ADVAXIA
BIOLOGICS

# Precision Biologics Solutions

*An Italy-based CDMO accelerating transformative therapies from concept to clinic*

Advaxia Biologics is a specialized CDMO located near Rome, Italy, focused on the GMP manufacturing of viral vector-based biologics for gene therapy and vaccine clinical programs. Advaxia supports AAV, LVV, MVA, and oncolytic viruses through both standalone and integrated services, while end-to-end, integrated development and manufacturing support is available for adenovirus (AdV) programs.

The organization has a 100% GMP batch release track record and extensive experience delivering clinical lots under EMA, FDA, and MHRA standards, including for programs targeting HIV, Ebola, and COVID-19.

- GMP Cell Banking
- GMP Viral Banking
- Technical Transfer
- Process & Analytical Development
- GMP Drug Substance Manufacture
- GMP Drug Product Manufacture
- Formulation, Fill & Finish
- Lot / Batch Release
- Stability Studies

**AAV/LVV/AdV/MVA | Oncolytic Viruses | Viral Vector Vaccines**

SCAN ME

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# Seamless QC Testing & Analytical Support for Biologics and Vaccines

Advaxia is your trusted CDMO partner offering a full suite of analytical, process development, and GMP manufacturing services for biologics and gene therapy products, as either stand-alone solutions, as part of your integrated project, or as a fully-managed analytical program.

## Comprehensive QC & Analytical Services

- Method selection & evaluation
- Method development & validation
- Release & stability testing
- Potency, purity, identity, and safety testing
- Advanced bioassays & functional assays
- Residuals & impurity analysis

## State-of-the-Art Technologies

- Cell-based & functional assays
- ddPCR, qPCR & ELISA for biologics characterization
- Chromatography (UPLC)
- Advanced electrophoresis & spectroscopy

## End-to-End Analytical Support

- QC strategy development & management
- Secure data storage
- Regulatory documentation & submission readiness
- CMC support & audit preparedness

## Why Partner with Advaxia?

- 15+ years of experience in biologics & vaccines
- Fully integrated QC programs—no fragmentation
- EMA / FDA certified site
- GMP-compliant & globally recognized standards (Ph. Eur., USP, and ICH guidelines)

## QUALITY CONTROL TESTING & SUPPORT

# From Bulk Drug Substance to Drug Product —Seamless, Compliant, Patient-Ready

Transitioning from BDS to DP requires precision at every step. Advaxia's state-of-the-art Fill & Finish services provide end-to-end aseptic processing, labeling, packaging, and cold-chain storage—ensuring your biologic or gene therapy product is manufactured to the highest regulatory standards and delivered without delays.

## Comprehensive Fill & Finish Services

- Two dedicated filling lines for sterile injectables
- BSL-2 certified – suitable for viral vectors
- Fully automated & semi-automated filling capabilities
- Closed RABS / CFR21-compliant equipment for operator-free filling

## End-to-End Drug Product Manufacturing

- Formulation & dilution procedures
- Aseptic filling (small & standard batch sizes)
- Manual visual inspection
- Labelling & packaging
- Cold chain storage
- Release testing & QP release on-site

## Scalable Solutions to Meet Your Needs

- Up to 2,700 vials per hour
- Batch sizes from 1,000 to 5,000 vials
- Small-batch capabilities with semi-automatic filling line (<1,000 vials) for gene therapy & early-stage programs

## Why Partner with Advaxia?

- Seamless transition from Bulk DS to DP to IMP
- Flawless track record of GMP-released DP batches
- Regulatory-ready solutions designed to accelerate clinical timelines

FILL & FINISH SERVICES

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# PROCESS FLOWCHART

Representative process flow (adenovirus). Services available for viral and non-viral complex biologics.