The University of Iowa Dezii Translational Vision Research Group

TITLE: Quality Assurance Group

SOP Number: D-QA-PRO-001 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This Standard Operating SOP (SOP) is to define the Quality Assurance (QA) Group and assign its responsibilities.

B. APPLICABILITY

This SOP applies to the Quality Assurance Group of The University of Iowa Dezii Translational Vision Research Group (DTVR)

C. RESPONSIBILITIES

1. The Quality Assurance group is responsible for ensuring that The University of Iowa Dezii Translational Vision Research Group (DTVR) follows the current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) as set forth in the Code of the Federal Regulations (CFR) for Food and Drugs.

    1.1. QA shall be responsible for generating or assisting with data generation to validate equipment and processes as needed to meet the cGMPs and cGTPs.

    1.2. QA shall be responsible for tracking the calibration of critical pieces of equipment, and calibrating those pieces of equipment that are within the capability of DTVR. All other pieces of equipment that cannot be calibrated by DTVR will be calibrated by an appropriate calibration service.

    1.3. QA shall oversee the record keeping procedures outlined in the DTVR SOPs.

    1.4. QA shall review all batch records after their completion by Operations. After this review, the records will either be released for archival or sent back to the responsible party for revision or correction. If the document was revised or corrected, it will return to QA for final approval before being released for archival.

    1.5 QA will review all laboratory data and reports prior to acceptance and archival.

    1.6. The Director of the DTVR and the QA officer shall, as much as possible, be present for and assist in all GMP audits conducted by the FDA. Additional assistance may be requested during the auditing process from appropriate DTVR personnel of the specific area(s) being audited.

    1.7. QA shall be responsible for performing an internal audit of DTVR. A facility wide audit shall be performed once a year within one month of the anniversary date of the previous audit. Each department shall be audited at a time prior to the facility audit.

    1.8. QA shall be responsible for the auditing of outside contract firms that are used by DTVR.

    1.9. QA shall be responsible for conducting initial GMP training for all new employees, and ongoing GMP training for other employees.

1.10 QA shall be responsible for documentation approval, oversight of investigations and deviations and oversight of change control.

1.11 QA will be responsible for reviewing government documents for updates. This will be done on a quarterly basis. This will include but not be limited to FDA, ICH and USP documents.

2. QA shall consist of the Director of QA, the Quality Assurance Officer and others necessary to help in collecting, recording, and reviewing data and records.

3. The QA group shall report directly to the Director of The University of Iowa Wynn Institute for Vision Research (WIVR).

D. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document