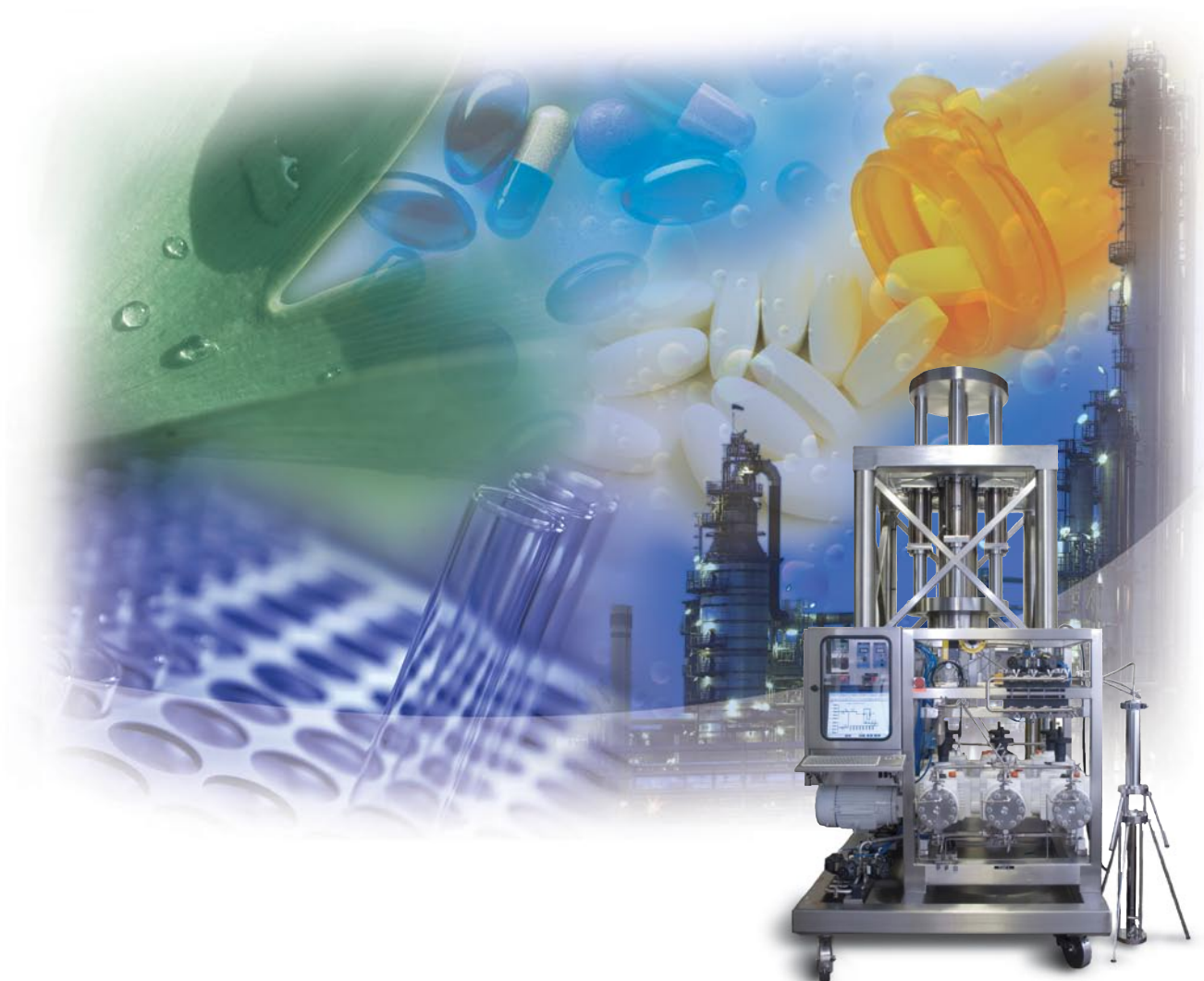


VARIAN, INC.

# Process LC Solutions

INSTRUMENTS AND CONSUMABLES FOR HIGH YIELD PURIFICATION



NOTICE: This document contains references to Varian. Please note that Varian, Inc. is now part of Agilent Technologies. For more information, go to **[www.agilent.com/chem](http://www.agilent.com/chem)**.

[www.varianinc.com](http://www.varianinc.com)**Agilent Technologies**

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# SepTech™ Skid Systems for High Yield Process Production

## The Flexible Approach to Process Purification

The goal of preparative LC is to isolate the maximum amount of product at a desired purity, in the least possible time. Preparative chromatography covers a broad range of purification processes – from purifying small amounts of highly pure substances, all the way up to the production of ton quantities. Fully automated SepTech Skid systems from Varian, Inc. are the solution for isolation and purification of high-value substances, such as active pharmaceutical ingredients (APIs), peptides, proteins and fine chemicals.

As a global leader in preparative chromatography, Varian offers complete automated process chromatography systems (LPLC (<100 psi), MPLC (100 – 300 psi), and HPLC (300 – 2,000 psi)) for the biotechnology and pharmaceutical industries.

Since every process has varying specifications, we at Varian, Inc. design fully customized SepTech Skid systems in compliance with typical process/chemical engineering formats. SepTech Skid systems are ideally suited to meet your facility requirements and specific process purification needs.

When you select a SepTech Skid system from Varian, you get more than a product. You benefit from more than 25 years of experience in the design and delivery of preparative and process liquid chromatography systems.

- cGMP compliance – High/low flow and high/low pressure HPLC and Bio-LC (sanitary) SepTech Skid systems supplied with standard process Load & Lock™ columns up to 24 in. ID
- Better separation management – UV, density, flow, pH, conductivity, NIR, high/low level and vapor sensing switches and pressure monitors
- 21 CFR Part 11 compliance – Total control and documentation with LC ReSponder™ Control Software. Capability to transfer data to external databases, such as corporate historian depository systems



SepTech 2.5 L/min. XP/EX high pressure Skid system with temperature control and Steady-State recycle technology



## Defining Your Purification and Application Requirements

	Low Pressure (Bio) Applications <100 psi	Medium/High Pressure HPLC Applications 100–2,000 psi
Application Types	Large (bio) molecules	Small (pharma) molecules
Separation Mechanism	Charge based/ affinity	Normal/reverse phase
Sorbent Types	Ion exchange/ affinity	Silica and polymer based
Solvent Types	Aqueous based	Organic based
Hardware Type (fitting connections)	Sanitary	Standard HPLC, sanitary as option
Sanitation Type	Sanitary fittings and valves	Cleaning in place (CIP)
Flow Rates	High flow rates up to 50 L/min	Flow rates up to 25 L/min
Detection	UV, pH, conductivity	UV, pH, conductivity, RI, NIR
Monitoring	Flow rate, pressure, temperature, vapor sensor, solvent management, fraction volume	
Software	LC ReSponder with Bio-LC features, column volumes, etc.	LC ReSponder with HPLC features, flow rates mL/min
Explosion Proofing Features (solvent oriented)	Less likely XP/EX proofing	More likely XP/EX proofing



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# Customized Design

## Varian Skids: Systems and Support from a Single Source

The key to achieving maximum performance for any purification or isolation is the application-based design of the purification system. Varian's manufacturing expertise is displayed in our custom engineered Process Skid systems. The design and manufacture of a Skid is based on your technical purification requirements and by the available space in the facility. This affects every stage of the design, making the sizing of each component and its associated pipe work and wiring, critical. Therefore, getting the design right the first time is our chief concern.

We will design, build, install, validate and service your SepTech Fluid Handling Skid and column systems based on your specific application and facility requirements. Once we have agreed on the process design and mechanical layout (DQ), Varian engineers can begin work on the Skid. System components and materials are isolated, coded, and traced throughout the ASME or CE-dictated manufacturing process. Material certificates are supplied for all cGMP oriented Skid systems/columns.

Bio-LC Skids are designed and manufactured to be truly sanitary in design to meet the stringent criteria of regulatory agencies.

### Standard features of Skid systems include:

- Double diaphragm duplex or triplex primary solvent pump(s)
- Dedicated sample injection pump
- PC or PLC control with LC ReSponder Control Software operation for total automation and internal software documentation of all operational events
- Solvent and column temperature control
- Manual and fully automated multi solvent selection, binary gradient formation, and fraction collection

### Standard features of low-pressure Bio Skid systems include:

- Wash down electronics enclosure
- Optional polypropylene fluid path
- UV, pH, conductivity, temperature, pressure, vapor, and tank level monitoring
- Sanitary valves and fittings (Triclamp) for fast and easy breakdown during the normal sanitization process

### Standard features of high-pressure HPLC Skid systems include:

- Wash down electronics enclosure or XP/EX provisions (solvent dependent)
- UV, RI, pH, conductivity, temperature, pressure, vapor, and tank level monitoring
- Clean in place (CIP) design



SepTech 15 L/min.  
Bio low-pressure  
Sanitary Skid System



SepTech 4 L/min. LPG  
high-pressure  
XP Skid System

# The Ultimate in Production Prep to Process Columns

## Load & Lock™ Columns

SepTech™ Skid systems combine perfectly with Load & Lock Dynamic/Static Axial Compression (DAC/SAC) columns to achieve the maximum yield. With a complete line of Load & Lock columns, from 1 in. to 24 in. ID\*, in low, medium, and high-pressure models, Varian delivers versatile column solutions for high performance, high throughput, and high yield preparative and process purifications.

Load & Lock columns provide:

- Highest performance – unique fluid/sample distribution system maximizes productivity
- Maximum flexibility – the only system that can perform both Dynamic Axial Compression and Static "locked" Axial Compression
- Greater convenience – designed for easy operation
- Manufactured to fit your production/facility space
- More than 25 years experience in pilot and production scale column design for low pressure, Bio-LC and medium/high pressure applications

Our Load & Lock columns are designed to get you up and running quickly when you pack your own high performance liquid chromatography columns. They combine excellent packed bed stability with enhanced flow distribution to deliver the highest quality purification with maximum speed, flexibility, and ease-of-use. Sample loading is 25% greater than other DAC type columns, saving time and reducing operating costs, because more material can be purified per unit time or smaller inner diameter columns can be used due to higher loadability.

- Integrated, mobile easy-to-handle hydraulic packing station and column system
- Scalable up to 24 in. ID in a variety of column lengths

Customized column sizes are also available. An optional column water jacket promotes separations at elevated temperatures, improving resolution by enhancing the mass transfer of large solutes.

*\* Scalable up to 24 in. ID in a variety of column lengths*



Pilot-scale L&L Columns – 6 in. IDs



Process-scale L&L Columns – 12 in. IDs



Process-scale L&L Columns – 24 in. IDs

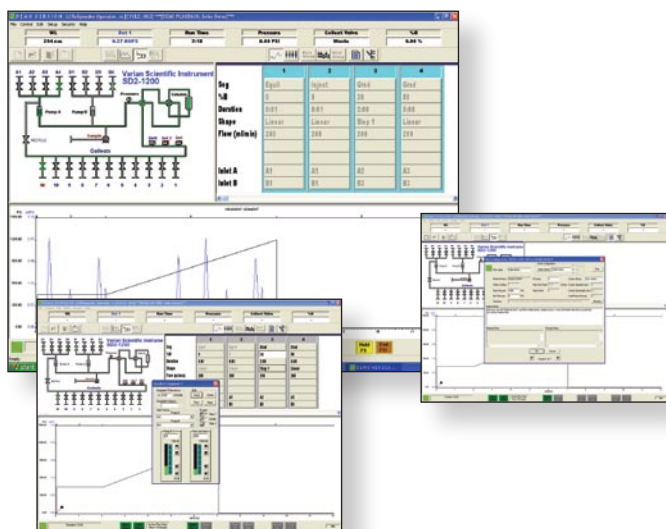
Process Load & Lock Column diameter	6 in.	8 in.	10 in.	12 in.	14 in.	16 in.	18 in.	20 in.	24 in.	Productivity per day
Solvent Delivery System Flow Rate 1 – 3 L/min.	•	•								0.1 – 5 kg
Solvent Delivery System Flow Rate 3 – 10 L/min.		•	•	•	•	•	•			0.2 – 20 kg
Solvent Delivery System Flow Rate 5 – 16+ L/min.								•	•	0.5 – 40+ kg

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# The Complete Solution

## LC ReSpender™ Control Software: For Total System Management

LC ReSpender is a single software platform giving you total system control and unalterable operational documentation of sample injection, solvent selection, gradient formation, and fraction collection.



The screen contains all the necessary operational information. The interface depicts a flow diagram of the process, the purification method, and the full chromatogram of the separation profile. The software has been designed to meet cGMP, GLP and 21 CFR Part 11 requirements, based on GAMP 4.0. Documentation and qualification protocols are provided for DQ, IQ, and OQ. LC ReSpender software provides multi level entry security and multi user password protection, so that unauthorized access is denied. An enhanced 21 CFR part 11 option provides features such as special data transfer to networking and distributive control systems, or even to a corporate historian system. These functions are all possible using the common OPC technology. Security options include administrator notification of unwarranted entry attempts and file security via a Microsoft Windows environment.

Operator control of the system can be handled at the console through a PC, and/or located remotely in a safe zone, i.e. at a manager's office desk. The systems can also be operated under a PLC platform, if desired.

## Varian Technical Support and Qualification: All the Support you Expect and Need

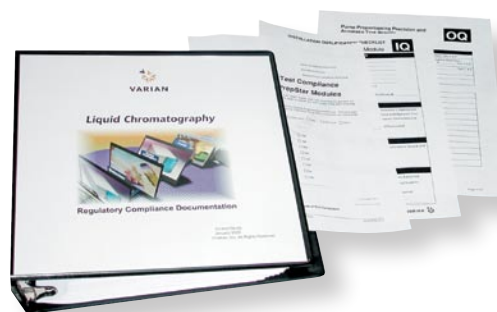
We follow a rigid manufacturing protocol and test every system to the highest standard. We also provide and perform a complete qualification package (DQ/IQ/OQ/PQ) on all of our SepTech process systems to ensure consistent system specification performance.



Varian, Inc. is ready to meet your installation, qualification, service, and application needs. Our comprehensive range of support with the Varian Care Program includes:

- Site preparation guidance, complete installation, and on-site introductory training
- Expert, factory-trained Varian, Inc. field service engineers for complete service needs
- Tools for 21 CFR part 11 compliance included with all system software
- Optional validation support and execution of the qualification requirements – DQ/IQ/OQ/PQ
- Technical assistance, with experienced scientists to address your purification-related questions
- Contract method development and scale-up procedures, plus out-sourced product purification
- Process system automation and plant integration services: OPC/DCS/ historian record keeping

Varian's reliable preparative instruments, consumables and superior customer support enhance productivity, minimize downtime, and maximize your return on investment.



Standard IQ/OQ protocols, along with on-site implementation and documentation, are available as options for all systems and software.





## Prep to Process Scale Separation Solutions from one Provider

From method development all the way up to the production plant, Varian has unique capabilities in purification technology.

Regardless of your purification application we offer more solutions to meet your preparative/process LC needs. Whether your application involves purification of small molecules, proteins, peptides, oligos, antibodies, natural products or antibiotics, we have the right instrumentation, media and customer-focused support to help you solve your preparative challenges.

With Varian's LC systems, moving from analytical LC and/or flash chromatography to preparative or process scale separations is simplified by applying either high performance linear scale-up or high throughput sample loading scale-up techniques. Varian doesn't limit you to one or the other; we do both types of scale-up to maximize your purification experience.

Whether your application requires pre-packed columns or multi-kilo batches of prep and process chromatography sorbents for packing your own DAC/SAC columns, Varian can help.

A key to maximum productivity for any purification is the selection of the sorbent. Varian has one of the most complete ranges of pre-packed columns and bulk sorbents for HPLC separations.



Whether you want maximum efficiency from silica-based sorbents, or optimum selectivity to increase your throughput from chemically and thermally stable polymeric, Varian has the materials to meet all your requirements.

The Pursuit™ XR C18 and SepTech™ C18 are the silica based products you need for high efficiency separations. VariTide™ RPC, PLRP-S, PL-SAX and PL-SCX are the polymeric sorbents of choice for demanding separations where their thermal and chemical stability can be used to maximum benefit.

We build our Prep to Process separation solutions to help you get the maximum productivity from your columns and media, whatever your sample type or purification scale.



VARIAN, INC.

# Process LC Solutions

## INSTRUMENTS AND CONSUMABLES FOR HIGH YIELD PURIFICATION

Varian offers robust instrumentation, application-based consumables, and customer-focused services, backed by our global team of product and applications experts, ready to help you solve your analytical challenges. Whether you're monitoring impurities in drinking water, designing new therapeutic drugs, or developing cleaner fuels, our solutions deliver the sensitivity, flexibility and productivity your laboratory requires.



### Varian Care Program

Our goal is to help you increase your productivity, maximize your uptime and achieve the highest return possible on your investment. Our experienced and highly-qualified support organization is strategically located throughout the world to ensure rapid response.

Be confident knowing that your instrument will deliver maximum performance, your users are fully trained and expert technicians will respond quickly to your support needs — because Varian cares.

### Shop Online

Varian offers the added convenience of purchasing products online. The products you need are just a few clicks away at [www.varianinc.com](http://www.varianinc.com)

We are committed to meeting your needs with a full range of consumable products and supplies. Call today to request your free copy of our comprehensive analytical supplies catalog or download it from our web site.

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