Bulletproof Purification Process Development

Developing robust manufacturing procedures for protein and viral therapeutics

by Pete Gagnon, Validated Biosystems Inc.

This intermediate/advanced 3-day lecture course is designed for professionals who want a thorough understanding of developing purification procedures capable of withstanding the rigors of a highly regulated manufacturing environment. This course is unique in its practical approach, based on more than 25 years of hands-on experience in downstream processing. Participants will obtain an integrated understanding of product chemistry, chemistry and behavior of major contaminant classes, how major purification methods exploit the physicochemical differences between product and contaminants, the strengths and weaknesses of major purification methods, fundamentals of process development, and building process control into manufacturing processes. This course will provide practical new tools to process developers at all levels, as well as support a deeper appreciation of process design by manufacturing process operators, quality control, quality assurance, and regulatory staff. Familiarity with fundamentals of biochemistry, purification methods, and previous hands-on experience will be helpful.

Day 1

Chemistry and Interactions
- Size, hydrodynamic radius, mass, diffusion constants

Charge characteristics
Hydrophobic characteristics
Metal affinity
Solubility, stability, kosmotropes, kaotropes
Purification Methods
- Precipitation; salts, polymers; organic acids, bases, solvents
- Chromatography
  - Diffusion, perfusion, convection
  - Microfiltration, ultrafiltration, diafiltration

Size exclusion, mechanism, strengths, weaknesses
- Ion exchange, mechanism, strengths, weaknesses

Day 2

Purification Methods
- Chromatography
  - Hydrophobic interaction, mechanisms, strengths, weaknesses
  - Immobilized metal affinity, mechanisms, strengths, weaknesses
  - Mixed mode, mechanisms, strengths, weaknesses
  - Biological affinity, mechanisms, strengths, weaknesses

Contaminants and Impurities
- Product variants, origins, characteristics, and removal
- Proteins, characteristics, product interactions, removal
- DNA, characteristics, product interactions, removal
- Lipids, characteristics, product interactions, removal
- Endotoxin, characteristics, product interactions, removal

Contaminants and Impurities (continued)
- Virus, characteristics, product interactions, inactivation, removal
- Metal ions, characteristics, product interactions, removal

Day 3

Building Process Control into Purification Procedures
- Qualifying process components
  - Consumables
  - Raw Product
  - Chromatography media
  - Chromatography equipment
- Process development basics
  - Selectivity screening
  - Method evaluation
  - Method selection
  - Method sequencing
  - Sample equilibration and application
  - Process modeling
  - In process assays
- Platform process development

Process documentation
- Purification as a process control tool

About the instructor

Pete Gagnon is an internationally recognized figure in the field of downstream processing. He is best known for his book Purification Tools for Monoclonal Antibodies, and his website www.validated.com where he maintains a free library of articles addressing a range of practical downstream processing issues. He is a member of the Editorial Advisory Boards for Genetic Engineering News, Bioprocess International, and Bioprocessing Journal, as well as a frequent contributor and reviewer to various journals in the field. Pete is also a frequent moderator and speaker at downstream processing conferences all over the world. He has been teaching courses in the field of downstream processing since 1987, including an evolving series of the present course since 1996. All of his publications, presentations, and courses are based on his personal hands-on experience as a process developer.

Pete has spent 15 of the last 19 years at the helm of Validated Biosystems Inc., an international consulting firm that he established in 1987. During that time he has supported the efforts of more than 50 biopharma companies worldwide, ranging from start-ups to multinational giants. His experience includes purification of numerous recombinant proteins, plasmids, and viruses. He has also worked with all of the major chromatography suppliers to develop applications and educational literature for a wide variety of purification products.

Course Schedule

Day 1

08:00 – 08:30 AM	Registration and breakfast
08:30 – 10:15 AM	Session
10:15 – 10:30 AM	Break
10:30 – 12:00 PM	Session
12:00 – 01:00 PM	Lunch
01:30 – 02:15 AM	Session
02:15 – 02:30 AM	Break
02:30 – 4:00 PM	Session

Day 2

08:00 – 08:30 AM	Breakfast
0:830 – 10:15 AM	Session
10:15 – 10:30 AM	Break
10:30 – 12:00 PM	Session
12:00 – 01:00 PM	Lunch
01:30 – 02:15 AM	Session
02:15 – 02:30 AM	Break
02:30 – 4:00 PM	Session

Day 3

08:00 – 08:30 AM	Breakfast
0:830 – 10:15 AM	Session
10:15 – 10:30 AM	Break
10:30 – 12:00 PM	Session
12:00 – 01:00 PM	Lunch
01:30 – 02:15 AM	Session
02:15 – 02:30 AM	Break
02:30 – 4:00 PM	Session/adjournment

For more information about this and other courses, please contact:

Pete Gagnon
Validated Biosystems Inc.
240 Avenida Vista Montana, Suite 7F
San Clemente, CA 92672
E: pete@validated.com
T: 949-276-7477