

Working in partnership

The best R&D and contract manufacturing partners offer expertise in product development, manufacturing, packaging, quality control and supply management.

IVAX Corporation is a multinational company engaged in the research, development, manufacturing and marketing of branded and generic pharmaceutical and veterinary products in the USA and internationally. It has direct operations in 30 countries, and markets products in more than 80 countries. The corporation has 8000 employees worldwide, with more than 700 involved in R&D. Net revenues for 2002 were approximately \$1.2bn, up 53 per cent since 2000.

IVAX Pharmaceuticals sro in the Czech Republic (formerly Galena as) has been part of the IVAX Corporation since 1994. The company was founded in 1883 in the former Austro-Hungarian monarchy under the name Gustav Hell & Co. It thus has 120 years of experience in pharmaceutical development and production, especially in the area of liquid dosage forms.

R&D services

IVAX offers complex manufacturing services, starting with R&D profiling (using standard pilot plant) up to large-scale production. Its R&D experts in the areas of chemistry, formulation development, manufacturing and controls can provide clients with technical expertise for selection and qualification of active pharmaceutical ingredient (API) suppliers, pharmaceutical product development and dosage form development. In-house specialists have significant experience in oral formulations of drugs and biological products. These include:

- Tablets, both immediate and controlled release
- Hard gelatin capsules
- Soft gelatin capsules
- Syrups
- Solutions
- Drops
- Nasal sprays
- Nasal and eye drops

In the area of API and product development, the company provides pre-formulation, formulation/scale-up, production planning, stability studies and specification development. In cooperation with its analytical department, it

performs product analytical testing as well as pre-formulation, formulation, in-process, release, stability and compatibility testing.

Organic synthesis capabilities

IVAX offers custom organic synthesis, contract process development and current good manufacturing practice (cGMP) manufacturing from gram to multi-kilogram lots of APIs. It can also provide support documentation associated with process validation, assay development, impurity characterisation and primary standard preparation.

Contract process API development & facilities

The company is ready to verify and scale up a client-provided chemical synthesis or to design a synthetic process from specifications provided. These services include:

- Complex multi-step synthesis development
- Development of gram to multi-kilogram lots for clinical studies and commercial production
- cGMP manufacturing in facilities approved by the US Food and Drug Administration (FDA)
- Impurity isolation, characterisation and synthesis

IVAX' R&D facilities are FDA-registered and -approved and cGMP-compliant. They offer:

- Cleanrooms for packaging/drying operations
- Temperatures from -90 to 250°C
- Glass-lined, stainless steel and Hastalloy reactors from 100l to 500l

Biotech R&D services

IVAX' biotechnologists are experienced in the isolation of micro-organisms (fungi and bacteria), screening methods aimed at production of secondary metabolites, selection methods aimed at yield increase, optimisation of strains and cultivation conditions, and scale-up to large-volume fermentation.

The biotech department is equipped with an experimental facility, including flow boxes, shakers, cascade of fermentors and high-performance liquid chromatography analysis. It is able to maintain, optimise and cultivate tissue cultures that produce monoclonal antibodies that isolate, purify and finalise the product.

Analytical chemistry services

The analytical laboratories are equipped with HPLC instruments with ultraviolet (UV), fluorescence, electrochemical and chemiluminescence detection, gas chromatography with flame ionisation detection and electrochemical detection, dissolution apparatus, UV spectrophotometers, automatic titrators, differential scanning calorimetry and other standard laboratory equipment. The company's analytical experts are able to develop and validate analytical methods for evaluation of products of chemical synthesis, chemical isolation and final dosage form. They also monitor and determine impurity profiles.

IVAX' R&D services comply fully with the GMP principles. The company also adheres to guidelines of the most recognised regulatory authorities: the FDA, the European Agency for the Evaluation of Medicinal Products, and the International Conference on Harmonisation.

Manufacturing services

IVAX offers proven expertise in developing, manufacturing and packaging a wide range of solutions, sprays, syrups/elixirs, sterile liquid ophthalmics, non-sterile suspensions/emulsions and solid dosage forms. Available options include galenic formulation, as well as stability testing and validation. Packaging facilities have passed GMP inspections, and are approved by EU and FDA regulatory authorities; they are hence equipped to meet even the most critical production standards.

Bulk manufacturing

The company's manufacturing facilities may be used for ophthalmic products. These facilities include large-volume, stainless steel, jacketed tanks for heat sterilisation and pasteurisation.

Suspensions/emulsions are manufactured using stainless steel kettles with controllable heating and cooling capabilities, along with a variety of mixing attachments to achieve uniform dispersion of ingredients. FRYMA VME 400, colloid mills and dissolvers, and homogenisers are available for particle sizing. Batch capacity ranges from 150kg to 400kg. To ensure proper particle/droplet size and dispersion, the FRYMA in-line mixer may be used. All of these processes are fully automatic and computer-controlled.

Filling of liquid dosage forms

IVAX has advanced technology for liquid filling. Aseptic solutions are filtered and filled into sterile bottles. Filling parts and equipment are sterilised or disinfected according to aseptic procedures.



The homogeniser FRYMA VME 400 is part of the suspensions and liquid dosage equipment at the product manufacturing facility

Blister packaging

The IMA C60+ packaging equipment used manages a wide range of configurations. Production lines are equipped with a barcode verifier to ensure accuracy; a plug-assist system for uniform cavities; cold-forming capabilities for maximal moisture protection; a camera inspection system that removes defective blisters; and the capability to monitor the final weight of the product and packaging. Furthermore, sealing foil may be pre-printed on-line.

Finishing

Cartons or packages can be shrink-wrapped on site. Lines are equipped for online case, pressure-sensitive and roll labelling. Jet-printing and crimp-stamping of product lot numbers and expiry dates are also available.

Trust and reliability

IVAX Pharmaceuticals has modern equipment and facilities, proven processes and highly qualified staff to meet the most stringent production specifications. The company prides itself on its ability to achieve the most productive working relationships with all its customers through seamless project management and reporting practices to final production and delivery. It offers 125 years of trust and reliability in product development, manufacturing, packaging, quality control and supply management – all at very competitive prices. ■

COMPANY PROFILE

IVAX Pharmaceuticals sro is a branch of IVAX Corporation, Miami, USA. It operates as an R&D and contract manufacturing partner to pharmaceutical companies.