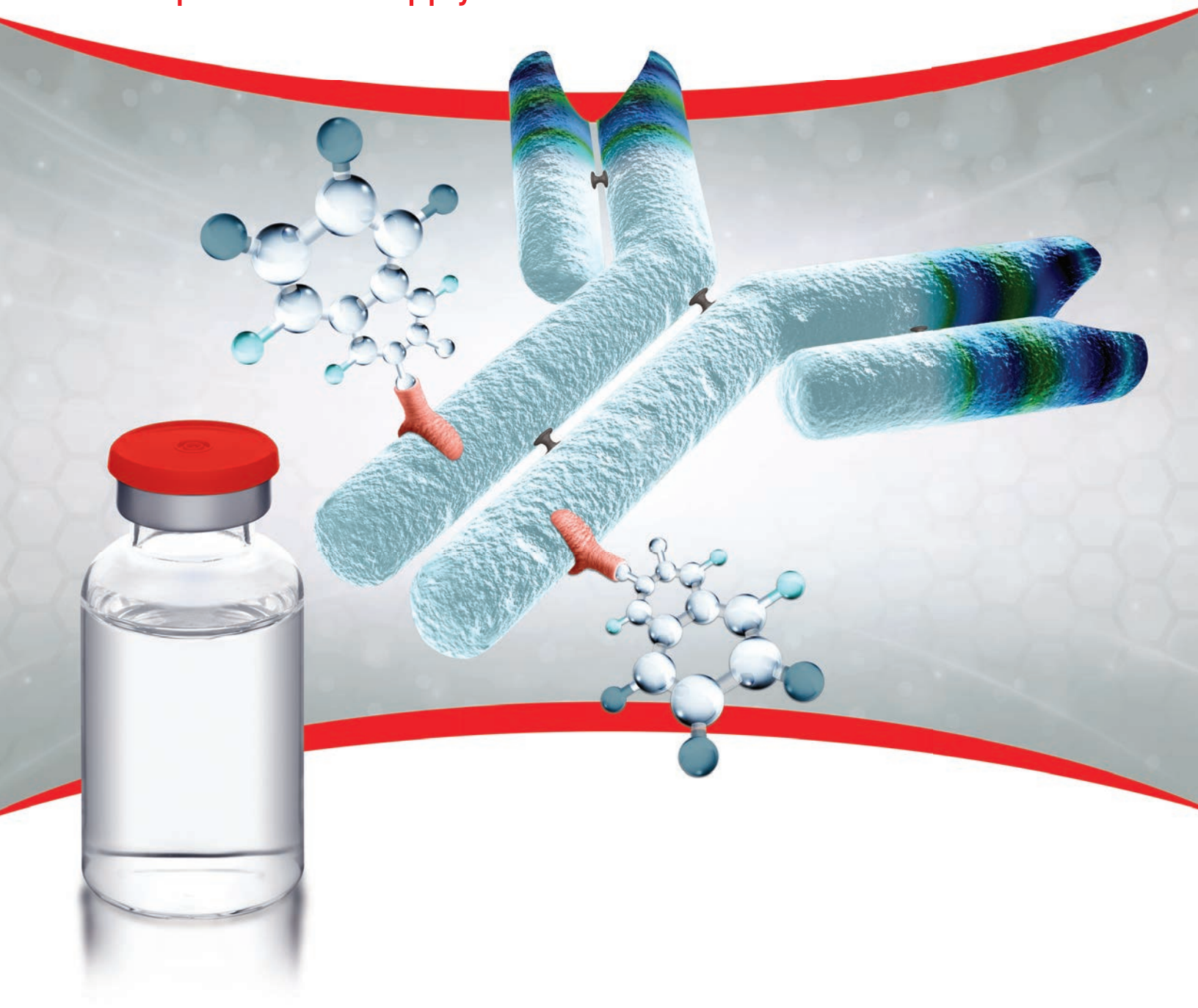
AJINOMOTO BIO•PHARMA SERVICES

Ajinomoto Bio-Pharma Services

Simplified ADC Supply Chain



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

Ajinomoto Bio-Pharma Services is an established premier US-based provider for high containment ADC 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 capabilities include 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. The Aji Bio-Pharma team will provide you with technical expertise, robust quality systems and experienced personnel to support interactions with regulatory bodies worldwide at all stages of your drug development process.

AJICAP™ Site-Specific Conjugation Technology

Ajinomoto Bio-Pharma Services is able to offer significant advantages for the next generation of ADCs through AJICAP™, an innovative direct chemical site-selective conjugation method for intact native antibodies. No genetic modifications required. Our advanced method allows for high productivity, short conjugation reaction times and ease of manufacture.

Fill/Finish & Lyophilization
- Industry leader in aseptic filling
- Over 20-years experience in lyophilization of biomolecule drug products

Conjugation & Purification
- Strong background in high potency conjugation
- Over 20-years experience tangential flow filtration & chromatography of biologics

Supply Chain
- Combine drug substance and drug product manufacturing for speed to clinic
- Secondary packaging and labeling which includes unit level and unit of sale serialization

Process & Analytical Development
- Experience with all conjugation chemistries
- Biophysical and biochemical characterization
- Phase appropriate validation
- Process development including small scale R&D

Quality & Regulatory
- Multinational compliance
- 15 pre-approval inspections from US, EU, Australia, Canada, Japan, Turkey, South Korea, Brazil, Russia
- US, EU, Japan and Taiwan GMP Certificates

Aji Bio-Pharma's Extensive Technical Expertise

Ajinomoto Bio-Pharma Services and Capabilities

Conjugation and Purification

- Process verification
- Preparation of GLP tox-study materials
- cGMP conjugation for clinical and commercial applications
- Isolator for potent compound handling
- Reactor sizes 10 L-100 L (single-use system)
- Single-use TFF unit with membrane capacity up to 2 m^2
- Single-use chromatography system
- Facility is designed and tested to handle compounds with OEL down to 1 ng/m^3

Fill & Finish and Lyophilization

- cGMP clinical and commercial fill finish
- 100% nondestructive weight checks
- Liquid or lyophilized products
- Piston or peristaltic product filling
- Vial size for liquid fill from 2 mL to 100 mL
- 100 Vials/Min for 2 mL vials
- Fill line batch sizes up to 50,000 (2 mL) vials
- Lyophilizer batch capacity up to 21,000 vials (2 mL vials)
- SKAN isolator technology
- External vial washer for cytotoxic products

Process Development

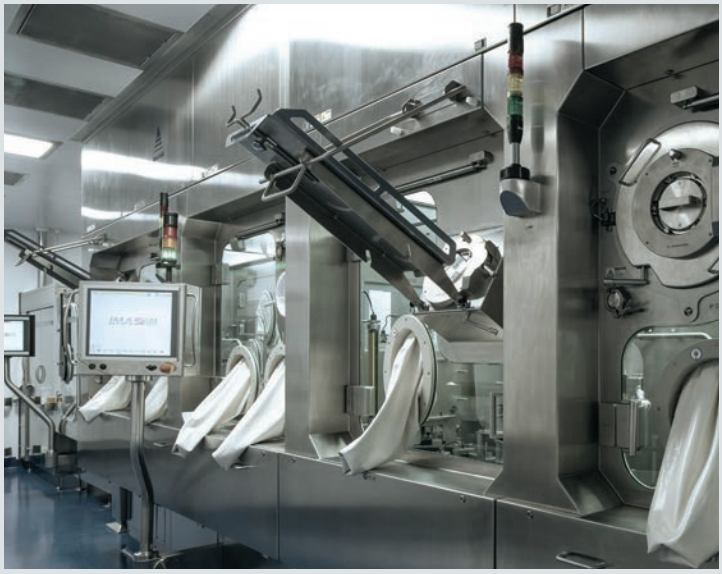
- AJICAP™ conjugation technology
- Conjugation process development milligram to gram scale
- UF/DF development
- Chromatography methods development
- Material generation for pre-clinical studies including analytical characterization

Analytical Development, Release and Stability

- HPLC, UPLC, LC/MS (QTOF & QQQ)
- MALS, QELS, RI (RI for refractive index, not IR for infrared)
- CE, cIEF
- UV-Vis
- ELISA/LBA
- SDS-PAGE
- Moisture, CCI
- Environmental / bioburden testing
- LAL

Aji Bio-Pharma's Integrated Service Offering

As your premier service provider, our ADC service offerings will simplify your complex supply chain by consolidating the process development/transfer, analytical, GMP bioconjugation and GMP fill finish services at a single location in San Diego, CA. Our clients supply us the key raw materials and we do the rest. The combination of bioconjugation and fill finish manufacturing services can mitigate risk in transportation of materials as well as shorten timelines to clinic.



Core Management Team

Ajinomoto Bio-Pharma Services supports our clients with seasoned professionals who have extensive experience and proven track records in contract development and manufacturing services.

Kristin DeFife - Sr VP of Operations & Site Head
- Accountable for Aji Bio-Pharma US Operations
- 20-years of bio-pharmaceutical development and contract manufacturing leadership
- Formerly oversaw PacificGMP (now Abzena) Bio-Pharmaceutical Contract Manufacturing Operations

Bert Barbosa - VP of Drug Product & ADC
- More than 35-years of bio-pharmaceutical production, QA and compliance leadership
- Leads the Drug Product and ADC Manufacturing Operations
- Formerly lead Allergan Biologics QA/QC Drug Substance Operations
- Oversaw contract commercial manufacturing in previous quality roles

Jason Brady - Sr Director of Business Development
- Over 15-years of experience in CDMO sales and business development
- Over 8-years working with clients on contracts for ADC services at Aji Bio-Pharma and Lonza
- Comprehensive understanding of client needs in establishing manufacturing partnerships

Brian Mendelsohn - Director of Process Development & Tech Transfer
- 20-years of ADC experience
- Developer of several ADC linker-payload and conjugation technologies
- Formerly part of the Seattle Genetics and Agensys ADC Chemistry R&D teams

Paul Ruther - Director of Drug Product Manufacturing
- Accountable for all formulation and filling activities for Aji Bio-Pharma US operations
- 24-years of research, bio-pharmaceutical development, and contract manufacturing
- Formerly oversaw an infectious disease laboratory at the University of Iowa and worked in the Antibody Production Group (Xenerex) at Avanir Pharmaceutical

Doug DeMoe - Sr Manager of Manufacturing
- 13-years of both drug substance and drug product experience
- Led Aji Bio-Pharma's facility expansion into commercial manufacturing
- Former group leader for validation of two Genentech commercial products

AJINOMOTO BIO•PHARMA SERVICES

THE POWER TO MAKE

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