



# The University of Iowa Dezii Translational Vision Research Group

## TITLE: Laboratory Documentation and the LabGuru System

SOP Number:           D-GLO-PRO-009          

Revision Number:                           0                          

Effective Date:                   09 Aug 2015                  

written to the manufacturing record. The explanatory note will be signed and dated by the individual making the change.

8. Only qualified individuals as defined by SOP D-GLO-PRO-003, D-QA-PRO-001 and D-QC-PRO-001 can make additions, deletions, or changes in a permanent, hardcopy record.
9. Additions -- New procedures, ingredients, processing steps, etc., shall be added, initialed and dated (actual date of entry change) by the individual making the addition.
10. Deletions – On hard copies a single line shall be drawn through the deletion. The individual making the deletion shall initial and date (actual date of entry change) the deletion.
11. Changes -- A single line shall be drawn through the entire entry to be changed. For example, if one digit in a six digit number is wrong, the entire six digit entry is lined through. Another example, if the day of the month is entered incorrectly, one would line through the incorrect portion of the day–month–year entry. The change shall be hand written near the entry to be changed. The individual making the change shall initial and date (actual date of entry change) the change.
12. Incorrect entries will be lined out using a single line, and be dated and initialed by the originator and re-entered. An explanation of the error will be given. A full written explanation may be given or the following codes may be used.

M	Misspelled	R	Rounding error
C	Calculation error	I	Illegible entry
W	Wrong Entry	U	Unnecessary entry
T	Transcription Error	A	Additional information

The error code will be written next to the initials and date and will be circled.

14. Explanatory notes and comments on observations made during the manufacture of the batch may be written in the batch record by any individual involved with the production process. The comments and notes must be signed or initialed and dated (actual date of entry change) by the individual making the comment or explanatory note.

### LabGuru Documents

15. Only qualified individuals as defined by SOP D-GLO-PRO-003, D-QA-PRO-001 and D-QC-PRO-001 can make additions or modifications in LabGuru. All LabGuru Users have unique username and Passwords, assigned by the director of the DTVR.
16. Additions – New experiments, procedures, documents etc. are automatically initialed and time stamped following entry.
  - a. Once an experiment, procedure or document entry is completed click the complete tab.
  - b. Following completion of an entry, i.e. experiment, procedure or document, the entry will be reviewed by QC.
  - c. Following review completed entries will be signed and locked by the individual who made the entry by pressing the sign & lock tab. Modifications cannot be made to completed signed and locked entries.

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- 17. Entry modifications – If entry errors are identified during review, modifications will be made by the individual who made the original entry and the entry will be re-reviewed by QC. Following re-review completed entries will be signed and locked by the individual who made the entry by pressing the sign & lock tab. Modifications cannot be made to completed signed and locked entries.
  
- 18. Any corrections made to a document, notebook, batch record or LabGuru entry during its review must be made by one of the individuals who signed or cosigned the original data.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original Document