The University of Iowa Dezii Translational Vision Research Group

TITLE: Quality Control Group

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

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

The Quality Control (QC) group is defined by 21 CFR 211.22. This document describes the QC group responsibilities, specific functions and organization at The University of Iowa Dezii Translational Vision Research Group (DTVR). The function of Quality Control at DTVR is performed by the Functional Analysis group.

B. APPLICABILITY

This document applies to all Quality Control/Functional Analysis (QC/FA) personnel at DTVR.

C. REFERENCES

21 CFR 211.22 Responsibilities of quality control unit

D. GENERAL INFORMATION

1. SOPs designated as QC-XXX-XXX govern all subgroups of QC unless specific departmental, such as raw materials, SOPs are different.

2. Work designated as supervisory within QC requires an associate scientist level or higher.

3. With proper training, subgroups may perform testing for other subgroups as needed.

4. If the product being tested is a compendial product, it will be assayed according to the tests in the appropriate compendium. If the product is not a compendial product, the product will be analyzed as directed by the cGMP Director of DTVR.

5. All subgroups of QC write and/or maintain:

   5.1 controlled documents relevant to QC (i.e. SOPs, forms, instrument protocols, investigation reports, analytical methods, etc.)

   5.2 LabGuru entries that capture raw data

   5.3 data generated in the course of analysis (i.e. Western Blots, ICC, Phase Microscopy, rt-PCR, chromatograms, etc.)

6. All subgroups of QC review and/or research methods and guidance documents (e.g., USP monographs and general chapters,FDA guidance documents, etc.) to ensure that all testing is accurate and current.

E. ORGANIZATION AND RESPONSIBILITIES

1. The QC/FA group at DTVR is a single group and individuals of this group report to the Director of Functional Analysis. The Director of FA reports to the cGMP Director of DTVR.

2. The QC/FA group:

   2.1. Conducts and/or coordinates testing for:
   - any raw material or component testing as requested by QA or the DTVR Director
   - cleaning validation
   - method development
   - method validation
   - analytical method transfers
   - final product functional analysis for release
   - stability studies analysis
   - supplemental analysis as requested
   - residue and detergent analysis for equipment cleanliness

   2.2. Writes and/or maintains:
   - method validation and analytical method transfer protocols
   - validation reports
   - analytical method generation

3. The Functional Analysis Director:

   3.1. Handles the daily operations. The Director of FA reports to the Director of DTVR.

   3.2. Conducts and/or coordinates:
   - the training of the FA staff
   - the final review for LabGuru entries, reports, analytical methods and data generated by the Functional Analysis group
   - laboratory and analysis equipment maintenance and calibration
   - the stability studies program
   - trending of data, investigations and reports as necessary

   3.3. Writes and/or maintains:
   - stability protocols for HCT/P or GT products as needed
   - software and networks for the Functional Analysis group

F. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document