PsychoGenics

Redefining Drug Discovery Through Innovation

QUALITY ASSURANCE AT PSYCHOGENICS

September 1st, 2020

The PsychoGenics Inc. Quality Assurance (QA) program provides a high quality and consistent end product. PsychoGenics has implemented a program of humane laboratory animal care and use based on the **Guide for the Care and Use of Laboratory Animals** (National Research Council 2011). PsychoGenics has been **AAALAC** accredited since June 28, 2007, and has maintained a **PHS OLAW Assurance** since May 3, 2005.

PsychoGenics is a co-leader in the **European Quality in Preclinical Data (EQIPD)** consortium. The project aims to establish simple, sustainable solutions that facilitate improvements in data quality without impacting innovation and freedom of research. The goal is to validate the principles, strategies, and research models impacting neuroscience and safety to enable a smoother, faster, and safer transition from preclinical to clinical testing and drug approval. This is accomplished by establishing harmonized guidelines designed to strengthen the robustness, rigor, reproducibility, and validity of research data to ensure drug safety and development of new neurological drugs. PsychoGenics employs **ARRIVE [Animal Research: Reporting of In Vivo Experiments]** guidelines in support of animal research reporting with the goal to improve the methodological rigor and transparency of the scientific process and thus data reproducibility of in vivo experiments.

Quality Control (QC) procedures can be customized and adapted to Client requirements. Multiple QC levels can be applied to a study. A study audit request defines the review process or inspection procedures of specific study components at periodic intervals to ensure integrity of the study. Post Approval Monitoring can be conducted to include test subject evaluation, test method and procedure assessment, staff proficiency, and equipment performance. A final report audit evaluates the study for completeness and accuracy of supportive data, appropriate data analysis, and compliance with IACUC, SOPs, and study protocol requirements. A QA Statement is issued for inclusion in the final report. Electronic Client computer and legal file oversight is maintained and study information is archived for a period of 2 years or as per contractual agreement with the Client.

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