ALTHEA

THE POWER TO MAKE

The Complete Solution:

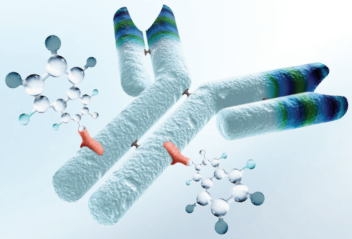
Althea's Simplified ADC Supply Chain


LET'S
MAKE
A DIFFERENCE

You have the power to make a difference.

To make new therapeutics that improve quality of life and inspire a healthier world. To do this, you need a manufacturing partner who embraces your every challenge as its own, who shares your unwavering tenacity and dedication from clinical studies through commercial success.

That's The Power To Make.



Antibody Drug Conjugates (ADCs) and Highly Potent Active Pharmaceutical Ingredients (HPAPIs)

Expanding upon our existing capabilities in biologics manufacturing, Althea is establishing itself as a premier, US-based provider for high containment ADC bioconjugate manufacturing as well as fill and finish services for both HPAPIs and ADCs. Our state-of-the-art 57,000 sq. ft facility is located a few miles from our Roselle St. campus in San Diego, CA. The facility and our service offerings have been designed to meet the current and future needs of ADC developers in order to ensure a stable supply of your promising therapeutics.

Our new facility will include capability for process development, analytical development, formulation, clinical and commercial manufacturing for bio-conjugation and fill finish along with all supporting services for release and stability testing. Althea staff will provide you with technical expertise, robust quality systems and experienced personnel to support interactions with regulatory bodies world-wide at all stages of your drug development process.

Althea's Integrated Service Offering

As your premier service provider, Althea's new ADC service offerings will simplify your supply chain by consolidating high containment conjugation, formulation, fill finish and release and stability testing at the same facility.

Fill/Finish & Lyophilization
- Industry leader in aseptic filling
- Over 2,300 drug products
- Over 10 years experience in lyophilization of biomolecule drug products

Purification & Conjugation
- Over 15 years Tangential Flow Filtration & Chromatography of Biologics
- Strong background in non-high potency conjugation

Supply Chain
- Over 2,300 drug products packed and shipped efficiently from Althea

Analytical Development
- Biophysical and biochemical characterization
- Phase appropriate validation

Quality and Regulatory
- Multinational compliance
- 5 Pre-approval inspections
- US, EU, Japan and Canada GMP Certification

Leveraging Althea's Extensive Technical Expertise

ALTHEA SERVICES AND CAPABILITIES

Conjugation and Purification

- Process verification
- Preparation of GLP tox material
- cGMP conjugation for clinical and commercial applications
- Isolator for potent compound handling
- Reactor sizes 10L-100L (single use system)
- Single use TFF unit with membrane capacity up to $2m^2$
- Single use chromatography system
- Facility will be designed and tested to handle compounds with OEL down to 1 ng/m3

Fill & Finish and Lyophilization

- cGMP clinical and commercial fill finish
- 120 Vials/Min for 2 mL vials
- Fill line batch sizes up to 70,000 vials
- Lyophilizer batch capacity up to 20,000 vials
- Vial sizes - 2 mL – 20 mL
- Isolator technology
- External vial washer

Process Development

- Conjugation process development milligram to gram scale
- UF/DF development
- Chromatography methods development
- Formulation development
- Material generation for pre-clinical studies including analytical characterization

Analytical Development, Release and Stability

- MALS/IR
- LC/MS, HPLC, UPLC
- CE, icIEF
- UV/VIS
- SDS-PAGE
- ELISA /LBA
- Moisture, CCI
- Environmental /bioburden testing
- LAL

CORE MANAGEMENT TEAM

Althea supports our clients with seasoned professionals who have extensive experience and proven track records in contract development and manufacturing services.

J. David Enloe, Jr. - President and CEO

- 20 years executive management
- Biotech drug development and CMO leadership experience
- Founded and sold CMO prior to joining Althea as President and CEO

Chris Duffy - Senior Vice President, Operations

- 30 years industry experience
- 11 years managing Althea's Drug Product Manufacturing Group
- Significant role in growing Althea's CMO offerings since inception

Elaine Sapinoso - Vice President of Quality & Regulatory Affairs

- 17 years quality assurance and regulatory experience
- 12 years of experience with contract biologics and aseptic filling organizations
- Successfully managed multiple FDA,EMA inspections

Jason Brady, PhD - Senior Director & Business Head, ADCs

- 10+ years experience in contract manufacturing sales and business development
- Experience in contract negotiation and creative deal making
- Designed and implemented ADC commercial strategies
- Experience leading capacity expansion projects

Stacy Sutton - Senior Director, Facilities & Engineering

- 20 years of biotech processing, facilities and engineering
- Led Althea's facility expansion into commercial manufacturing
- Extensive experience in procurement and validation of capital equipment

Bob Bayer, PhD - Director, ADC Process Development & Tech Transfer

- 27 years industry experience in biotech/pharma
- Developed the process for Novartis' first clinical ADC using lysine conjugation chemistry
- CMC team leader for ADC in clinic employing cysteine conjugation chemistry
- Site specific bioconjugates using glycosyltransferases

Michael Molony - Director of ADC Analytical Development

- 27 years industry experience in biologic drug development for several major biotechnology companies
- 10 years in Quality Control and 17 years in Analytical Development roles including ADCs and first approved radiolabeled mAb.
- CMC team leader for ADC, multiple mAbs, scaffold protein, and multiple neurotoxins

WHAT DO YOU WANT
TO MAKE?

We're looking forward to hearing from you.

For more information visit:
www.altheacmo.com/ADC

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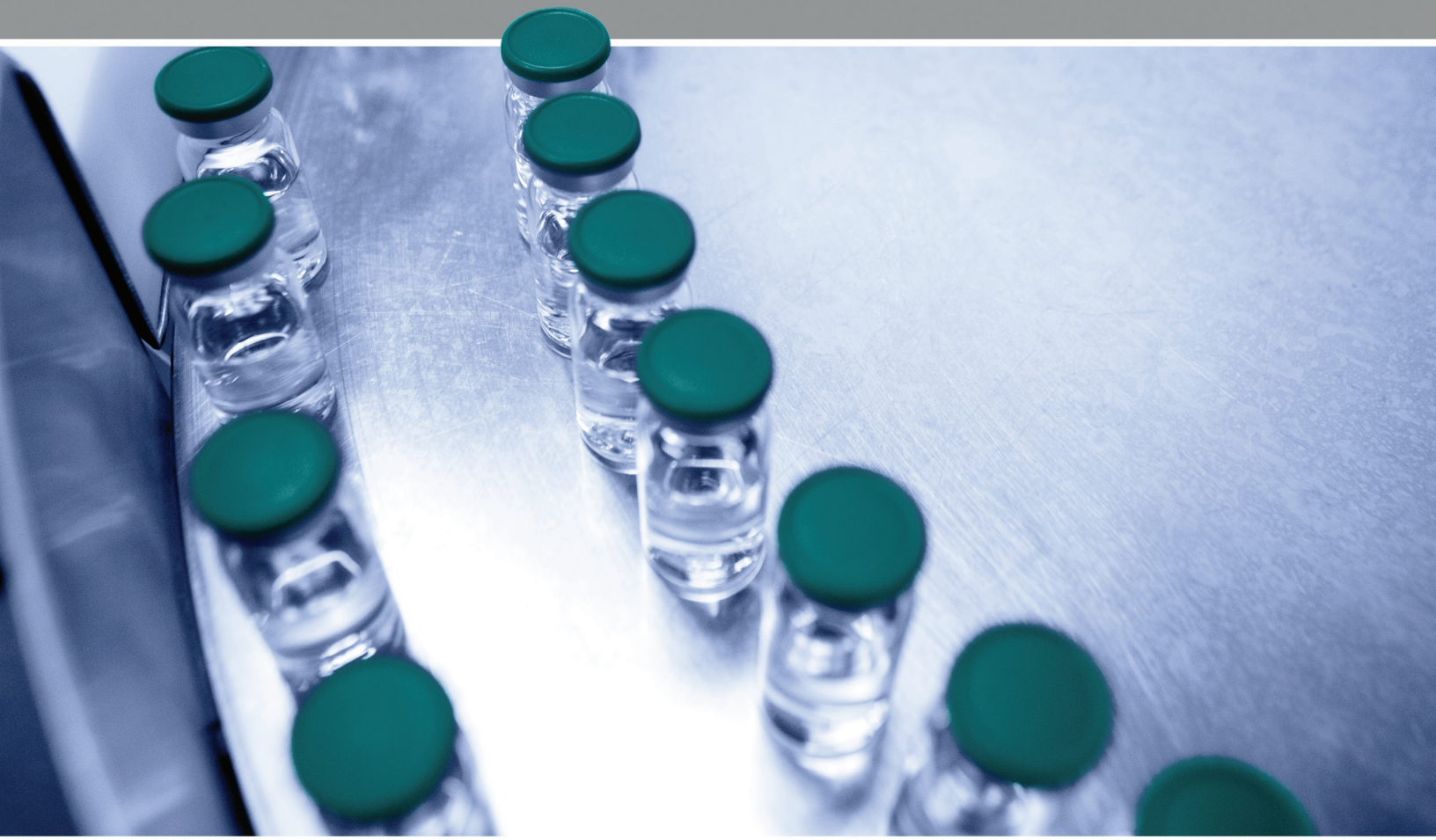
www.AltheaCMO.com



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