Short Course in

Protein Chromatography

Engineering Fundamentals and Measurements
for Process Development and Scale-up

October 2-7, 2016
University of Virginia, Charlottesville, Virginia, USA
Course Director - Prof. Giorgio Carta

Equipment Sponsor: GE Healthcare

http://faculty.virginia.edu/shortcourse/HomePage.html
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Aim
Chromatography is an indispensable tool for the industrial production of proteins and other biotechnology products. Process development usually begins with laboratory scale scouting tests to determine suitable stationary phases and operating conditions. If successful, the next step is the optimization of operating conditions and scale-up. The aim of this course is to provide insight in the theory of chromatography, an understanding of fundamental engineering scale-up relationships, and an overview of methodologies for the experimental measurement of scale-up parameters and of optimization tools.

Course description
The scope of the course, now in its 12th year at UVa, is to provide insight in the application of chromatographic theory with special emphasis on the determination and use of key scale-up parameters. The course will include both lectures and hands-on laboratories. The lectures will cover downstream processing of biotechnological products, the different modes of operation of chromatography, the characteristics of chromatographic media, the description of adsorption equilibria and mass transfer and their effects on chromatographic performance, frontal analysis and linear gradient elution theories, and protein-protein and protein-surface interactions. The laboratory sessions will comprise pulse response experiments, the determination of retention factor and HETP, frontal analysis and dynamic binding capacity experiments, and linear gradient elution experiments. An optional column packing session on Sunday will address practical aspects of packing and validating lab columns. The experiments will be carried out with typical chromatography media using ÅKTA Pure workstations with the latest Unicorn software from GE Healthcare and will explore the effects of pore size, particle size, the size of the protein, and the choice of operating conditions. The participants, divided in teams, will set up the experimental runs, analyze the experimental results, calculate performance metrics, determine scale-up parameters, and present the results for discussion in a group setting. A final exercise will provide the opportunity to develop a column design that maximizes productivity based on the experimental data acquired during the week. Detailed course notes and spreadsheet-based tools for data analysis will be available. Ample opportunities will also be provided for interactions among participants, lecturers, and staff.

Who should attend
The course is aimed at bioprocess development engineers, separation scientists, biologists, biochemists, technical managers, validation specialists, and regulatory agents having some familiarity with downstream process development who want to develop a deeper understanding of chromatographic processes and their scale-up. Graduate students and separation scientists in academia will also benefit from this course.

Lecturers
Prof. Giorgio Carta, Department of Chemical Engineering, University of Virginia, Charlottesville, Virginia
Prof. Alois Jungbauer, Department of Biotechnology, BOKU, Vienna, Austria
Graduate assistants will support the participants during the laboratory and data analysis sessions

Venue
The course will be held at the University of Virginia in Charlottesville, Virginia. Located in the foothills of the Blue Ridge Mountains approximately 110 miles from Washington, DC, 70 miles from Richmond, 20 miles from the Shenandoah National Park, and 5 miles from Monticello, the historic home of Thomas Jefferson, Charlottesville can be reached by rail, bus, and direct flights from several major US cities.
Course Program

Sunday, October 2
14:30 - 16:30  Lab column packing (optional but must preregister)
16:30 - 17:00  General registration
17:00 - 17:30  Introduction to the course
17:30 - 19:00  Lecture: Downstream processing and biophysical properties of biotechnological products
19:00 - 21:00  Reception and dinner

Monday, October 3
8:30 - 10:30  Lecture: Introduction to chromatography, basic principles, modes of operation, columns
10:30 - 12:00  Lecture: Band broadening factors, plate model, scale-up relationships
12:00 - 13:00  Lunch
13:00 - 14:00  Lecture: Chromatographic workstation and process systems
14:00 - 16:00  Laboratory I (Pulse response, determination of retention factor and HETP)
16:00 - 17:30  Lecture: Categories and properties of chromatographic media

Tuesday, October 4
8:30 - 11:00  Evaluation of Laboratory I data
11:00 - 12:30  Lecture: Mass transfer effects - Fundamentals
12:30 - 13:30  Lunch

Wednesday, October 5
8:30 - 11:00  Evaluation of Laboratory II data
11:00 - 12:30  Lecture: Antibody capture with Protein A media
12:30 - 13:30  Lunch
13:30 - 14:30  Lecture: Gradient elution theory
14:30 - 17:30  Laboratory II (Frontal analysis, determination of DBC and scale-up parameters)

Thursday, October 6
8:30 - 11:00  Evaluation of Laboratory III data
11:00 - 12:30  Lecture: HIC and biomolecular perspectives
12:30 - 13:45  Lunch and tour
13:45 - 15:30  Lecture: Chromatographic column design and optimization for capture and resolution
15:30 - 17:00  Laboratory IV (Gradient elution, HETP from gradient runs and optimization)
17:30  Course banquet

Friday, October 7
9:00 - 10:30  Evaluation of Laboratory IV data
10:30 - 12:30  Optimum column design exercise
12:30 - 13:30  Lunch

For further information about the course program contact: Prof. Giorgio Carta, Department of Chemical Engineering, University of Virginia, Charlottesville, Virginia 22904-4741, Phone: (434) 924-6281, gc@virginia.edu

Registration & Fees: The course fee is $4,500 and includes lodging at the Courtyard Marriott, daily continental breakfast and lunch, Sunday and Thursday dinners, course notes, USB flash drive with all course materials (also available in downloadable format), and lab supplies. Enrollment is limited to 24 people. Registration deadline is September 1, 2016.

Cancellation Policy: Cancellations must be made in writing. Cancellations after September 1 will be subject to a 25% cancellation fee. Cancellations after September 6 are subject to the total fee. In any case, a colleague or an associate may be substituted without penalty. Full refunds will be made in case the course is cancelled due to insufficient enrollment.

Registration Form - Protein Chromatography Short Course October 2-7, 2016, University of Virginia, Charlottesville, Virginia, USA

Name:  Dr. □ Mr. □ Ms. □
Company: ___________________________
Address: ___________________________
City/State/Zip: _______________________
Telephone: ( )_________________ Fax: ( )____________ Email: _______________________

I will attend the optional lab column packing session on Sunday:  □ (check the box to pre-register)

REGISTRATION MUST BE ACCOMPANIED BY PAYMENT

Before registering, contact Prof. G. Carta (gc@virginia.edu) to make sure space is available

Payment: $4,500 (includes 5 nights lodging, daily continental breakfast and lunch, Sunday reception, Thursday banquet, course notes, USB flash drive with all course materials, and all lab supplies)

To pay by check, fill out and mail this form with enclosed payment to:

Giorgio Carta
Department of Chemical Engineering, 102 Engineers’ Way, University of Virginia
Charlottesville, VA 22904-4741 USA
Phone: (434) 924-6281

Check must be drawn on a US bank and payable in US dollars to: University of Virginia/Chromatography Course

To pay by credit card, fill out and email this form to Prof. G. Carta (gc@virginia.edu) requesting a link for on-line payment
Excerpts from past Short Course evaluations by the participants

“The Excel spreadsheets provided are very useful tools and will definitely help us improve our evaluation process.”

“I thought the entire course was carefully set-up, so that everything was a “best feature”. It is excellent that we can take all the reference materials, lab results, and spreadsheets with us.

“I loved the course. Learned so much and met many great people.”

“The course will help me to better understand our current process and to make educated decisions and recommendations.”

“Working in groups in the labs was very helpful. The tutors were great. The labs brought the lectures together.”

“The best feature of the course was] the general overview of what is happening inside a chromatographic column and detail given on how to exploit the interactions for process development and improvement”.

“The labs really highlighted well the important concepts.”

“Friendly and knowledgeable instructors. Excellent class pace and good combination of class and lab work.”

“Understanding how flow rate and bead size/structure can affect peak shape and HETP will be helpful for troubleshooting elution issues at the manufacturing scale.”

“Exploring the various features of the AKTA system and applying the theory to future development experiments [will be most useful in my current/future job].”

 “[The best feature of the course was] learning the concepts/theory in class and applying them directly in the lab.”

“[The course provided me with a much better understanding of principles for understanding critical parameters for validation.”

“[The course] provided practical ways to gather data and understand my purification process, to optimize parameters methodically, to be able to predict behavior when parameters are varied (flow rate, column length, etc.).”

“What will be most helpful in my current job] is that it helped me understand the science behind the process.”

“[The best feature of the course] was the detailed explanations of most relevant parameters for process development and scale-up. Excellent instructors and friendly attitude of all participants.”

“[What will be most helpful in my current job] is being able to compare and analyze different chromatography media and the process of evaluating which resin is best for different applications.

“The theory I learned will help with making better decisions on preparing scale-down purification models.

“[This course] was well above my expectations and I would recommend this to anyone in bioprocess industry.”

“The laboratory sessions were the best feature of the course. It was a practical way to integrate the lectures.

“I think the modeling will be helpful in understanding any unusual behaviors of new technologies (resins) that I try to implement. Also a better understanding of resins will allow me to narrow the resins that I screen upfront.”

“[The best feature of the course was] discussion of practical applications of modeling and molecular level understanding of chromatographic processes.”

“Coming from a background with little chromatography/engineering training, this course provides great overview of chromatography in an industrial production setting.”