# CHAMOW & Associates

## Biopharmaceutical Product Development

www.chamowassociates.com | +1 650 345 1878

Chamow & Associates is a leading provider of consulting services to the biopharmaceutical industry.

Established by Dr. Steven Chamow in 2004, Chamow & Associates provides expert advice and guidance on the preclinical to commercial phases and costs of biopharmaceutical product development.

Our expert team focuses exclusively on chemistry, manufacturing and controls (CMC) and specifically on biotherapeutics, with an emphasis on monoclonal antibodies.

Our services include the key areas of CMC: technical design for production of drug substance and drug product, formulation and delivery of drug product, quality control and quality assurance, regulatory compliance and filing, and coordination of CMC activities between ourselves, clients and vendors.

## ABOUT STEVEN CHAMOW, Ph.D., PRINCIPAL

Steven Chamow, Ph.D. is a biotechnology consultant, with over 27 years of experience in biopharmaceutical product development. Dr. Chamow has served as senior vice president of CMC at Intradigm Corporation; vice president of process sciences at Genitope Corporation and Abgenix, Inc.; director of biopharmaceutical development at Scios, Inc. and scientist and senior scientist in process development at Genentech, Inc. During his career, Dr. Chamow has contributed to the development of three marketed products – Avastin, Natrecor and Vectibix.

Dr. Chamow is the author or co-author of more than 50 scientific publications and patents, and has co-edited two books: "Antibody Fusion Proteins" (1999) and "Therapeutic Fc Fusion Proteins" (2014). He holds a B.A. in biology from the University of California, Santa Cruz and a Ph.D. in biochemistry from the University of California, Davis. He completed postdoctoral training at the National Institutes of Health.

## SERVICES

### Consulting

Providing strategic advice and guidance on the stages and costs of biopharmaceutical drug development. Assist management with:

- Preclinical proof-of-concept studies
- Process design and optimization
- Assay development and qualification
- Formulation development and stability
- Preparation of reference standards
- Production of toxicology and cGMP lots

### Process Development/Optimization

Develop technical design for biotherapeutic production. Optimize manufacturing processes with respect to:

- Cell line development
- Upstream development
- Downstream development
- Formulation development and method of delivery
- Product and process characterization

### Outsourcing

Identify, evaluate, select and manage contract manufacturing organizations (CMO's) for all CMC tasks. Provide assistance with:

- Process and assay transfer
- Clinical production
- Clinical filling
- Commercial manufacturing
- Process validation
- Facility design

### Quality and Regulatory

Support quality and regulatory processes:

- Design quality management system
- Write SOP's
- Review and approve quality agreements
- Approve quality documents of CMO's
- Perform vendor audits

### Project Integration

- Integrate development activities with manufacturing processes; partner with clients and CMO's to form an integrated CMC team and coordinate activities of the team
- Develop timelines and budgets for IND/BLA activities
- Prepare pre-IND briefing package and CMC section of IND

### Training

On-site, in-depth, CMC and regulatory compliance training. Train clients to plan and execute product development and manufacturing strategies, and to integrate CMC activities with regulatory requirements to ensure quality and compliance throughout the product life cycle

If you would like to learn more about our services, discuss your requirements, or ask questions, please don't hesitate to contact us.


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