

The University of Iowa Dezii Translational Vision Research Group

TITLE: Generation, Review, and Archiving of Batch Records

SOP Number: D-GLO-PRO-018

Revision Number: 0

Effective Date: 09 Aug 2015

6. After the production supervisor's review, the BR will be given to Quality Assurance (QA). The QA review will be performed to verify that the total BR package is complete and accurate. The BR will then be signed off by the Director of Quality Assurance or a designate.
7. The original completed BR and corresponding FM will be archived by DTVR in the QA office.
8. In the event that a correction/addition/deletion needs to be made to a BR that has already been signed off, as described in steps 5 and 6 above, the addition/correction/deletion will be initialed and dated by the person making the change and by the individuals who previously signed off as described in steps 5 and 6 above. In addition, documentation will be placed in the batch record file summarizing the changes that have been made. In the event that the person making the change originally signed off the record it is only necessary to obtain the initials of the other original signatory.
9. In the event a BR has already been signed off, as described in steps 5 and 6 above, but requires further processing (such as labeling, re-labeling, packaging, repackaging, etc.) it will be permissible to add an addendum to the BR. The following procedure will be used to generate, execute, approve, and archive an addendum.
 - 9.1 An addendum will consist of a new blank copy of the original cover page, any pages necessary to complete the additional processing, an explanation of the reason for the additional processing, and a new blank copy of the original final approval page.
 - 9.2 An addendum will be prepared and approved prior to use in a fashion similar to an original Formulation Master and Batch Record as described in SOP GLO-PRO-030.
 - 9.3 An addendum will be executed, reviewed, and signed off as described in steps 3-6.
 - 9.4 Once signed off addendum pages will be sequentially numbered A1 – AX from front to back where X is the number of the last page. At this time the total number of pages in the BR noted on the front page of the originally completed BR will be changed to reflect the new total number of pages
 - 9.5 A completed addendum will be distributed and archived (in the original BR file folder) as described in steps 7, 8, and 10 through 12).
10. The BR and FM will be scanned into LabGuru and archived indefinitely. Hard copies will be kept for a minimum of 6 years (4 years past expected product usage date of 2 years).

G. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document