AliraHealth

Advancing Biologics Development with

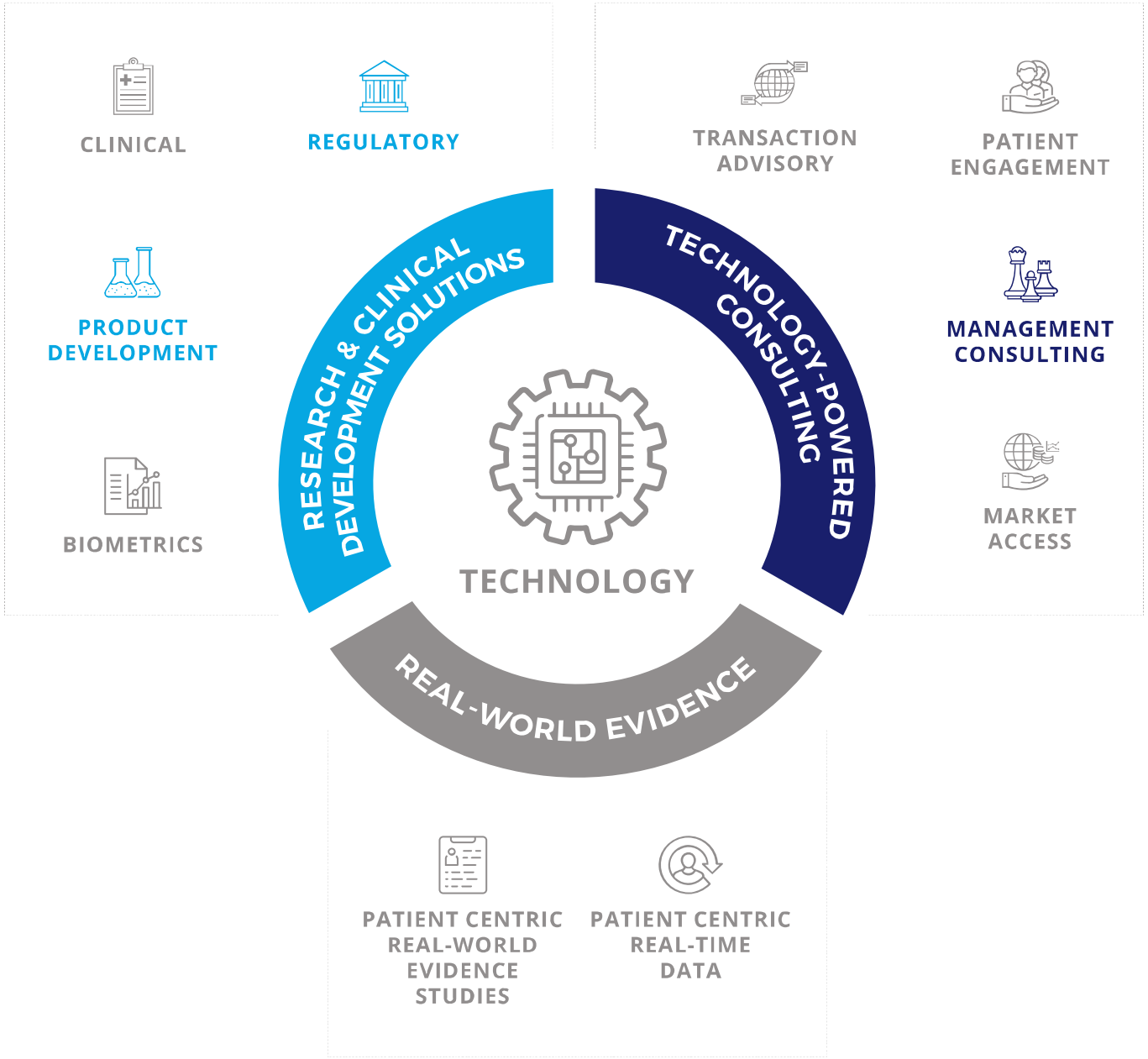
Integrated CMC Solutions

For more information:

ABOUT US

Alira Health provides a suite of integrated services designed to help life sciences and healthcare organizations innovate and grow, impacting the patient experience and ushering in the new standard of care.

Our comprehensive CMC services are a part of Alira Health's Product Development, Regulatory and Management Consulting practices, which offer a full range of services from discovery to approval across the USA and EU.



INTEGRATED CMC SOLUTIONS

We offer preclinical- and clinical-stage biotechnology companies integrated solutions to bring new therapies to patients. Our CMC focus is primarily on biotherapeutics including monoclonal antibodies, derivatives and antibody-drug conjugates.

Within CMC, we **provide integrated services in four key areas:** technical design for clinical production, quality assurance, regulatory compliance and filings, and project management.

In addition, we support toxicology studies to complete the non-clinical requirements for drug development.

ALIRA HEALTH'S CMC PRACTICE

\+ Toxicology
Regulatory
Clinical

CMC SERVICES

PRODUCT DEVELOPMENT

- Support clinical development with strategic CMC consulting
- Manage outsourcing for virtual companies
- Develop/optimize manufacturing processes
- Provide Quality and Regulatory services to build sponsor's quality management system, and file documents with regulatory agencies
- Provide technical and GMP training
- Integrate timelines and coordinate efforts of sponsor and contract facilities to hit milestones

BUSINESS CONSULTING

- Conduct market assessments for CDMOs to sharpen competitiveness
- Help to design/validate GMP facilities
- Perform due diligence on assets being considered for acquisition by sponsors
- Act as expert witnesses to support patent litigation

CMC EXPERTISE

For more than a decade, our therapeutic areas of expertise have included oncology, infectious disease, cardiovascular disease, and diabetes.

We cover all phases of product development, from discovery to commercial to meet short-term and long-term needs.

- Protein engineering and manufacturability
- Cell culture and purification process development
- Formulation development
- Scale up
- GMP manufacturing of drug substance and drug product
- Assay development and quality control
- Quality assurance and regulatory affairs
- Project management
- Toxicology

CMC VALUE PROPOSITION

We offer a **team** of industry experts in key aspects of CMC.

We **advocate** for our clients' interests with vendors.

We support product development with comprehensive, **integrated** services coordinated between client and vendor.

We apply a **flexible** service model. Our scope of services adjusts with our clients' programs.

We provide a **continuum of services** to accelerate innovation and deliver tomorrow's standard of care.

CMC LEADERSHIP

Steven Chamow, Ph.D.

Senior Vice President, CMC Development

Steve is a recognized expert in monoclonal antibodies and derivatives with 27+ years of biopharmaceutical experience. As Senior Vice President, CMC Development, Dr. Chamow draws on his extensive technical and product development background to assist biotechnology companies in designing and developing CMC strategies for products in development, including transfer to and implementation by qualified CDMOs.

> More information

Sangita Seshadri, Ph.D.

Process Development

Sangita is an expert in drug formulation and delivery. She provides expertise and technical leadership in strategic development and commercialization of traditional and novel platform and product-specific dosage forms and delivery systems.

Stephen Nava

Quality Assurance

Stephen is a quality assurance and regulatory affairs professional with 25+ years of experience in cGMP compliance and quality systems. Stephen is an ISO 9000-trained auditor with a solid foundation in worldwide quality and regulatory requirements and a thorough knowledge of cGMP guidelines.

Wendy Lin

Regulatory

Wendy has 20+ years of professional, multidisciplinary biotech and pharmaceutical experience. She has successfully led and designed global development strategies for regulatory, clinical, CMC, and companion devices for over 30 early-to-late-stage programs across oncology, infectious disease,immunology, and inflammation indications.

Jennifer Bratt, Ph.D.

Project Management

Jennifer assists Alira Health project leaders by planning, directing, and coordinating activities of team members for designated client projects. For 5+ years, she has ensured that goals and objectives are accomplished within prescribed time-frame and funding parameters as a project manager.

AliraHealth

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