

THE NEXT GENERATION BIOMANUFACTURING CENTER



Accinov offers a unique solution in Europe for GMP manufacturing of drugs & medical devices

Accinov provides both a GMP capacity and pharmaceutical responsibility as a service. First-time players will find a supportive environment to produce their initial GMP batches themselves. Experienced users can quickly operate GMP activities just as they would have done at their own site.

« Our mission is to accelerate and secure the development of innovative bioproducts »

André Dupont, President

Accinov has the pharmaceutical establishment status since September 2014 and hosts more than 12 companies and projects per year.

HOSTED BIOMANUFACTURING ACTIVITIES

Microbial and mammalian MCB and WCB manufacturing & storage

Accinov manufactures Master and Working banks in state-of-the art A/C or A/B laboratories according to GMP and ICH requirements.

Cell banks are stored in dedicated storage rooms in the gas phase of liquid nitrogen or in -80 ° C freezers continuously monitored at the highest security level.

Process development

Accinov is associated with a partner able to carry out the development of culture, fermentation, and purification processes for its customers or to provide advice and expertise for this stage.

Active Pharmaceutical Ingredients (APIs) manufacturing

Accinov's production units are designed for the production of active pharmaceutical ingredients from cell cultures up to 500L or microbial fermentation up to 200L. Accinov integrates mainly single-use technologies for upstream, downstream phases and solution preparation steps.

Drug Products: Fill & Finish

Accinov offers on site flexible solutions for aseptic filling of small batches in a class A / B environment or with an innovative technology of single-use isolator.

PRODUCT TYPES

- Recombinant proteins
- Antibodies
- Recombinant vaccines/viral vectors/DNA-RNA
- Class III medical devices

« DO IT YOURSELF » BIOMANUFACTURING

**A specially tailored offer
for biopharmaceutical companies
developing innovative drugs and
breakthrough technologies**

Uncertainty and risk are definitely major issues faced during early stages of biological product development. The model proposed by Accinov makes it possible to produce under GMP conditions without the constraint of managing infrastructures. This new concept offers flexibility for GMP biomanufacturing in a pay-as-you-use model.

Advantages of the Accinov's model:

- Shorten time-to-market with an access to ready-to-use GMP authorized facilities
- Save all the time of the technology transfer
- Reduce capital expenditures and costs for completing GMP bioproduction
- Control internally CMC operations during strategic product development & fully manage costs & timelines
- Reduce effort & resources to operate under cGMP compliance
- Build invaluable capital of internal know-how & experience for future projects

Do It Yourself

When it's time to move from preclinical to clinical-phase product testing, many biopharmaceutical companies face a difficult decision: whether to build or buy a biomanufacturing facility for in-house production or outsource the work. Accinov proposes a new solution that straddles the line between those concepts. The biomanufacturing center supports client companies toward clinical development in an innovative way.

HOSTING & SERVICES OFFER OF ACCINOV

A modular & ready-to-use laboratory offer

Accinov offers ready-to-use laboratories from 20 to 200 sqm, GMP biomanufacturing pilot units, shared equipment and offices in a brand new building of 6,500 sqm.

Access to laboratories and pilot units is provided within a broader services offer that allows hosted companies to start their activities in a very short time frame.

Facility design and management of the site allow to control the risks cross-contamination risks and to ensure confidentiality of each project. Qualified persons of Accinov ensure GMP compliance of the quality system and activities carried out by customers within the pharmaceutical establishment.

Tailored services suited to customer needs and product development stages:

- Operational quality assurance support services
- Pharmaceutical support services
- Expert advice, guidance and hands-on support for the drug development
- GMP audits of suppliers & sub-contractors
- Raw materials, cell banks, batch GMP certification by Accinov's qualified person
- General services, maintenance, safety
- Lab support (deliveries, laundry, sterilization, waste management)

KEY FACTS & FIGURES

- 3 biomanufacturing units of 200 sqm dedicated to sterile drug production
- 1 manufacturing unit of 20 sqm dedicated to non-sterile drug production
- 17 R&D labs of 20 or 50 sqm
- Biosafety level 2, GMO authorized facilities
- Standard equipment provided and renting solutions for specific process equipment
- GMP production and QC additional staff recruitment, GMP staff training services
- Storage of the manufactured products & stability studies



ACCINOV LOCATED AT THE HEART OF LYON'S BIODISTRICT, WORLD LEADER IN HEALTH AND BIOTECHNOLOGY

Accinov is part of the infrastructure offer of Lyonbiopôle, the health biocluster of the Auvergne Rhône-Alpes Region, located at the heart of the Biodistrict of Lyon.

The Biodistrict of Lyon brings together an exceptional concentration of life sciences stakeholders. The perfect mix of major groups (Sanofi Pasteur, Merial, Genzyme, bioMérieux), promising start-ups, research laboratories (P4 Jean Mérieux laboratory) and higher education institutions - with 5,000 jobs and 2,750 researchers – sets up a fertile ground for innovation.

Accinov, an infrastructure of:

LYONBIOPOLE

Accinov, a project supported by:



GRAND LYON
la métropole





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