

# BIONEER – COMPANY PRESENTATION

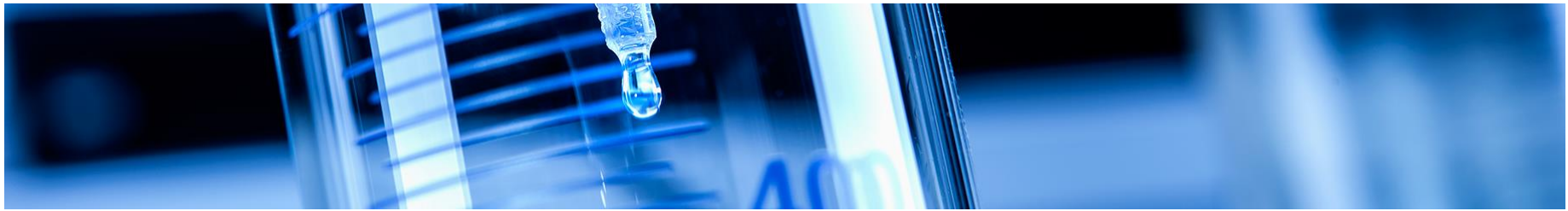


bioner



## Agenda

- Quick intro to Bioneer as an organization
- Bioneer Services:
  - Stem Cell Technology
  - Immune Bioactivity – human DC's
  - Biomarkers and Molecular Histology
  - From Active Compounds to Patient Administration
  - Recombinant Protein Production
- Current partnerships and international projects



## Bioneer organization

- Bioneer is owned by the Technical University of Denmark, and...
- ...is an approved Advanced Technology Institute -> basic funding from the Danish Ministry of Science and Education
- Not-for-profit contract research organization offering test- and development services to the Danish and international life science industry

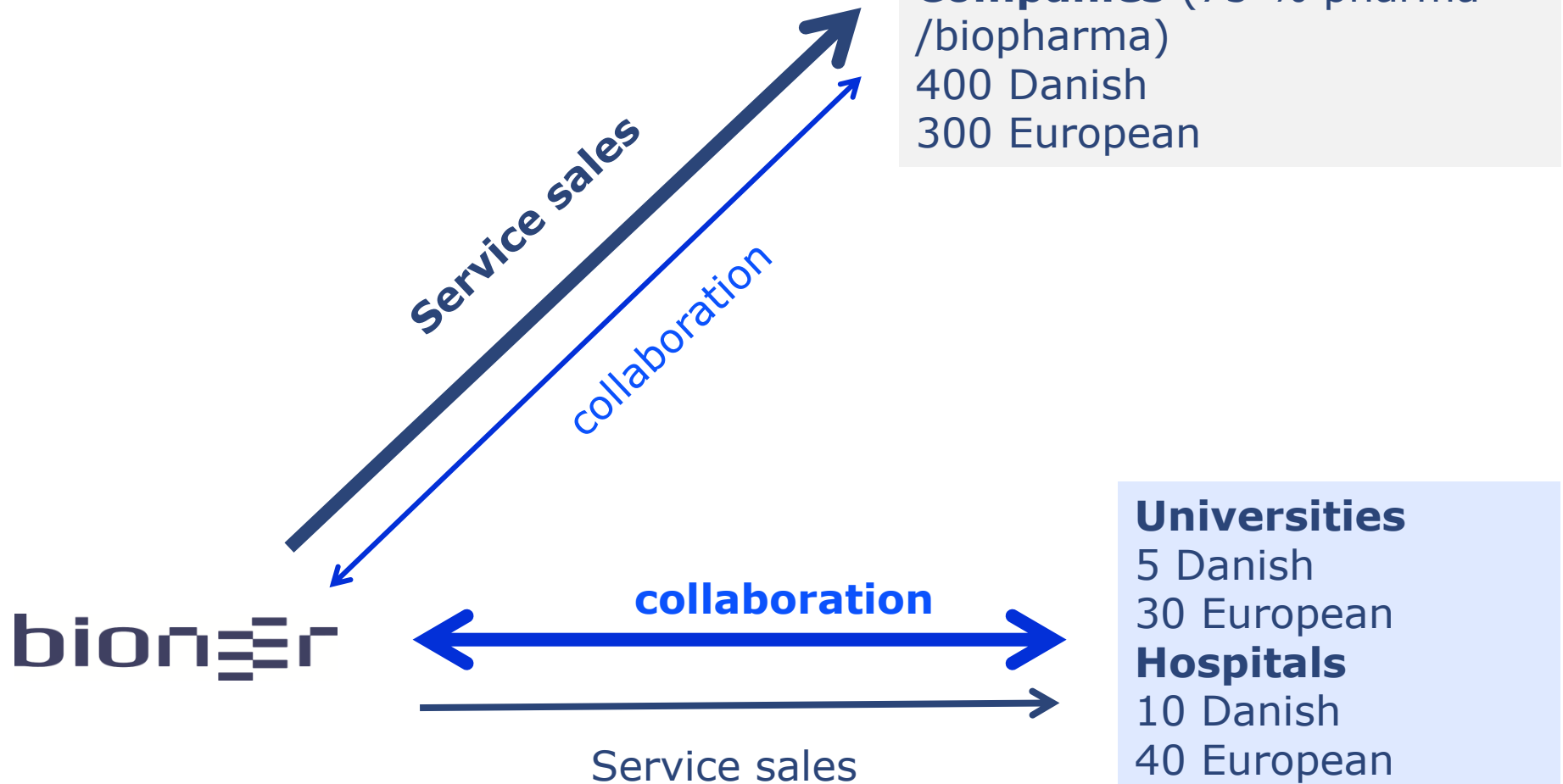


Bioneer building, office and lab: Bioneer is located in the SCION.DTU science park, north of Copenhagen

**bioneer**



## Collaboration



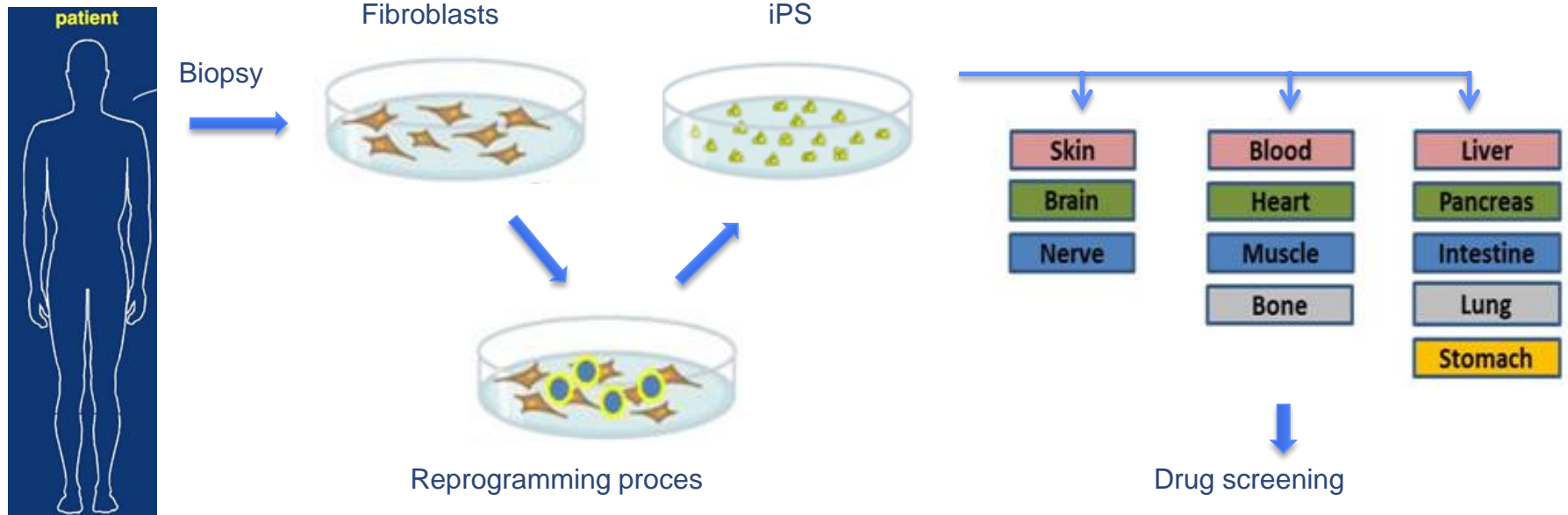


## People

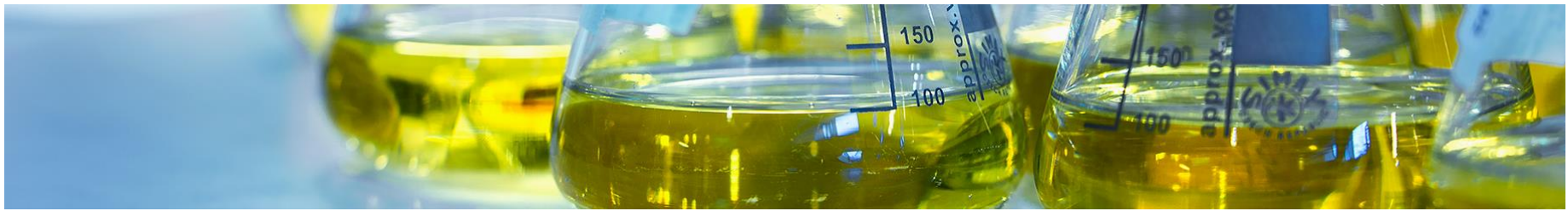
- Scientific staff
  - 40 with academic degrees (M.Sc., M.Tech.Sci., B.Sc., M.Pharm.)
    - 25 Ph.D.'s
  - Covering: molecular biology, microbiology, protein chemistry, immunology, pharmacology and small molecule chemistry
- Technical staff
  - 11 highly trained technicians
  - 2 laboratory assistants
- Administrative staff
  - 3 reception
  - CEO



# iPS Cell Technology







## Key applications

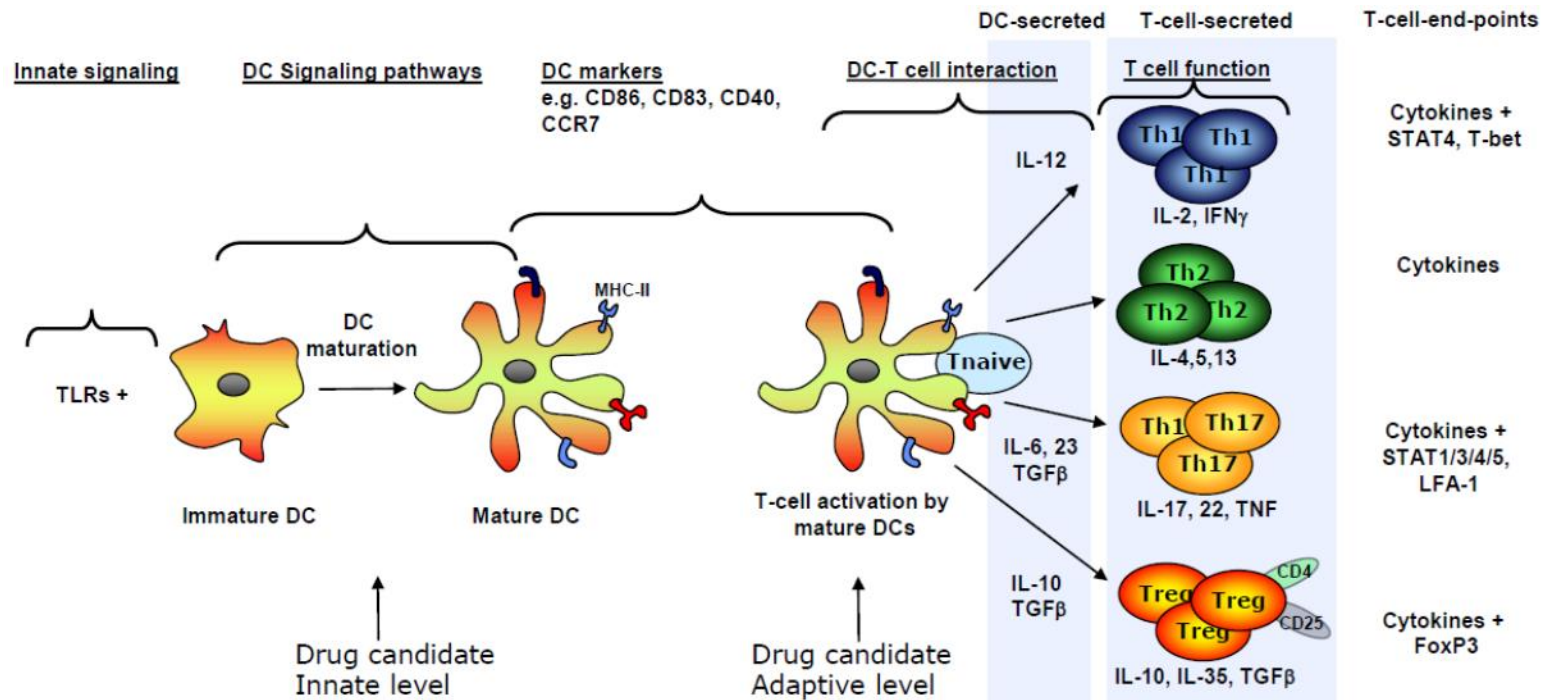
- Patient specific disease models
- Development of novel drug screening tools
- Tissue specific disease models
- Personalized drug discovery
- Efficient early discovery process
- Infinite supply of patient specific cells

## Services offered

- iPS cell line production from biopsies and blood
- Analytical validation
- Banking and transfer of iPS cell line to client
- Differentiation to various cell types
- Full traceability
- Customized testing of drug candidates



## DC models for evaluating immune modulating effects



### Immune Bioactivity

We investigate the effect(s) of potential immune modulating compounds

### Immune Toxicology

We analyse off target effects and immuno-safety





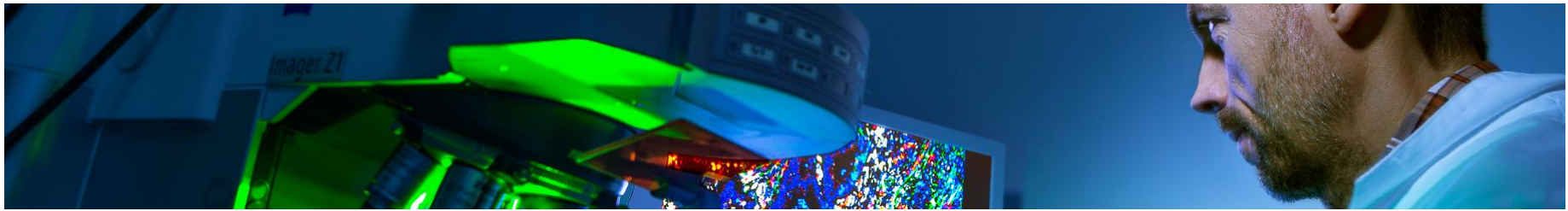
## Immune Activities

### Immune Toxicology Services

- Test your compound in human immune cells
- Risk assessment for induction of cytokine storm
- Evaluating off target effects and immunocompatibility

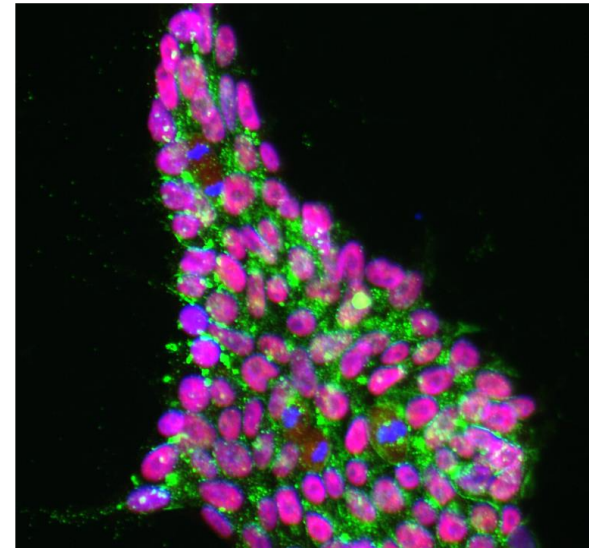
### Immune Bioactivity Services

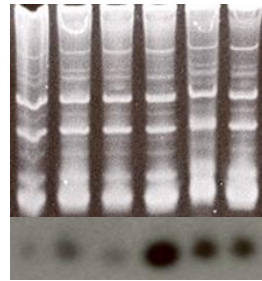
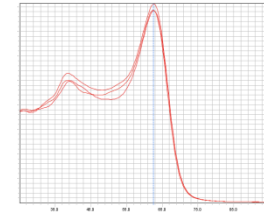
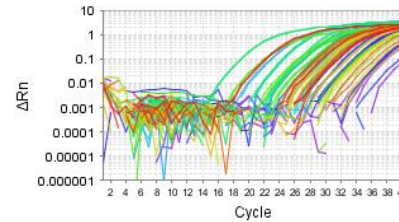
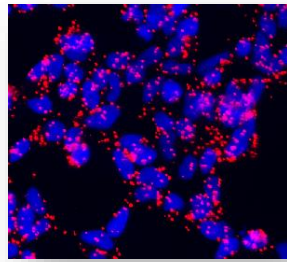
- Discovery of lead candidates for inflammation and autoimmunity
- Analyse MOA of your lead candidates
- Determine drug potency in primary human immune cells
- Drug potency and batch to batch variations



## Biomarkers and Molecular Histology

- Immunocytochemical (ICC)
- Immunohistochemical (IHC)
- nc/mRNA *in situ* hybridization (ISH)
- Flow cytometric analysis
- RT-qPCR



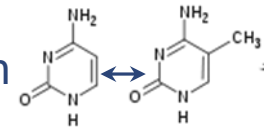


Molecular interactions

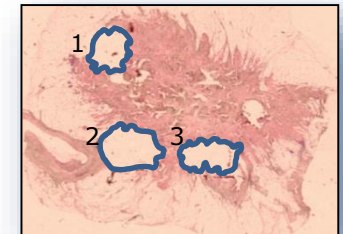
qPCR technologies

Melt curves

DNA methylation

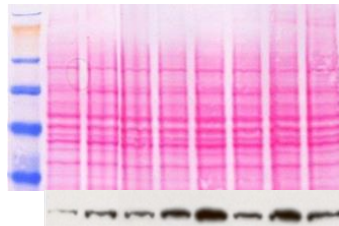


Laser-capture microdissection - qPCR



Northern blotting

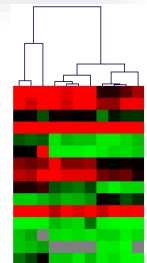
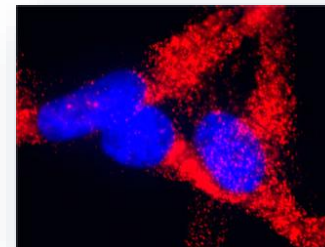
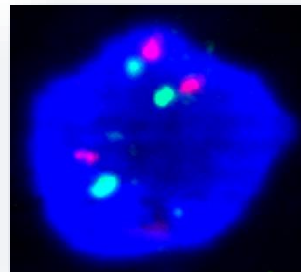
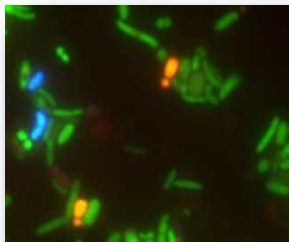
Western blotting

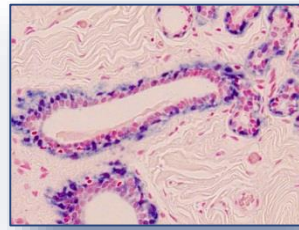


Bacterial FISH

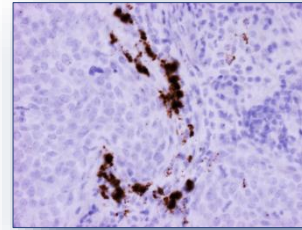
Cell RNA ISH

Chromosomal FISH

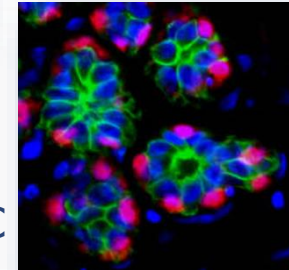




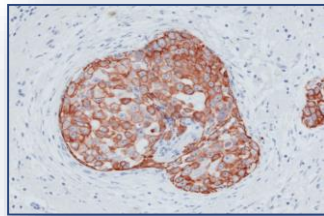
mi/ncRNA *in situ* hybridization



mRNA *in situ* hybridization



ISH + IHC



IHC

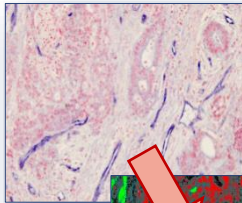
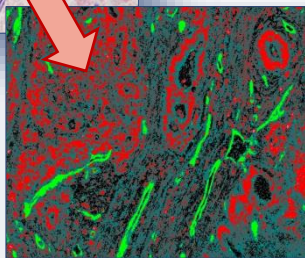
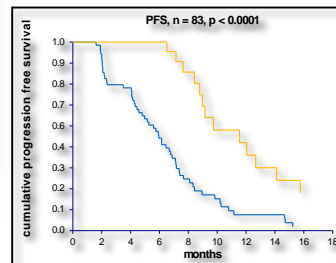


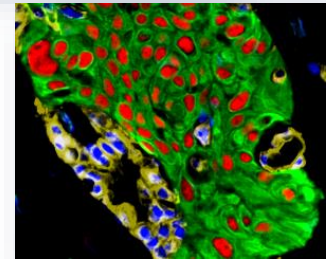
Image analysis



Quantitation



High throughput ISH/IHC



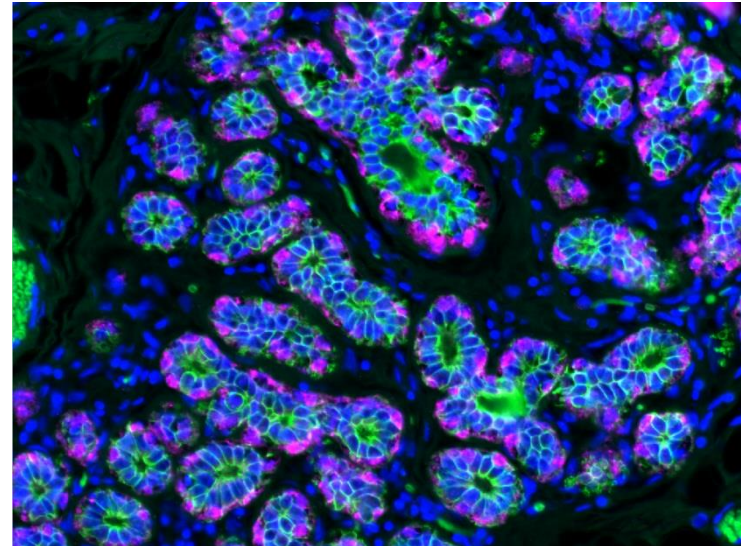
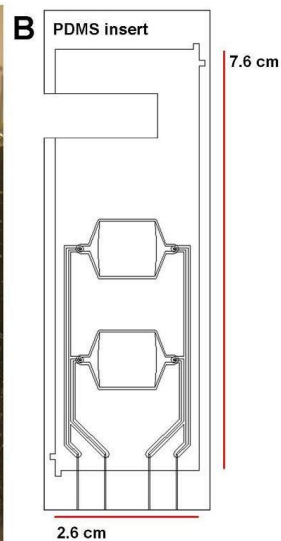
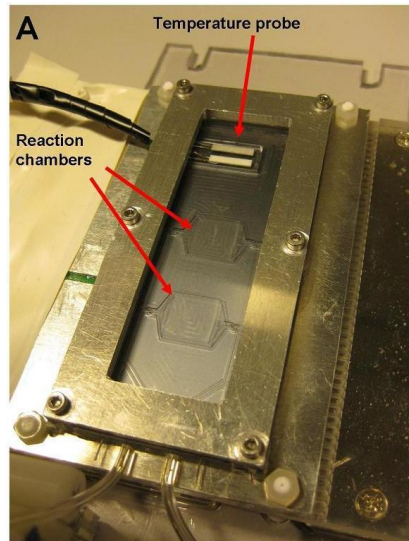
Multiplex IHC/IF



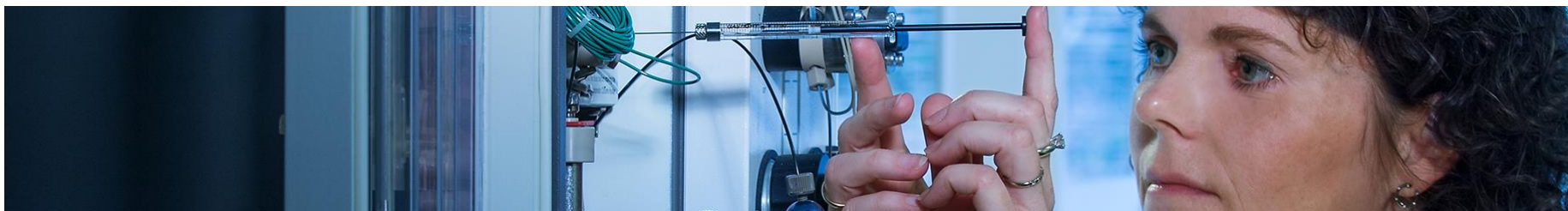
# Molecular Histology Service



A novel instrument for histological analysis -  
enabling the detection of *multiple* biomarkers  
on the *same* tissue section







## Bioneer:FARMA

- Compound characterization (small molecules & biologics)
  - LogD/pK<sub>a</sub>
  - Solubility/Dissolution
  - Solid state characterization
- Absorption and permeability
  - Caco-2/transfected cells/ex situ models
  - Franz diffusion cells
- Formulation development/characterization
- PK studies – together with Bioadvice A/S



## Dynamic Gastric Model

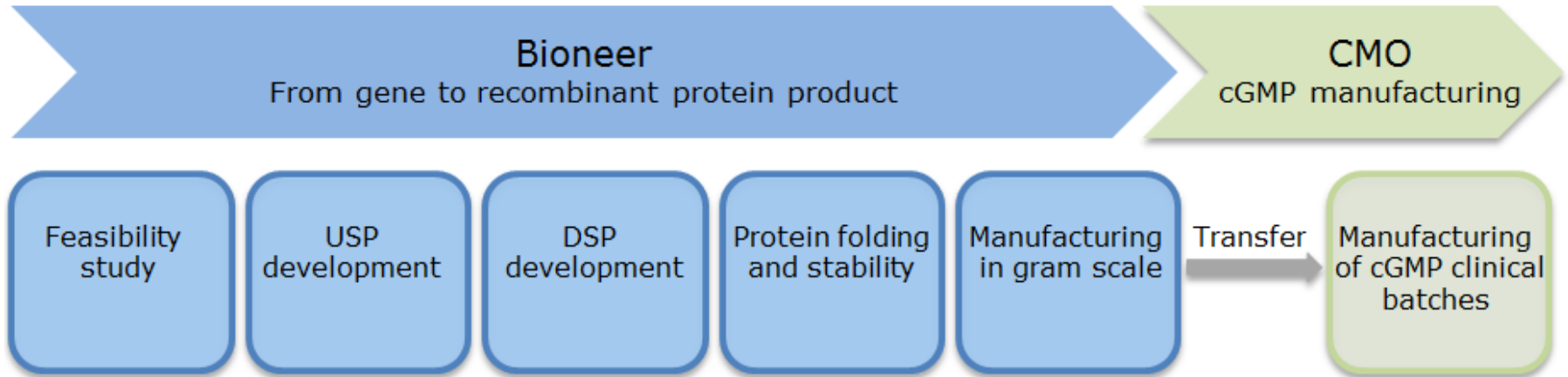
Advanced *in-vitro* model of the human stomach for predicting the bio-performance of oral pharmaceuticals and food products



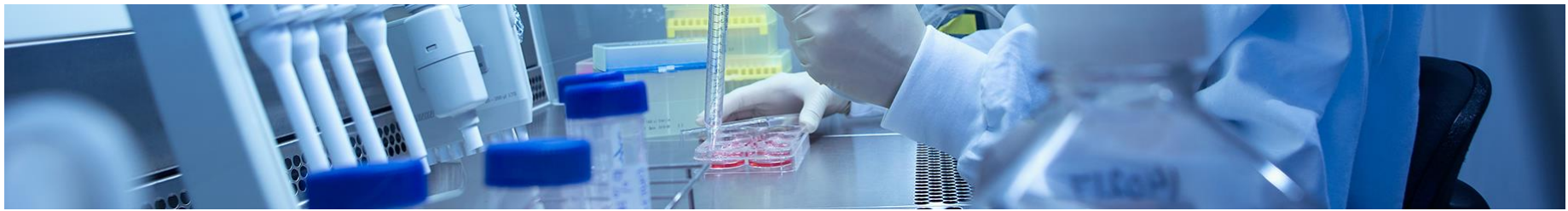
## Applications

- Bioequivalence assessment
- Food-effect evaluation
- Dose-dumping assessment
- Alcohol interaction
- Gastro-retention
- Metabolism and stability evaluation
- Nutrient delivery profiling
- Functional food analysis

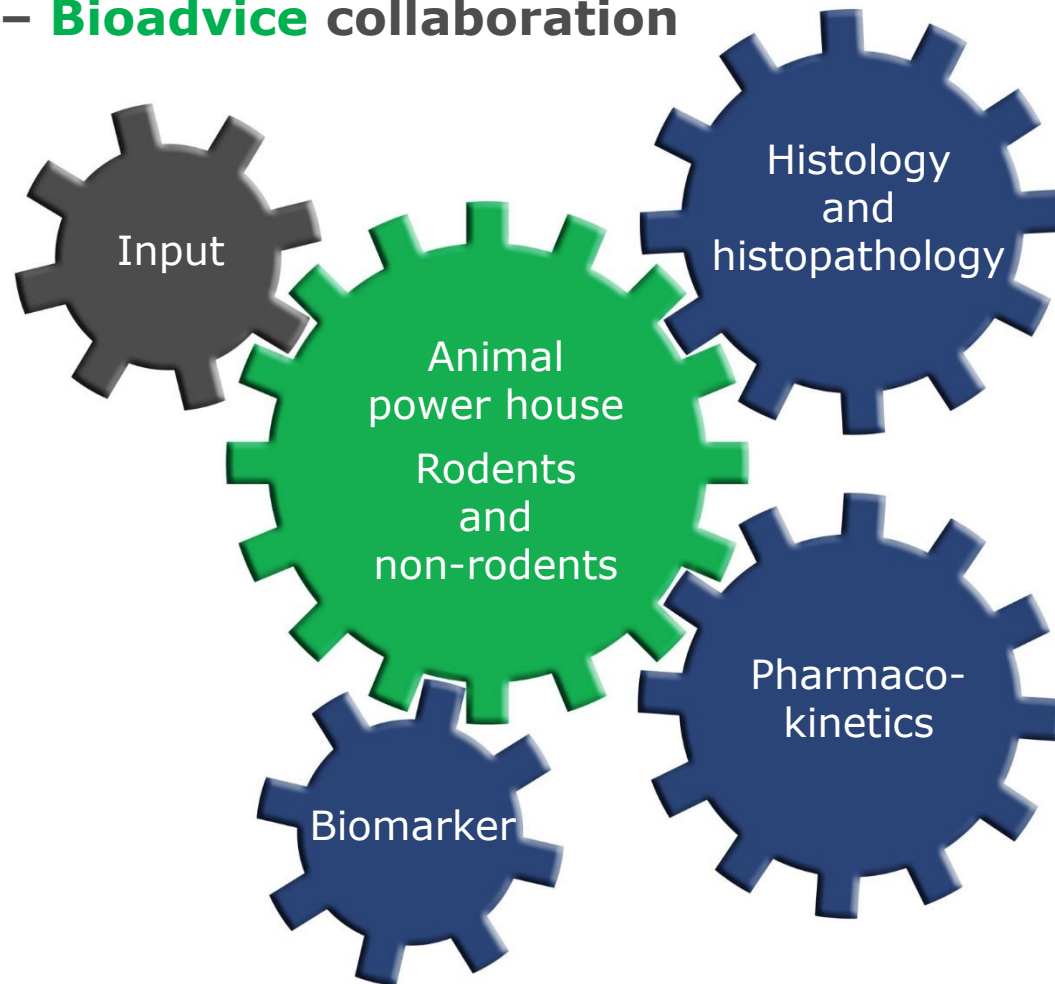
# Recombinant Proteins

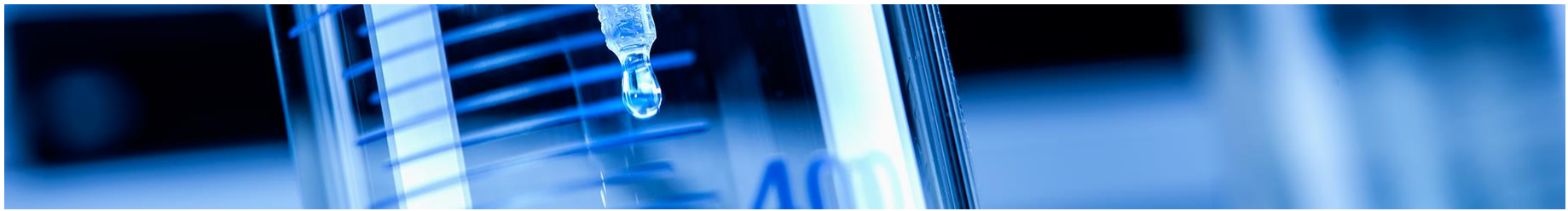


- **Feasibility study** (bacterial and/or mammalian systems)
  - *E. coli*, *L. lactis*, *B. subtilis*, CHO, HEK293
  - Gene design and codon optimisation
  - Vector construction and cell banking
  - Product localization (intra/extracellular)
  - Evaluation of productivity and protein quality
- **Upstream process development** (small scale)
  - Induction conditions
  - Fermentation strategy (batch, fed-batch)
  - Analytical methods for in-process control
- **Downstream process development**
  - Harvest and extraction of recombinant protein
  - Inclusion body preparation, solubilisation and refolding
  - Chromatography (tagged, non-tagged)
  - Analytical methods for in-process control
- **Protein folding and stability**
  - Conformational analysis (FTIR/CD/DLS)
  - Stability studies
  - Formulation design and optimisation
- **Manufacturing of non-cGMP batches**
  - Fermentation in 15L scale
  - Purification
  - Batch characterisation



## Bioneer – Bioadvice collaboration





### International projects

- FP7 { HIV vaccine development (11 partners/5 companies)  
Stem cell cultivation Techniques (6 Partners/3 companies)
  
- IMI { Oral delivery of biologics
  
- Euro-stars { Drug delivery thorough silicone structures (3 partners/3 companies)  
3D liver cell CYB models based on stem cells (3 partners/3 companies)  
Drug delivery to human monocytes (4 partners/3companies)  
Stem cell expansion technology (3 partners/3 companies)  
Optical cell sorting (3 partners/2 companies)

### National projects

- Innovation consortia { Regulatory T cells in autoimmune disease (6 partners/4 companies)  
Prediction of drug absorption in humans (7 Partners/5companies)  
microRNA Biomarkers for segmentation of breast cancer (6 Partners/4 companies)
  
- Strategic Research { Release of drugs from liposomes (2 Partners/1company)  
Stem cells i disease (4 Partners/2 cpanies)  
Vaccine development (4 Partners/2 companies)
  
- High Tech Fund { Alzheimer models derived from reprogrammed cells – iPS (6 partners/3 companies)



For inquiries:

Sales and licensing

Hans Christian L. Wegge

Business Development Manager

[hcw@bioneer.dk](mailto:hcw@bioneer.dk)