
DIATHEVA
BIOTECH CDMO

# WHY CHOOSE DIATHEVA BIOTECH CDMO

## SMALL-SCALE BATCHES

Extensive experience in R&D support, process development, and small-scale GMP manufacturing of APIs and sterile liquid finished forms - providing agile and reliable collaboration across early clinical stages.

## CUSTOMIZED SOLUTIONS

Customer-focused and innovation-oriented mindset, offering tailor-made biotech CDMO services built around each project's specific needs, ensuring flexibility, quality standards, and end-to-end scientific alignment.

## SMART COST EFFECTIVENESS

Lean and efficient processes designed to increase productivity, enhance quality, and reduce costs, delivering timely solutions and maximum value to our client partners.

## WIDE RANGE OF ANALYTICAL CAPABILITIES

Comprehensive in-house analytical services supporting R&D and GMP productions, further assisting our client partners in analytical methods development and validation.

DIATHEVA
Bringing Research to Application

DIATHEVA is an Italian Biotech company, founded in 2002 as a spin-off from the University of Urbino.
The company specializes in the **Research, Development and Production of:**

- **Biotechnological Products**, including monoclonal and polyclonal antibodies, antibody fragments, recombinant proteins, recombinant enzymes and antigens.
- **Molecular and Immunoenzymatic Assays**, such as clinical and veterinary diagnostics, food tests and environmental kits.

**With 70% of its employees holding at least a PhD,** DIATHEVA ensures high expertise across all activity phases.

DIATHEVA is part of the **SOL Group**, an Italian multinational company present in over **30 countries** with over **7.000 employees**.

# R&D AND MANUFACTURING OF BIOLOGICS

As part of our integrated R&D offering, **we support our partners in the development of biologics** from early discovery to process optimization, with a focus on quality, scalability, and future GMP compliance.

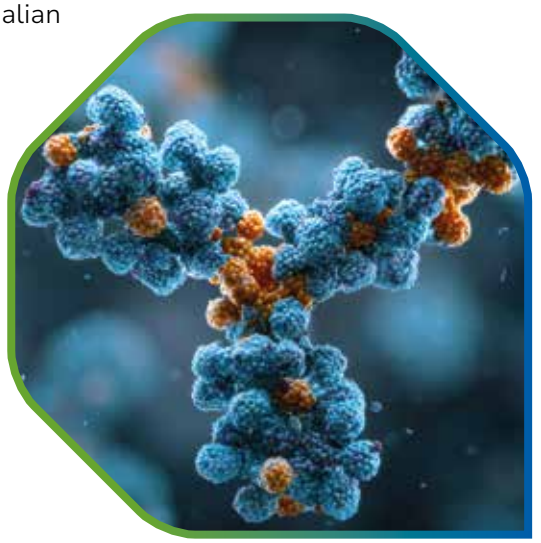
## OUR R&D SERVICES

### Antibodies & Proteins - Discovery
We provide discovery, target identification, and protein engineering for monoclonal antibodies and recombinant proteins, including hybridoma screening and candidate selection in mammalian or microbial systems.

### Cell Line Development
We generate and optimize stable cell lines to support the production of a wide range of biologics. Services include vector selection, transfection, clone selection, expression optimization, and initial small-scale production and cell line stability studies across both bacterial (*E. coli*) and mammalian (CHO) systems.

### Process Development
We develop and scale up robust upstream (cell culture/fermentation) and downstream (purification) processes tailored to the target molecule for pilot and clinical supply.

### Analytical Methods Development
We develop, optimize, and validate analytical assays to support full product characterization, in-process control, lot release, and long-term stability studies.



# GMP SMALL-SCALE MANUFACTURING

We provide **GMP-compliant manufacturing services** for **clinical-grade biologics**, with a focus on monoclonal antibodies, recombinant proteins, enzymes, and other biologically active molecules.

Our services support the transition from R&D to clinical supply, ensuring full compliance with **international GMP standards** and **regulatory requirements**.

## OUR GMP SERVICES

- **Master Cell Bank (MCB) and Working Cell Bank (WCB) Production**
  Developed under aseptic conditions in qualified cleanrooms, with comprehensive testing according to ICH guidelines. We also offer cryogenic storage.
- **API manufacturing for clinical trials**
- **Upstream fermentation**
  Bioreactors from 20 L to 300 L for tailored fermentation protocols.
- **Downstream purification**
  Bioprocess Modular System (max flow rate: 60 L/h) for tailored purification protocols.
- **In-process controls and final product testing**
  According to regulatory requirements, with full traceability and documentation.
- **Batch record preparation and GMP documentation**
  Master and executed batch records, Certificates of Analysis (CoA), and other requested GMP documentation.
- **Lot release and quality certification by Qualified Person (QP)**
  Released by our in-house QP, ensuring compliance with EU GMP frameworks.

# GMP CONTRACT ANALYTICAL SERVICES

DIATHEVA provides **Contract Analytical services** approved by regulatory authorities for third-party pharmaceutical and biotech companies, supporting investigational medicinal products (IMPs) **from preclinical stages through Clinical Phases I and II**.

## OUR CORE QUALITY CONTROL CAPABILITIES

- **Physicochemical Analysis**
  Structural characterization, purity and identity verification, and stability studies.
- **Microbiological Testing**
  Bioburden monitoring and hygiene quality control for intermediates and finished products.
- **Biological Assays**
  Development, optimization, and validation of bioassays to determine molecular potency and biological activity.
- **Bacterial Endotoxins**
  Crucial safety testing in compliance with international pharmacopoeias.
- **Analytical Methods Development & Validation**
  We also offer customized development and validation of analytical methods.

# STERILE FILL & FINISH
# Early Clinical Phase

Our Sterile Fill & Finish platform is designed to support the production of **investigational medicinal products (IMPs) for clinical trials.**

Operating under GMP conditions, we offer a fully integrated and flexible service that includes formulation, aseptic filling, and batch release.

## OUR F&F SERVICES

**Formulation**
Formulation for drug products intended for clinical trials.

**Fill & Capping**
Performed using advanced aseptic filling technology to guarantee sterility throughout the process.

**Customized Batch Size**
Filling line accommodating a wide range of vial formats - from 0.5 to 30 ml - for batch sizes from 200 to 3,000 vials.

**Comprehensive Quality Control**
In-process and release testing aligned with clinical GMP standards.

**Regulatory Compliance**
All Fill & Finish activities are conducted under strict GMP guidelines, in full compliance with EU regulatory frameworks (Annex 1).

From **early-stage studies** to **complex clinical designs**, our team ensures sterility, precision, and full regulatory compliance.

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