

# Process Validation

## ABL Europe

ABL Europe has experience supporting clients with GMP supply of viral vectors for use in phase 3 pivotal efficacy trials. Regulatory authorities worldwide require sponsors to expand their CMC section content, as a part of their product licensure applications, for e.g. Marketing Authorization Application (MAA), Biologics License Application (BLA).

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

## How can we help you?

Managed by ABL Europe's validation department, the team has experience performing small scale process qualification and characterisation studies, GMP process performance qualification lots / validation batches, and analytical methods validation; all captured under respective validation protocols and reports, defined from the validation master plan. In collaboration with the client, ABL will perform a GAP analysis and quality risk assessment, to identify and document the process inputs (material attributes, process parameters) that are able to influence the quality attributes and process parameters, implementing a process design and control strategy as part of a product lifecycle approach.

ABL Europe is actively preparing for preapproval inspection in 2021 and is expanding capacity availability to meet the increased demand. At the current time, approved / licensed products are not yet manufactured by ABL.

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.



## **Quality Control**

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.



## **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.