

# EXPERIENCE UNRIVALED

## ANTIBODY DRUG CONJUGATES (ADC)

**When selecting AbbVie Contract Manufacturing**, you are partnering with a leading developer and manufacturer focused on accelerating and mitigating risks to program timelines and on efficiently fast-tracking your program to completion. AbbVie's mAb and ADC state-of-the-art facility and expert scientific team are located in Worcester, Massachusetts, where we specialize in treating your product as our own and have demonstrated the capability to optimize success from innovation through commercialization. In addition to our expertise, our customers also benefit from a simplified supply chain as both mAb and conjugation manufacturing are conveniently located at one site.



mAb



Conjugation

## MONOCLONAL ANTIBODY

### Capabilities

- › Pre-clinical to clinical capacity is 300 L, 500 L, 3 KL and 6 KL
- › Commercial capability is 500 L, 1,000 L, 3 KL, 6 KL and 12 KL
- › Able to do both biologics and ADCs together at one site
- › 5 suites
- › Approvals for global markets and comprehensive regulatory expertise
- › Structured planning
- › Capability to handle many projects simultaneously

### Process development

- › Offer full development package
  - Cell line development
  - Analytical development
  - Late clinical transfer
  - PPQ efforts to post-commercial offering
- › Cell culture process development
- › Purification process development
- › Media development and optimization
- › Analytical method development
- › Extended product characterization
- › Viral clearance studies
- › Provide technical expertise and assistance from cell line development to commercialization
  - Process transfer/development method (analytical, scale-up, etc.)
  - Process validation and mapping
  - Process characterization studies
  - Process data trending
  - Continuous process verification
- › Quality assurance
- › Quality control
- › Project management

**Process scale-up** labs featuring single-use and stainless technology, with scales ranging from 3 L to 1,000 L

### Analytical development, release and stability

- › HPLC (SEC, IEX, affinity, reverse phase)
- › Host-cell protein
- › Electrophoresis (CE, IEF, SDS-PAGE)
- › ELISA
- › Peptide structure determination (LC, MS)
- › Oligosaccharide analysis
- › DNA quantification (threshold)
- › DNA identification (PCR)
- › Spectrophotometry (FT-IR, US VIS)
- › Bioburden/endotoxin

### CONTRACT MANUFACTURING

USA +1 800 240 1043 | Outside USA +1 847 938 8524 | [abbviecontractmfg.com](http://abbviecontractmfg.com)

# EXPERIENCE UNRIVALED

## ANTIBODY DRUG CONJUGATES (ADC)

### CONJUGATION

#### Capabilities

- › Designated and tested facility able to handle compounds with OEL down to < 10 ng/m<sup>3</sup> containment
- › Handle up to category 5 compounds: auristatin, PBD, and calicheamicin
- › Process validation
- › 2.5 L to 32 L columns
- › cGMP conjugation for clinical and commercial
- › Preparation of GLP tox material
- › Single-use TFF unit with membrane capacity up to 2 m<sup>2</sup>
- › Reactor volume 30 L to 500 L stainless steel and single use
- › Single-use chromatography columns used on Akta skid

#### Process development

- › Conjugation scale for process development is milligram to gram scale
- › Formulation development
- › UF/DF development
- › Manufacture material for pre-clinical studies including analytical characterization
- › Chromatography methods development

#### Analytical development, release and stability

- › Onsite quality and testing
- › R&D onsite testing
- › UV/VIS
- › MALS/IR
- › CE, icIEF
- › CE-SDS (Beckman), mCE-SDS (Perkins Elmer)
- › HPLC, UPLC, LC/MS
- › LAL
- › ELISA
- › Environmental/bioburden testing
- › HIC for DAR

### Why choose AbbVie?

- › **SPEED/CAPACITY** suite and tech transfer capacity readily available, enabling us to move quickly for new projects and support commercial launch from fast-track molecules
- › **STRONG** regulatory track record/metrics
- › **FULL SERVICE** ability to package mAb production with conjugation services
- › **LEADER** in monoclonal antibody (mAb) production and process development for over 40 years

#### CONTRACT MANUFACTURING

USA +1 800 240 1043 | Outside USA +1 847 938 8524 | [abbviecontractmfg.com](http://abbviecontractmfg.com)