

ADVANCED THERAPY MEDICINAL PRODUCT (ATMP) ANALYTICAL DEVELOPMENT & CHEMISTRY, MANUFACTURING, AND CONTROL (CMC) SUPPORT

Regulatory compliant (GLP / GMP) assays for characterisation, stability and release testing

The complexity of ATMPs and their mode of action, present many challenges to development. Our experts provide analytical development and routine testing to help you meet regulatory expectations for safety and efficacy.

Complexity and challenges

ATMPs are complex medicines for human use that are based on genes, tissues or cells. In addition, these may also be incorporated into a delivery technology or a medical device, for example, cells embedded in a biodegradable matrix or scaffold and are referred to as combined ATMPs. The wide variety of products within this category and their inherent complexity means that each will present different analytical development challenges, and so specific characterisation, potency, purity and identity assays are required for each product. Regulatory requirements for these classes of medicines are evolving in the EU and US currently and further guidance documents are expected in the near future.

From a best practice perspective, there is an expectation for orthogonal analytical techniques to be applied to characterisation, stability and release testing, with methods adapted to deal with, typically, small sample volumes.

ATMPs in Europe

- >500**
CLINICAL TRIALS USING ATMPs IN EU
- 20**
MAAs REVIEWED / UNDER REVIEW
- 10**
ATMPs APPROVED

REF: EMA & EC-DG SANTE WORKSHOP MAY 2018

Expert analytical services for ATMPs

Our GLP / GCP / GMP laboratories have supported developers and manufacturers for over 20 years through the provision of advanced characterisation programs. We have worked on multiple studies involving cell or gene therapies, mRNA and plasmid DNA based products. With specialist laboratory facilities, we can handle Class I and Class II Biological Agents. The facility has been designed to handle recombinant genomic materials for the purposes of research and compliant testing.

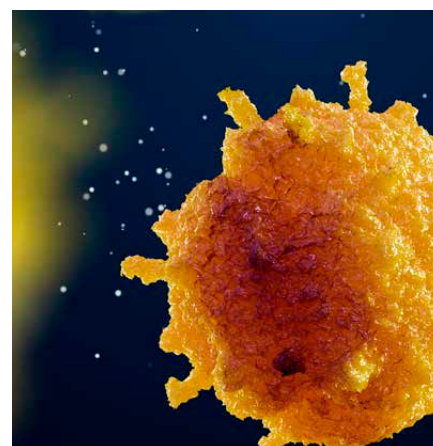
Our solutions:

- Cell and virus characterisation
- Viral vector identity
- Virology assays
- Host cell and residual plasmid DNA
- Cell-based assays / potency testing
- General compendial testing
- GMP analysis
- GCP/GLP bioanalysis
- ICH stability storage and testing
- Method development and validation
- QC release testing
- Advanced delivery technology analytical support

Viral vector characterisation

Our experts have worked on multiple studies involving Adenovirus, Adeno-Associated Virus (AAV) and Lentivirus based products. With a wide range of expertise and technology in-house, we deliver comprehensive characterisation packages or specific services:

- Aggregation analysis (AUC, DLS, TEM/Cryo-TEM)
- Empty vs full capsid analysis (TEM/Cryo-TEM)
- icIEF – Charge heterogeneity
- Transgene expression (RTqPCR and ELISA)
- Liquid chromatography and mass spectrometry (LC-MS) studies on whole virus species to characterise the viral proteome
- Rapid screening of viral proteome fingerprinting by chromatography (HPLC), MALDI mass spectrometry and gel electrophoresis (SDS-PAGE). MALDI is useful for proteins up to around 150 KDa.




- Separation of empty capsids from intact viral particles by anion exchange chromatography
- Digestion of isolated proteins followed by LCMS and / or MALDI-MS to give detailed information to assist identification of viral proteins

Your Total Quality Assurance partner

We can support your product development from early-stage, through to in-process control and product release assays. Our experts are adept at developing, optimising, qualifying and validating methods for each particular class of ATMP. We also have significant experience in method transfer. With a heritage of supporting advanced pharmaceutical product development, coupled with a comprehensive range of analytical technology, our experts offer Total Quality Assurance expertise to help you ensure the safety, efficacy and quality of your ATMP product.

FOR MORE INFORMATION

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