

# GxP Services

in BioTurku®

BIOCIDES  
BIOLOGICALS  
BIOMATERIALS

**GLP**

MEDICAL DEVICES  
SAFETY STUDIES  
CHEMICALS  
VACCINES

**GMP**

CMO  
API

**GCP**

CLINICAL TRIALS  
PET-TRACERS  
MEDICINES





PCAS Finland Ltd is a fine chemicals company specialized in the development and manufacturing of active pharmaceutical ingredients (APIs) and advanced intermediates for the pharmaceutical industry.

The company carries out its operations in FDA-inspected cGMP plant in Turku, Finland. PCAS Finland Oy is a subsidiary of PCAS S.A., a French chemical Group having 9 sites worldwide and capable of offering support and service for the company in many areas.

Our quality system is based on cGMP (Good Manufacturing Practice) and we are committed to develop it sys-

tematically. We have been regularly inspected by US FDA since 1982. We are also approved by the Japanese authorities.

Services offered by PCAS Finland include state-of-the-art production of active pharmaceutical ingredients (API) and their intermediates and the development of methods for the synthesis of APIs. PCAS have license to manufacture APIs granted by FIMEA (Finnish Medicines Agency).

You can find our product list for generic APIs on PCAS website [www.pcas.com](http://www.pcas.com). We also offer custom manufacturing services.



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# BIOVIAN

Biovian Ltd is a one-stop-shop in GMP contract manufacturing of biopharmaceuticals covering services from early development to finished vial. Biovian's 2300 m<sup>2</sup> facilities are EMA and FDA certified for GMP production of investigational and commercial products.

## **Biovian GMP services:**

- Stability studies
- Analytical Quality Control Services
- Formulation
- Aseptic Fill & Finish
- Drug product labelling, packaging, storage and QP release
- Microbial fermentation
- Mammalian cell culture
- Viral vector production
- MCB and WCB manufacture and storage
- Protein Purification

## **Biovian development services:**

- Cell line Development
- Process Development
- Analytical Development

Biovian's quality management system complies with GMP requirements and has been certified since 2003. The latest inspections by authorities have been EMA in 2012 and FDA in 2011.

Biovian's GMP certificate covers the manufacture of commercial and investigational human and veterinary medicinal products:

## **Biological medicinal products**

- Biological medicinal products
- Gene therapy products
- Biotechnology products
- Biological active starting materials

## **Sterile products**

- Aseptically prepared
- Terminally sterilized

## **Quality control testing**

- Microbiological: Sterility
- Microbiological: Non-sterility
- Chemical/Physical





Galilaeus Oy (Ltd) is a Finnish company specialized in fermentative Contract Manufacturing in three main sectors: API, Biocatalyst and Nutra-ceutical. We have the knowhow in commercial manufacturing, with over 30 years' experience in fermentation. Galilaeus' technology platform is well-suited to e.g. evaluate alternative routes and improve the strain/process. Our Polish facility offers one of the biggest fermentation manufacturing capacities in Europe, with access to 12 times 150 000 liter fermentors. At our manufacturing site in Warsaw,

Poland, GMP is applied in all operations (ICHQ7). We also have HACCP (Hazard analysis and critical control points) certification and we are entitled to work with genetically modified organisms (GMO).

- Food quality– HACCP, Codex Alimentarius, Rev. 4 (2003)  
- for probiotic production
- Food premises for dietary supplement products
- Pharmaceutical quality – we work according to ICHQ7
- GMO; BSL1



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Syrinx Bioanalytics Ltd is a Contract Research Organization (CRO) offering bioanalysis of biologicals, biomarkers, vaccines, anti-drug antibodies (immunogenicity testing) and small molecules in GLP. SYRINX was founded in 2007 as a spin-off from Bayer Schering Pharma. It is 100% owned by its management team. SYRINX is supporting full development programs by utilizing its in-house scientific expertise, 'Gold' standard methods, novel innovative techniques and modern GLP facilities. The services include method development, validation and routine studies with special expertise in difficult or bespoke situations offering large variety of modern immunoassay techniques.

SYRINX Bioanalytics is a full member of the good laboratory practice (GLP) monitoring program to carry out bioanalytical studies in compliance with GLP. Inspections are carried out every two years by the Finnish authority, Finnish Medicines Agency (Fimea).

**Services:**

- Analysis of drugs, vaccines, biomarkers or immunogenicity testing in various biological matrices for the entire span of a drug development project (preclinical and clinical phases)
- Method development, validation and routine studies in GLP

**Available techniques:**

- AlphaScreen/AlphaLISA homogeneous assays
- Bioassays (cell based functional assays)
- Electrochemiluminescence (ECL) assays
- Enzyme-linked immunosorbent assays (ELISA)
- Gyros CD microlaboratory assays
- Radioimmunoassays (RIA)
- Surface plasmon resonance (SPR) methods
  
- Time-resolved fluoroimmunoassays (TR-FIA)
- Mass spectrometry (GC-MS, LC-MS), FPLC and HPLC methods

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# Turun yliopisto University of Turku

## Central Animal Laboratory, UTUCAL

The Central Animal Laboratory of the University of Turku provides services to biomedical research supplying and producing animals. Skilled staff take care of animal welfare daily and assist the experimenter to perform procedures. Also complete studies with CRO service is provided. Animal experiments will be performed according to the 3R's ethical principles.

With the quality systems we ensure that our work is in accordance with the accepted operational procedures. The internal and independent external quality assurance secure the proper procedures to be followed. UTUCAL follows the quality policy of the University of Turku as described in the University quality book for leadership and development.

UTUCAL is also a certified GLP compliant Testing Facility according to the Principles of OECD GLP Guidelines.

UTUCAL has over 10 years of expertise in conducting preclinical toxicology studies of medicinal products, medical devices and chemicals in compliance with GLP and is included in the national GLP Compliance Program of Finland.

Certified inspections have been done by the Finnish authorities starting year 2000 till 2012.

### Routine services include

- safety pharmacology
- pharmacokinetics also with different imaging modalities
- short term safety evaluations in different species
- repeated dose administration thorough different routes
- embryotoxicity
- species selection from mouse to pig/dog
- customer tailored studies





# Turun yliopisto University of Turku

## Forensic Medicine, Histotechnology service



The Department of Forensic Medicine carries out scientific research in forensic medicine and related areas and provides undergraduate education in medicine, as well as specialist education in forensic medicine. The department has modern facilities and laboratories for histology and forensic biochemistry.

Our histology laboratory was the first University laboratory of its kind in Finland to be certified and has been providing histology services in compliance with the OECD GLP Guidelines for over 10 years since year 2000 for safety studies of medicinal products, chemicals and pesticides.

### Services include

- High quality processing of fixed human and animal soft and hard tissues for routine paraffin embedded slides or cryosectioning of fresh tissues for immunohistochemistry.
- Outstanding experience with a great variety of routine staining methods as well as automated staining methods for routine immunohistochemistry or staining with custom delivered immunochemicals.



CLINICAL RESEARCH SERVICES TURKU



## Turun yliopisto University of Turku



CRST is a University-based contract research unit serving the pharmaceutical and biotechnology industries.

CRST aims to provide its customers with proof of concept with regard to safety, pharmacokinetics and efficacy. In preclinical experiments and in early clinical trials, surrogate markers of efficacy, based on imaging technologies or various biomarker approaches, are often employed. The combination of positron emission tomography (PET) imaging with pharmacokinetic and pharmacodynamic assessments is a core competence area of CRST. CRST has been conducting GCP-compliant clinical trials

since 1995 and has been included in the Finnish GLP compliance program since 2002.

CRST performs early-phase clinical trials with pharmaceuticals, medical devices and nutritional products. CRST has a wide network of experts in the different medical specialities. Preclinical testing is carried out in collaboration with the Central Animal Laboratory of the University of Turku. CRST's GLP-certified analytical laboratory performs analysis of biological, environmental and pharmaceutical samples. In addition to modern LC-MS/MS, other analytical technologies are also available.





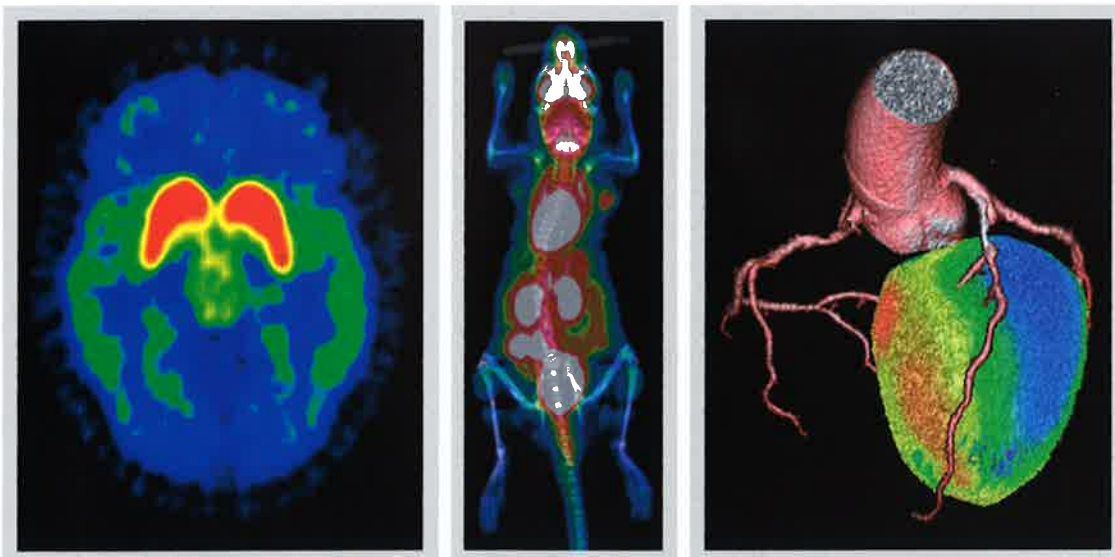
# Turku PET Centre

Turku PET Centre is a Finnish National Research Institute for the use of short-lived positron emitting isotopes in the field of medical research. Currently, the centre employs more than 150 staff members and investigators from various research fields. The facilities utilize 3 cyclotrons, 19 hot cells for GMP level tracer production, 6 PET, PET/CT and PET/MRI(3T) scanners, 1.5 T MRI, digital ultrasound systems and optical imaging systems. Both clinical and preclinical imaging, with dedicated small animal devices, are performed.

The Centre has two major functions, high quality scientific research and diagnostic service for the whole country. The scientific research strategy of the Turku PET Centre involves 5 topics: Cellular Energy Metabolism, Neurotransmission, Preclinical Imaging and Drug Research, Oncology and Radiochemistry.

Turku PET Centre produces short-lived radioactive ligands, PET tracers, in accordance with GMP for Pharma, diagnostics and academic research involving imaging. PET tracers include a wide variety of different tracers for different targets such as perfusion, metabolism and receptors, and with different isotopes (labels), e.g.  $^{11}\text{C}$ ,  $^{18}\text{F}$ ,  $^{68}\text{Ga}$ ,  $^{15}\text{O}$  and  $^{64}\text{Cu}$ . The Centre operates also according to GCP in human studies for Pharma trials.

Turku PET Centre provides preclinical and clinical Phase I-IV imaging studies with GMP level PET tracer production. In addition, we offer new radiotracer development and testing services for e.g. finding receptor occupancy levels of new drug molecules for dose selection in Phase II trials.





Suomen Arkistovoima Oy - SAVE Ltd.

SAVE archives the whole lifespan of a biotechnology company: paper documents, electronic records, test samples and biological samples. etc. Suomen Arkistovoima Oy – SAVE Ltd is owned by Karhukopio Oy. Other group companies use Multiprint brand. SAVE's limited quality criterias in archiving are based on OECD GLP-regulations and ISO 9001:2000 quality system. SAVE focuses on archiving medical data (GLP, GCP, GMP documents and other highly confidential materials). SAVE's facilities have been approved by the authorities.



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## BioTurku® Scientific and Business Community

BioTurku® is the leading biotechnology cluster in Finland, an active and dynamic community of bio-actors and a centre of top expertise in Northern Europe. Around half of Finland's pharmaceutical and diagnostic industry is located in the Turku region in South West Finland. The BioTurku cluster comprises about 90 biotechnology companies, two universities as well as several educational and research institutes and the Turku University Hospital. It forms a continuous chain of education, research, product development, production and commercialisation. BioTurku is part of Turku Science Park. One of Finland's oldest and largest science parks.

Invest in and Locating Services; [teppo.laaksonen@turkusciencepark.com](mailto:teppo.laaksonen@turkusciencepark.com)

In BioTurku® cluster many companies and university units offer service fulfilling the regulatory needs of value chain for medicinal products and chemicals. BioTurku is one of the few clusters in Europe where all these needs can be fulfilled within the same cluster.

PCAS Finland Ltd

[www.pcasfinland.com](http://www.pcasfinland.com)

Biovia Ltd

[www.biovia.com](http://www.biovia.com)

Galilaeus Ltd

[www.galilaeus.com](http://www.galilaeus.com)

Syrinx Bioanalytics Ltd

[www.syrinxbioanalytics.com](http://www.syrinxbioanalytics.com)

University of Turku

UTUCAL

[www.animalcenter.fi](http://www.animalcenter.fi)

Forensic medicine

[www.med.utu.fi/oikeuslaaketiede/index.html](http://www.med.utu.fi/oikeuslaaketiede/index.html)

CRST Clinical Research Services Turku

[www.crst.fi](http://www.crst.fi)

Turku PET Centre

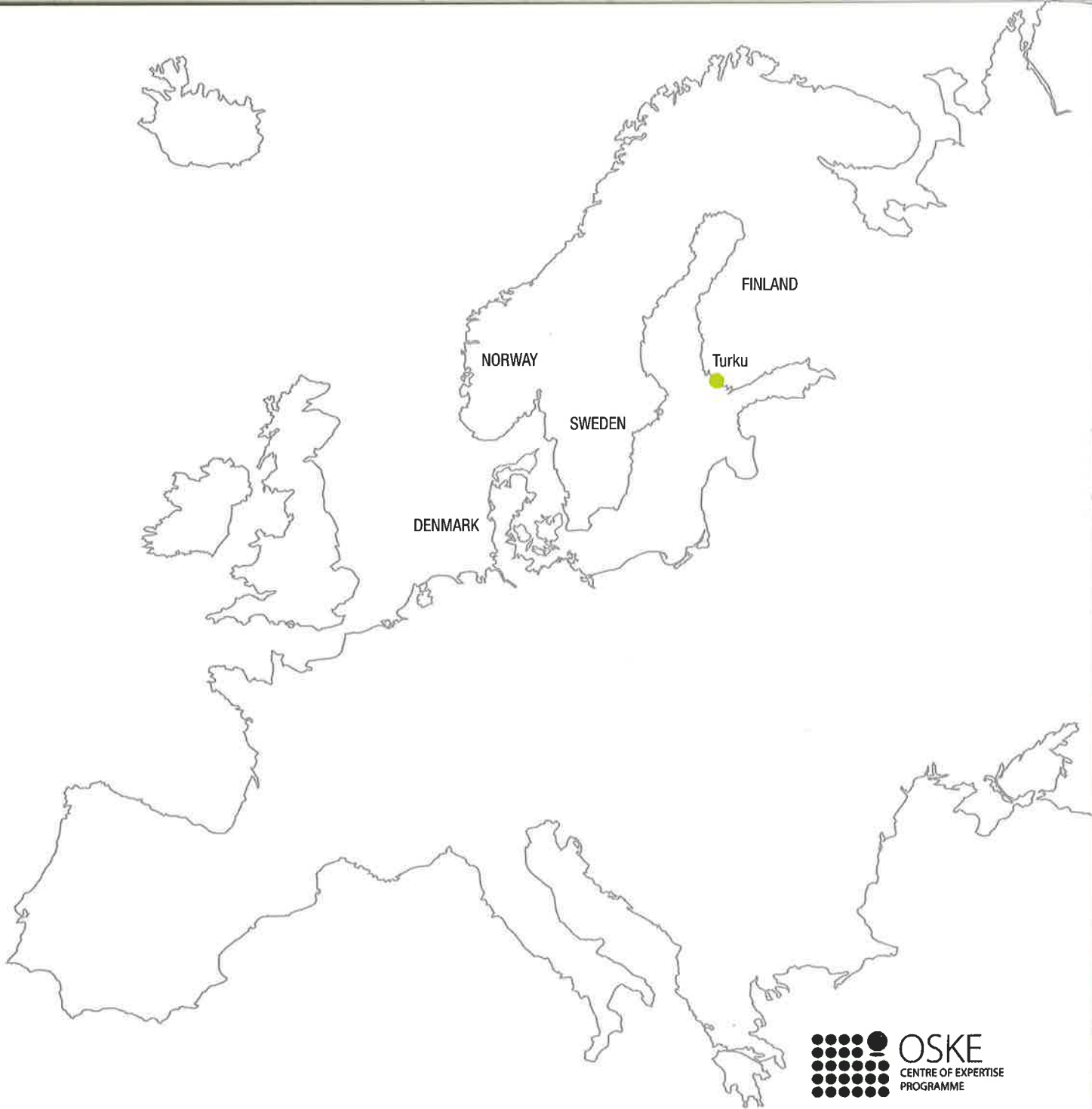
[www.turkupetcentre.fi](http://www.turkupetcentre.fi)

SaVe Suomen Arkistovoima Ltd

[www.arkistovoima.fi](http://www.arkistovoima.fi)



See other Bioturku companies at our web page [www.turkusciencepark.com](http://www.turkusciencepark.com)  
Also the Finnish Medicines Agency Fimea provides guidance [www.fimea.fi](http://www.fimea.fi)



BioTurku® and ICT Turku are part of the  
Turku Science Park

[www.turkusciencepark.com](http://www.turkusciencepark.com)