1.0 Purpose

The purpose of this procedure is to define the general requirements and guidelines for all cGMP records and documentation, such as recording data in batch production records (BPR), log books, and official forms.

2.0 Scope

This procedure applies to all cGMP paper documents in use at Ion Labs, specifically batch records, CQS documentation, calibration records, and all other records that are governed by standard operating procedures.

3.0 Responsibility

3.1 It is the responsibility of all employees to strictly follow this procedure.

3.2 It is the responsibility of department managers and supervisors to ensure that all employees strictly follow this procedure.

3.3 It is the responsibility of Quality to ensure that every employee strictly follows this procedure.

4.0 Definitions

4.1 **cGMP** – Current Good Manufacturing Practices

4.2 **BPR** – Batch Production Record

4.3 **CQS** – Core Quality System

4.4 **Permanent** – lasting indefinitely, enduring; data cannot be changed, erased or washed off

4.5 **Legible** – capable of being easily read

4.6 **Accurate** – having no errors; correct and carefully recorded

4.7 **Prompt** – done without delay; immediate

4.8 **Clear** – capable of easily understanding; free from confusion or doubt

4.9 **Consistent** – compatibility or agreement among ideas, acts or events; standardized

4.10 **Complete** – having all necessary parts; whole.

4.11 **Truthful** – honest; corresponding to fact or reality

4.12 **PQC** – Process Quality Check

4.13 **PQV** – Process Quality Verification

5.0 References

5.1 21 CFR Part 111 Subpart F & I

5.2 21 CFR Part 210 and Part 211

5.3 A-114, SOP, Employee Signature Recording

5.4 A-114-F1, Form, Employee Register

5.5 QS-116, SOP, cGMP Electronic Signatures

5.6 QS-112, SOP, Core Quality Systems and Quality Events

6.0 Procedure

6.1 Acceptable Documentation Practices

6.1.1 Data entry must be clear and legible using an acceptable writing instrument such as a ballpoint pen with permanent black or navy blue ink. Ensure that the pen is working properly and has good ink flow.

6.1.2 The ink used must allow for clear photocopies to be made.

6.1.3 Documentation must be completed in English.

6.1.4 All documentation is to be made promptly while the work is being done, not at a later time and date. If something needs to be added at a later time, the entry must be initialed and dated, and include a brief explanation.

6.1.5 Use of a red non-erasable ballpoint pen is acceptable to propose changes to current/effective documents that have been identified as "For Reference Only" and to review draft documents.

6.2 Unacceptable Documentation Practices

6.2.1 Never use erasable pens, correction fluid (white out), felt tip pens, gel pens, erasers, or ink which is any color other than black or navy blue when recording on official documents.

6.2.2 Official data recorded on other non-standard or unapproved forms is not allowed.

6.2.2.1 Do not use note sheets, sticky notes, pieces of paper, or surfaces in the manufacturing area to record or transfer information or data. All data and information recorded should be made directly in the BPR, log books, and all other official forms.

6.2.3 Arrows or quotation marks (ditto marks) to indicate repeated information are not allowed.

6.2.4 Never use multiple "lines through" or "scribble out" entries.

6.2.5 Never document a check or activity that was not performed.

6.2.6 Never discard original data or make original data unable to be read. Keep all original documents included with the cGMP record. This includes any items that may have been made unreadable. They are still an official part of the cGMP record and need to be retained.

6.2.7 Falsification of documentation will not be tolerated under any circumstance. Examples of falsification include but are not limited to:

6.2.7.1 Writing data, information, initials, or date before a task, calculation, or test is actually performed.

6.2.7.2 Writing initials in any space for information or data that has not been performed.

6.2.7.3 Knowingly writing incorrect information, data, or dates, or destroying official documents.

6.2.7.4 Writing someone else's signature or initials that are not your own.

6.2.8 Overwriting is NOT acceptable on any documentation. Overwriting includes making one number appear to be another number, multiple tracing of the same entry to make the ink appear darker, adding letters or numbers in between other letters or numbers, and any entry that makes the original entry illegible.

6.2.8.1 Overwriting: when a character is written in the same spot more than once (tracing over a character).

Example: 1234-S The S is overwriting

6.3 Data Correction Guidelines

6.3.1 If a mistake is made, correct the entry as follows:

6.3.1.1 Cross out the mistake using a single horizontal line. Crossing the entry, using multiple lines or completely defacing the error is not acceptable. The original marks must be clearly visible below the single line correction.

Example: ~~01/28/17~~ Correct

~~01/28/17~~ Incorrect

~~01/28/17~~ Incorrect

[redacted] Incorrect

~~01/28/17~~ Incorrect

~~01/28/17~~ Incorrect

6.3.1.2 Correct the mistake as close as possible to the space designated for the entry.

6.3.1.3 Provide a complete truthful explanation for the correction, if appropriate.

Example: Wrong Entry, Entry Error, Calculation Error, etc.

6.3.1.4 All corrections must be initialed and dated.

Example: ~~30kg~~ 40kg KB 01/28/22

6.3.1.5 If space does not permit the correction to be made as stated, correct the entry as follows:

6.3.1.5.1 Cross out the mistake using a single horizontal line. The original marks must be visible under the single line correction.

6.3.1.5.2 Place an identifiable mark beside the single line to be referenced as a footnote. Using sequential numbers is preferred for footnotes, i.e. each subsequent entry correction by individuals on the same page will be footnoted as 1, 2, 3, etc., to clearly track and identify corrections.

6.3.1.5.3 Place the same identifiable mark preferably at the bottom of the same page and write the relevant explanation for the correction.

6.3.1.5.4 Initial and date the correction.

Example:

~~26.00 kg~~ ①
30.00 kg
15.00 kg

① 26.50 kg – Entry Error KB 01/28/22 (This comment is to be entered as close to the bottom margin of the page as possible)

6.4 Unused Spaces Marked as N/A (Not Applicable):

6.4.1 All non-applicable areas will be marked N/A by recording N/A in the space.

6.4.2 N/As should be justified if they are not self-explanatory. Record a brief justification on the document, initial and date.

6.4.3 Computer-driven N/As do not need to be lined through, initialed or dated.

6.4.4 Cross out any unused page(s) or section(s) of a document or logbook with a single line, identify with N/A, initial and date.

6.4.5 All blank spaces requiring data entry, signatures, or dates must be completed at the time the task or check is performed.

6.4.5.1 Missing information added after the occurrence must be initialed and dated at the time the information is added. Do not back date at any time.

6.4.6 Spaces where data entry is not applicable must be marked as N/A.

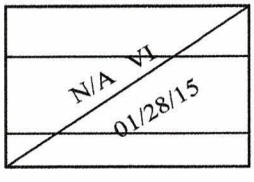
6.4.6.1 If a single blank space needs to be N/A, mark the space with N/A.

Example:

N/A
30.00 kg
15.00 kg

6.4.6.2 If a large section needs to be N/A, draw a line through the entire section and N/A followed by initials and date.

Example:



6.4.6.3 Cross out any unused pages or sections of a controlled document with a single line and identify with N/A, initials, and date.

6.5 Date Format

6.5.1 Use a numerical representation of a 2-digit month, a 2-digit day and a 2-digit year with a slash (/) or dash (-) between each segment.

Example: March 31, 2017 would be written as 03/31/17 or 03-31-17

6.5.2 Exception would be if a customer specifically requires a different format. In this case, the format will be outlined in documents specific to that customer.

6.6 Time Format

6.6.1 A colon (:) should separate the hours and minutes. After the minutes, AM or PM must be recorded. Military time is unacceptable.

Example: Eight thirty-five in the morning would be written as 8:35AM.

Example: Ten thirty in the evening would be written as 10:30PM.

6.7 Signatures

6.7.1 Signature/Initials on all documents should be consistent with those entered in the employee register on Form A-114-F1 Employee Register, per SOP A-114 Employee Signature Recording.

6.7.2 Employees must always use the same unique signature and initials when signing or initialing controlled cGMP documents.

6.7.3 When a document requires a signature, it should be recorded as a signature (not as initials) and should be clearly written.

6.7.4 Stamps for signatures, initials, and/or dates are not allowed.

6.7.5 Your signature/initials indicate that you have taken responsibility for the accuracy and correctness of the information that you have written or verified.

6.7.6 Refer to SOP QS-116 cGMP Electronic Signatures to see guidelines for using electronic signatures.

6.8 Missing Information

6.8.1 Any missing information found and corrected must include the author's initials and the date.

6.8.2 Missing information added after the occurrence must be initialed and dated at the time the information is added.

6.8.3 The best practice is that the person who failed to enter the missing information is the person who records the missing information. If this cannot be accomplished in a reasonable timeframe, a superior (manager, supervisor, assistant supervisor, or lead) can enter the missing information, as long as they can verify the information. An explanation/comment must be included.

6.8.4 An employee cannot delegate signing authority to another employee.

6.9 PQC

6.9.1 A PQC is a process quality check. PQC activities include but are not limited to:

6.9.1.1 Logging of various activities throughout multiple departments (such as Warehouse and QC Laboratory)

6.9.1.2 Documentation of various BPR requirements (such as room startups and in-process checks)

6.9.1.3 Calculation of batch yields and reconciliations

6.9.2 The person responsible for the action is also responsible for the completion of the PQC. Any qualified employee may complete a PQC.

6.10 PQV

6.10.1 A PQV is a process quality verification. A PQV is necessary for critical activities that require documentation of the completion of an activity (i.e. a PQC) as well as the verification of that activity (i.e. a PQV). Examples of PQV activities include but are not limited to:

6.10.1.1 Room startup readiness verification

6.10.1.2 Verification of cleaning effectiveness

6.10.1.3 Verification of in-process product inspections

6.10.1.4 Verification of logbook entries

6.10.1.5 Batch yield verification

6.10.2 A department manager/supervisor typically will complete PQV activities. However, any qualified individual may complete a PQV as long as the employee completing the PQV is different from the employee completing a corresponding PQC for the same activity.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	11/01/10	New procedure.	-	-
1	11/20/12	Changed SOP title. Added more responsibility. Made SOP more detailed to be in compliance with 21 CFR Part 111.	12-205	V. Iltcheva
2	01/29/15	Biennial Review. Updated SOP format. Replaced QA with Quality in responsibility section.	15-0043	V. Iltcheva
3	04/11/17	Biennial review: corrected spelling errors; changed date references.	17-0403	K. Burris
4	08/27/17	Updated SOP throughout for flow, titled each section for easy to find sections. Added definitions, SOP references to A-114, added arrows and dittos are not acceptable on cGMP documents, date, time and signature format requirements.	17-0840	S. Mann
5	10/19/20	Scheduled review: added gel pens as unacceptable writing utensils. Added navy to blue ink requirements.	CC-20-0728	K. Burris
6	06/03/22	Updated logo and format. Added references to SOP QS-112 and QS-116. Clarified procedure throughout.	CC-22-0257	K. Burris
7	03/13/23	Added section for PQC and PQV requirements.	CC-23-0131	K. Burris