InKemia IUCT group

our knowledge at your service

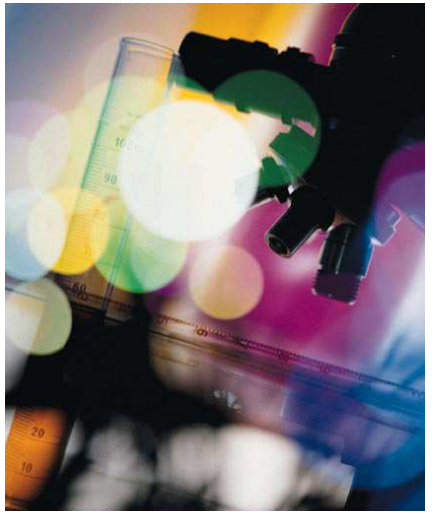
PRODUCTS AND SERVICES

Products / services

InKemia IUCT group

InKemia IUCT group offers

1. Contract research and/or codevelopment projects to companies looking for partners in R&D.
2. Consultancy and audit services to companies interested in introducing their products in the EU.



Contract Research, R&D Projects

1. Active Pharmaceutical Ingredients (APIs), excipients and/or Herbal products

- Synthesis
  - Design and development of new synthetic routes
  - Regio and/or stereo selective synthesis
  - Biotech processes for the production of APIs
  - Preparation of new micro-organisms for application in chemical synthesis and food industry
- Process improvement
- Extraction
  - Development of extraction processes for active products in natural extracts
- Impurities
  - Study and definition of impurity profiles
  - Synthesis, isolation, purification and identification of impurities and/or metabolites in APIs and pharmaceutical products
  - Study of the components in natural extracts
- Structural characterization of chemical compounds (APIs, impurities, actives in natural extracts, etc.)
- Development and validation of analytical methods

APIs
Intermediate
Impurities and metabolites
Biocatalysts
New molecules
Natural extracts…

Experience in biocatalysis applied to API manufacturing

- Inkemia IUCT group has developed production processes based on biocatalysis for different types of APIs such as nucleosides, vitamins and antibiotics among others.
- Inkemia IUCT group companies have a wide experience in nucleosidic API development:
  - Such as Brivudina, Clofarabina, Floxuridina, Idoxouridina, Trivirina cladribine, capecitabine, Fludarabine, AZT or zidovudine, Broxuridina, 5-chloro-2'-deoxiuridina 5-Fluorouridina, 2-Fluoroadenosine ...
  - Other types of APIs developed are: menadione, Aceclofenac, linezolid, Pimocide, Loperamide ..
- Different biocatalytic steps have been used in the development of biocatalytic synthetic routes for APIs. Some examples of enzymes used are:
  - Nucleoside phosphorylase. (NP's) - PB
  - Nucleoside Desoxiribosil transferase. (NDT's) -PB
  - Lipase
  - Oxidase
  - Proteases
  - Desaminasas
  - glycosidases

Contract Research, R&D Projects

2. Pharmaceutical product development

- Design of new products and formulations
- Pharmaceutical dosage forms:
  - Solids: tablets, coated tablets, hard gelatin capsules, granules, powders.
  - Semisolids (no sterile) : creams, ointments, gels.
- Development of generic medicines and new pharmaceutical dosage forms
  - Pharmaceutical development and preformulation studies.
  - Manufacturing and packaging of batches for its use in clinical trials and/or stability studies.
  - Development and validation of analytical and microbiological methods.
  - Process development, validation and scale-up.
  - Isolation, characterization and synthesis of impurities, metabolites and degradation products.
  - Forced degradation tests, stress tests, and stability studies according to the International Conference on Harmonisation (ICH) guidelines.
- Chemical characterization and quality control

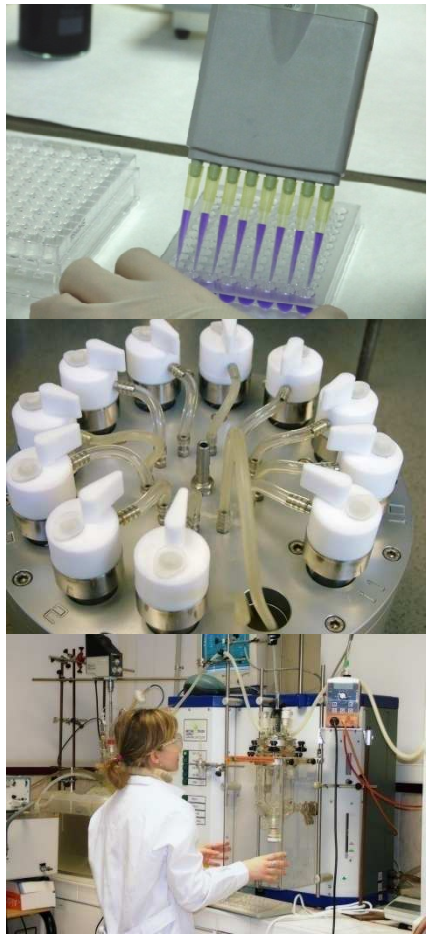
Codevelopment Projects

Potential cooperation areas in joint developments,

- Active Pharmaceutical Ingredients (APIs), excipients and/or Herbal products
  - Development of new synthetic routes
  - Process optimization
  - Development of biotech processes
- Pharmaceutical products
  - Pharmaceutical development

Risk sharing model,

- Inkemia and its partner share the R&D and business risk.
- Inkemia develops the product at lab scale, partner scales-up the process and sells the product.



Consultancy

1. Active Pharmaceutical Ingredients (APIs), excipients and/or Herbal products

- Advice, preparation and support on
  - Certificates of suitability to the monographs of the European Pharmacopoeia (CEP)
  - European Drug Master Files (ASMF)
  - Implementing and maintaining GMPs and/or GLPs
- GMP and/or GLP Audits
- Industrial safety and environmental consultancy : Diagnosis, audits and consultancies

2. Pharmaceutical products

- Advice, preparation and support on
  - Common Technical Document (CTD) for European Marketing Authorization Applications (MAA)
  - Preparation and review of variation applications in Europe
  - Investigational Medicinal Product Dossiers (IMPD)
  - Implementing and maintaining GMPs and/or GLPs
- GMP and/or GLP Audits
- Industrial safety and environmental consultancy : Diagnosis, audits and consultancies

Certificates of suitability to the monographs of the European Pharmacopoeia (CEP)

Used for

Marketing authorization applications to demonstrate the compliance of the substance used with the monographs of the European Pharmacopoeia and Directives 2001/83/EC and 2001/82/EC.

Who can apply

- Active substances or excipients to control the chemical purity and microbiological quality of their substance,
- Products with TSE risk to evaluate the reduction of TSE risk according to the general monograph,
- Herbal products used in the production or preparations of pharmaceutical products to be evaluated according to the suitability of the monograph for the control of herbal drugs and herbal drugs preparations.

Advantages

- Simplifies the approval of a medicinal product compared to the Active Substance Master File (ASMF) (commonly known as European Drug Master File (EDMF)).
- Recognized by all registration authority within the states of the European Pharmacopoeia Convention and by the European Union.
- Recognized by the following countries and institutions: Canada (HPFB), Australia (TGA), New Zealand, Tunisia and Morocco.
- Simplifies the trading with pharmaceutical substances and ingredients.

European Pharmacopoeia member states

Certifications

- PHARMACEUTICAL LABORATORY AUTHORISED FOR DRUG MANUFACTURING, authorization nº 4155-E. Spanish Agency of Medicines and Medical Devices
- GMP CERTIFICATE FOT THE MANUFACTURING OF HUMAN AND VETERINARY MEDICINES AND INVESTIGATIONAL MEDICINAL PRODUCTS (IMP), registration nº ES/026HVI/12. Spanish Agency of Medicines and Medical Devices
- AUTHORIZATION AS CONTROL LABORATORY FOR THE QUALITY CONTROL OF COSMETICS AND PERSONAL HYGIENE PRODUCTS, authorization nº 8611LC. Spanish Agency of Medicines and Medical Devices
- AUTHORIZATION AS ENVIRONMENTAL AND NUTRITIONAL HEALTH LABORATORY, reg. nº: R7-120-98. Directorate general of public health. Department of Health and Social security.
- REGISTER OF AGRICULTURAL AND FOOD LABORATORIES, reg.306. Directorate general of production and agriculture and food industries. Departament of Agriculture, livestock and fisheries
- CERTIFICATION AS A SUPPLIER OF R&D SERVICES IN FRANCE. Direction générale pour la recherche et l'innovation (République Française)
- ISO 9001, quality certification E201316, LLOYD's Register
- AUTHORISED TO CONDUCT ACCIDENT PREVENTION AUDITS ALL OVER SPAIN, company registered under nº A-025-B. Territorial Delegation of the Government in Barcelona. Generalitat de Catalunya, Department of employment, industry, commerce and tourism.
- AUTHORISED FOR TYPE 1 ACTIVITIES WITH GENETICALLY MODIFIED ORGANISM (GMO) (Nº A/ES/13/76) IN IUCT FACILITIES (Nº A/ES/13/I-38). Directorate General of agriculture. Generalitat de Catalunya, Department of Agriculture, Livestock, Fisheries, Food and Environment


inKemia
Innovation in Chemistry & Life Science
IUCT GROUP