康龙化成 PHARMARON

Biologics & CGT

Preclinical and CMC Services for AAV-based Therapies

Pharmaron's team has more than a decade of experience supporting the development and approval of ocular therapies. Services include preclinical testing (efficacy, PK and biodistribution, safety and GLP toxicology studies), CMC development and manufacturing support for clinical trials. Our ocular experience in the preclinical and CMC disciplines spans the full drug development lifecycle, including IND, IMPD, BLA submissions and post market support.

Services

- **Preclinical study design, data acquisition**
- **Efficacy, biodistribution, GLP tox study** execution and interpretation
- **Authoring preclinical study report**s for regulatory submissions dossiers supporting clinical and market approval (US, EU and global)
- **Supply of drug substance for preclinical, toxicology and clinical studies** at a range of scales
- **Analytical and product characterisation** services
- **Bioassay development** and testing
- **Authoring CMC sections** for regulatory submission dossiers for clinical and market approval (US, EU and global)

pharmaron.com ■ bd@pharmaron.com

Preclinical and CMC Services for AAV-based Therapies

Capabilities: Preclinical

- Broad range of disease models in different species, including wet AMD, inherited retinal disorders, diabetic retinopathy, glaucoma
- Expertise across all routes of administration
- Access to expert ocular scientists and board certified veterinary ophthalmologists
- Experience collecting comprehensive tissue list for biodistribution
- Functional and structural evaluation of critical endpoints

Capabilities: CMC

- 80,000 ft^2 state-of-the-art development and manufacturing
- Platform manufacturing process up to 500L
- Scalable suspension culture systems
- Chromatography based purification with focus on high purity for ocular administration
- High throughput process development
- Suite of analytics
- Best-in-class product characterisation of ocular targets

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Laboratory Services

Chemistry, Manufacturing & Control

Clinical Development

Biologics & CGT

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