



NCSRT Introduces WORKS™, an Integrated Program of Products, Applications Guides, Optimization Tools, and Services

Apex, NC, October 30, 2007 --(PR.com)-- NCSRT Introduces WORKS™, an integrated program of products, applications guides, optimization tools, and services to dramatically improve downstream processing in the biopharmaceutical production environment. With the patented SmartFlow™ TFF modules and industry leading PUROSEP® filtration skids at the core of the program, WORKS provides customers the ability to increase downstream yields and significantly reduce capital costs.

Supported by Optimization Procedures, Case Studies, and easy to implement Protocols, WORKS not only provides you the products to improve your downstream processing, it provides a detailed road map on how to quickly implement the SmartFlow technology and optimize it for each customer's unique products. These support materials are combined into application based WORKbooks that are available from NCSRT.

Combined with the WORKbooks, WORK also includes the AT WORKS customer support services. These services range from system FAT, SAT, IQ, and OQ support, custom applications development and optimization services, and on-site training for operators, managers, and process development personnel.

Additional products in the WORK program include CHROMAPURE™ chromatography control systems and StepWise™, an integrated process control software suite that can control downstream filtration and chromatography operations locally or integrated through plant SCADA systems. GAMP4 and 21CFR Part 11 compliant features of the software suite incorporate the ease of use operators love, the system definitions and recipe builder modules managers count on to accurately describe their process, and the control and security QA requires.

For more detailed information on the WORKS program visit www.ncsrt.com/Application_works.html
To request copies of application specific WORKbooks, visit www.ncsrt.com/Works_request.html

WORKS™ Optimization Procedures

The Optimization Procedure provides a detailed protocol and data collection instructions to optimize SmartFlow™ TFF based separations. Systematic evaluations of membranes, process conditions, and sample make-up are featured.

WORKS Case Study

The Case Study provides examples of how others have applied the principles of the Optimization Procedure to their specific application.

WORKS Protocol

Where appropriate, NCSRT has developed a simple protocol to address specific applications. Protocols provide exact instructions including membrane, pore size, filter area, and shear to achieve >90% yield in most cases. The protocol is not optimized for any individual product, but for classes of products like Mabs, page, and whole cells. Designed to provide acceptable results for over 80% of those who try it,



the protocol is an excellent way to jump start the improvement in separation efficiency while optimizing the SmartFlow filter process.

WORKS Products:

OPTISEP® filter modules - utilizing the patented SmartFlow technology to assure the optimum performance and yield in critical biopharmaceutical applications.

PUROSEP™ filtration systems - state of the art filtration systems that incorporate over 25 years of systems design experience to provide unparalleled operational efficiency, ease of use, and quality.

CONSEP® filter modules - apply SmartFlow technology to food, beverage, and chemical applications benefiting from optimized TFF solutions and the economics of improved yield and lower operational costs.

CHROMAPURE™ chromatography control systems - designed with the input of hundreds of manufacturing operators, the industry leader in ease of use, programming elegance, and reliability.

StepWise™ process control software - developed by working side by side with industrial chromatographers, production managers, and QA personnel the StepWise software incorporates the ease of use operators love, the system definitions and recipe builder modules managers count on to accurately describe their process, and the control and security QA requires.

AT WORKS Services:

FAT program - Industry leading FAT program to assure your system operates the way it was designed to before it leaves the factory. Accompanied by a comprehensive documentation library, the systems ship ready to install.

SAT program - On-site acceptance testing to assure there were no problems during transit or installation and that the programming and control systems integrate to the plant SCADA system as it was designed.

On-site customer support - depending on your needs, NCSRT offers operational, engineering, software, training and applications support programs to meet your specific requirements.

On-site system maintenance - Both annual and semi-annual system check and calibration services. System checks include replacement of elastomer seals, o-rings, and valve diaphragms.

On-site operator training - cGMP compliant training programs for the safe operation of PUROSEP and CHROMAPURE systems.

Custom support programs - if you have needs that are not covered by the standard NCSRT AT-WORKS programs, contact your regional representative to design a program for your company.

WORKS WORKbooks:



- • Isolation of secreted proteins from mammalian cell lines
- • Isolation of small molecules
- • Simultaneous isolation and concentration
- • Ultrafiltration, concentration, and diafiltration
- • Secreted proteins from whole cells
- • Isolation of proteins from cell lysate
- • Isolation of secreted proteins from mammalian cells
- • Concentration and diafiltration of whole cells
- • Purification of secreted viral antigens from mammalian cells
- • Viral antigen purification by diafiltration
- • Isolation of bacterial phage
- • Purification of viral antigens by continuous diafiltration
- • Isolation of a secreted protein by continuous cell diafiltration
- • Concentration and diafiltration of viral antigens

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