clean biologics
MAKING IT POSSIBLE

Our services for Animal Health

Clean Cells has collaborated with the **main stakeholders of Animal Health internationally** for many years. Our company is widely recognized for its expertise by both the industry and the regulatory authorities. In this context, agencies have taken to Clean Cells to help them improve the regulatory framework relating to medicines for veterinary use. In this respect, Clean Cells will host a webinar next October delving into regulatory changes instated in Europe last year.

Our company is supported by a Good Manufacturing Practices (GMP) certification and substantial experience in collaboration with customers, large and small. Our starting material manufacturing services and identity & biosafety testing capacity helps Animal Health sponsors generate safe and qualitative products.

Our facility consists of BSL-2 and BSL-3 laboratories where we perform services according to applicable specifications issued by health authorities, including the **EMA[1] and the EDQM[2] for Europe, and the FDA[3] and the USP[4] for the USA**.

Manufacturing starting material

Biological starting material is an essential part of the manufacture of **vaccines and immunological veterinary medicinal products**.

Clean Cells benefits from an experience **of culture spanning hundreds of cell and virus models** and from numerous production projects in a GMP setting. Our capacity includes **cell (mammalian and microbial) and virus banking** activities to generate Master and Working seeds.

This manufacturing activity is supported by extensive environment control and allows for the production of **safe and potent** starting material. This material may undergo short, middle, or long-term **storage** at Clean Cells within our secured area.

Quality control testing

Clean Cells is a world leader in **biologics quality control testing** and takes advantage of more than 20 years of experience working with all categories of biological products for human health and veterinary use. Our tests and assays are addressing **biosafety, identity, purity, and potency** evaluation needs expressed by biomedicine stakeholders, from starting material to final lots.

A large number of assays have specifically been **developed and validated** as part of our veterinary activities, including:

- **More than 200 qPCR assays** for the detection and quantification of virus and agents from numerous species (including avian and bovine/porcine) – list available **upon request**
- **Adventitious agent testing** on permissive cell models
- **Retrovirus testing** (QPERT and infectivity assays)
- **Karyotyping**
- Species qPCR authentication
- Mycoplasma testing (direct and indirect culture, qPCR)
- Sterility
- Bespoke design of assays

Our services are available **in compliance with GMP** for clinical and commercial-graded products, and in a non-GMP environment for R&D and preclinical-graded projects.

[1] European Medicine Agency
[2] European Directorate for the Quality of Medicines & healthcare
[3] Food and Drug Administration
[4] United States Phamarcopeia