Quality Control

ABL Europe

ABL Europe has a particularly strong in-house analytical function providing a wide range of viral vector product specific QC methods in addition to generic pharmacopeia procedures. Any outsourced tests are performed under ABL's quality system management by approved vendors. ABL's analytical services cover methods development, transfer & optimisation through to qualification and full validation respective to the phase of clinical development; supporting QC release and stability testing according to ICH guidelines.

https://www.youtube.com/watch?v=wyaoELqF1Vs

In-house QC testing capabilities include:

General / Physical

Appearance
pH
Osmolality
Extractable volume
Container closure integrity
Cell viability
Intact cells

Product Specific

Infectious titer (PFU)
Viral genomes (qPCR)
Genomic integrity & identity
Transgene expression
Functionality bioassays
Identity (cells, virus, insert)
Genetic stability
Selective tumour cell killing

Purity

Total protein
Host cell protein
Host cell DNA
Process related impurities (BSA, Benzonase, Serine proteases, etc.)

Safety

Endotoxin
Bioburden
Sterility
Observation

Hemadsorbing viruses
Extraneous agents
Adventitious virus (in-vitro)

How can we help you?

Contact Us Now

Process Validation

ABL draws on its expertise & experience to design production processes that optimize product yields, minimize regulatory risk & speed the time to clinic.

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GMP Manufacturing

With a brand new 200 L stirred single use bioreactor (SUB) facility, ABL has strengthened its position in the GMP viral vector CMO market to support clients

Fill / Finish

ABL Europe provides viral vector aseptic drug product manufacturing services in-house using a Bausch and Straubel filling machine located in a rigid isolator.