Iris Pharma is a worldwide Contract Research Organization (CRO), dedicated to preclinical and clinical research in ophthalmology. We take a global approach to the ophthalmology drug and device development process, and support clients ranging from small start-ups to large pharmaceutical companies in moving forward products that directly or indirectly affect eye health.

Since our founding in 1989, we have been based on the science of ophthalmology and have expanded our expertise in the field. Our unique, specialized knowledge ensures that our clients receive high-quality services delivered by well-informed and experienced staff who will guide their drugs or devices to market in the most efficient manner possible.

We are proud to have partnered with clients to bring more than 70 ocular drugs and medical devices to international market in the past 30 years.

Wherever our clients stand with their projects and wherever they want to go, Iris Pharma is able to guide them through the appropriate steps by bringing personalized advice and offering programs and study designs that perfectly suit their needs.

**COMPANY OVERVIEW**

Iris Pharma Services

**SOLUTIONS FOR ANY OCULAR CHALLENGES**

**VALIDATION**

«I’d like to assess the possible therapeutic value of my lead compound»

**POSITION FOR SUCCESS AND EFFECTIVENESS IN OPHTHALMOLOGY**

**ASSURANCE**

«I need a full preclinical package or clinical trials for my ocular product»

**MAXIMIZATION**

«My product shows promise in treating ocular diseases... Help me to achieve high added value!»

**EXPERTISE**

«I need a step-by-step approach and “à la carte” studies»

**GET EXPERT SUPPORT AT ANY POINT IN YOUR DEVELOPMENT PROGRAM**

**QUALITY**

At Iris Pharma, quality is a state of mind. Our quality assurance program is designed to ensure compliance with GLP, ICH-GCP and GCLP requirements, guidelines (FDA, OECD, etc.) and local regulatory laws and to maintain Iris Pharma’s standard of excellence in our work.

**KEY FACTS**

**Founded:** 1989 by Pierre-Paul ELENA, PhD.

**President:** Yann QUENTRIC, M.Sc.

**State of ownership:** Private

**Headquarters:** Nice, France

**Employees:** 60+

**2020 Turnover:** 7.8 M€

**Clients:** 380+ international customers

**FDA & EMA New Drug Approvals:** 70+

**THERAPEUTIC EXPERTISE**

Age-Related Macular Degeneration

Diabetic Retinopathy

Neurodegeneration

Retinal Ischemia

Glaucoma

Dry Eye Syndrome

Corneal Wound Healing

Ocular Infection

Ocular Inflammation

Conjunctivitis

Ocular Allergy

Ocular Pain

Ocular Surgery

Orphan Diseases

Cataract

Etc.

**CERTIFICATIONS & ACCREDITATIONS**

- Statement of compliance with GLP and GCLP
- Adherence to all the trial-related requirements (ICH-GCP)
- Authorization No. D 06-065-9 for experiments on live animals
- French research tax credit accreditation (CIR)
SERVICES FOR OCULAR DRUGS & MEDICAL DEVICES DEVELOPMENT

Benefit from the unique experience and background of an expert in ophthalmology

PRECLINICAL DEVELOPMENT SERVICES
We manage the complete animal ophthalmic development of drugs and devices using state of the art apparatus (e.g. Spectralis® HRA+OCT, tomography, in vivo confocal microscopy, electroretinography, laser flare meter).
• Early testing (proof of concept and pilot studies)
• In vivo pharmacology studies and animal efficacy models
• GLP regulatory studies: ocular pharmacokinetics, safety and tolerability
• Applied research (set up and validation of new and existing models and methods)
All studies are performed in-house by our technicians who have been trained to perform microsurgery of the eye and experimental procedure.

CLINICAL DEVELOPMENT SERVICES
We perform phase I to IV clinical trials and medical marketing surveys throughout Europe, North Africa, and North America. We provide our customers with the high-quality services necessary for evaluating new drugs and devices on patients, respecting regulatory authorities’ requirements.

• Regulatory support
• Study monitoring
• Site management
• Project management
• Data management and biostatistics

BIOANALYTICAL TESTING SERVICES
We develop, customize and validate assays of drug candidates and metabolites in a variety of ocular matrices to support preclinical, biopharmaceutical, and clinical pharmacology programs.
Analytical methodologies used include mass spectrometry, high-performance liquid chromatography coupled with different detectors, hematology analyzer, cell-based fluorescence assay (flow cytometry), immunoassays (Luminex, ELISA and EIA).

PRECLINICAL FORMULATION
We offer adequate non-GMP formulation of ocular drugs to be tested in preclinical studies, depending on the chemical properties of the compounds and the dosage form desired. We can also evaluate and improve the solubility of the compounds, with or without preservatives.

HISTOLOGY
We have been working for three decades on detailing and analyzing every structure of the eye, even going so far as to observe inflammatory cells in the vitreous body and aqueous humor.

CELLULAR AND MOLECULAR BIOLOGY ASSAYS
We work with our customers to identify and qualify predictive ocular biomarkers in many animal models - such as those involved in neovascularization. We also incorporate biomarkers quantification into clinical trials design such as HLA-DR (human leukocyte antigen) for ocular surface disease studies.

STRATEGIC CONSULTING SERVICES
We supply the necessary understanding and experience to guide new ophthalmic products through the development process. As a partner we help to direct preclinical and clinical drug development, to anticipate and plan for any issues which may arise, to design and manage drug and device development programs, or to provide strategic study design.

PARTNERING
• Institut de la Vision (a research center for eye diseases) to strengthen the bond between industry and academic research
• Virsco (a specialty preclinical CRO) to offer fully integrated “bench-to-bedside” ophthalmology research services
• Promedica International (a US-based CRO) to provide clinical research services in North America
• StreetLab (an innovative company for people with disabilities) to integrate quality of life in the clinical assessment of new products for use by the visually impaired
• Keen Eye Technologies (an image analysis specialist for the life sciences) to improve ophthalmology studies with artificial intelligence

3,000+
preclinical ocular studies completed
3,500
intravitreal injections/year
40+
preclinical animal models of human eye diseases
100%
labs and animal husbandry dedicated to ophthalmology
125
clinical studies and surveys conducted
43,000
patients involved in clinical studies and surveys
5,000
sites opened in 36 countries