

GMP production of APIs, Intermediates and other fine chemicals

Outsourcing production under good manufacturing practices



To develop their products portfolio, [fine chemical and, pharmaceutical](#) and biotechnology companies need to optimize their capability. The chemical synthesis of new GMP products requires highly specialized technologies, facilities and staff. Outsourcing part of this production allows companies to become more flexible to develop multiple substances at the same time and face the market's competitiveness.

Our solution

Applus+ Laboratories offers a comprehensive GMP production outsourcing service, which includes:

- Overall project management
- Raw material purchasing
- Production of validation batches
- Production of APIs, intermediates and other fine chemicals
- Product quality control

Our expertise and our facilities allow us to participate in all the stages of the development of chemical processes:

- Fine chemistry process development
- Scale-up of chemical processes
- Analytical methods development and validation
- Production under GMP

Our pilot plant offers great versatility and can adapt to a large number of reagent and separation processes:

Reaction equipment

- Single fluid thermal oil and liquid nitrogen temperature control system
- Operating range from -80 °C to 200 °C
- 6 vitrified reactors from 63 liters to 500 liters
- 9 stainless steel or Hastelloy reactors from 40 liters to 500 liters
- High pressure reaction plant: reactors from 0.5 liters up to 50 liters and pressures from 400 to 100 bar, respectively.

Separation/Finishing equipment

- Stirred and thermostated Nucha filters of different capacities and construction materials (stainless steel and Hastelloy)
- Stainless steel filtering centrifuges of various capacities
- Cuno filter cartridges
- Stainless steel Sparkler filters
- Other finishing equipment (granulation, drying, etc.)
- Open cycle spray dryer
- Isolation in ISO-8 clean room

Applus+ Laboratories has worked for over 15 years with companies in the fine chemicals, pharmaceutical and biotechnology industries offering services from the development stage to the product marketing stage.

We work under global reference standards (FDA and EMEA). We apply the highest criteria of confidentiality.

Benefits

- Production flexibility
- Access to 'a la carte' products and specific technologies
- GMP compliance can be audited by the client.