B&R Compliance Associates LLC

Regulatory Update Bulletin

Bulletin Number

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7/10/11

"Quality Records"

If you produce gases, which bear the "USP", or "NF" label you are a drug manufacturer. As such, the FDA expects you to comply with Current Good Manufacturing Practices which includes maintaining appropriate documentation (which would include the documentation covered in this article). Current Good Manufacturing Practices (cGMP's) relative to human drug products are found in 21 CFR, §210 and 211. Failure to comply with these requirements and the requirements of your own SOPs can result in serious consequences.

General Quality Record Filing/Storage

- The Q/A Coordinator or their delegate will maintain files for all applicable (completed) medical gas quality records.
- Authorized personnel will file records in a neat and orderly fashion, preferably using a chronological file.
- Records shall be stored in a manner to prevent their degradation from environmental conditions and weather while in storage.
- The Q/A Coordinator or his delegate will assure records beyond current fiscal year are removed and placed in storage for the required retention time(1 Year past expiration date or 3 + current year if not using expiration dating).
- Program member companies shall not store records in unmarked files, boxes or cabinets. Records must be easily identified and retrievable during their retention period.

Data / Information Recording

- Only current and approved forms will be utilized for Quality Records unless otherwise specified by procedure or approved exception.
- Data and entries will be made on Quality Records as the event or result occurs. Post or Pre-dating is not permitted. The Q/A Coordinator or his delegate will assure all entries on Quality Records referenced in this manual are made in a timely and accurate fashion.
- Entries on Quality Records will be made in ink or marker only. Pencil entries shall not be permitted.

For more information on this subject, or any other medical gases compliance issue please contact Ron Ball at (317) 297-8518, or ron.ball@brcompliance.com.

Quality Record Corrections

Corrections to initial entries on Quality Records can only be made in the following fashion:

- Erroneous entry shall have a single pen line drawn through it and the correct entry made directly adjacent to it.
- The corrected entry shall be initialed by an authorized person, and dated with the date of the correction. If it cannot be easily determined why a correction was made from the notation on the correction, a written explanation that will be attached to the record and noted as attached on the original entry.
- Write over, the use of whiteout, or other correction methods are not permitted.

Control of Product

- Product shall remain in a state of quarantine until all records are reviewed and approved as indicated by a dated signature.

Record Review

- Prior to approval of a Quality Record and the release of a lot of Medical Gas product for distribution, the Q/A Coordinator or other qualified and designated individual shall review and approve all lot records, and other compliance documentation against identified standards such as specifications or other procedures in the SOP Manual.
- Individual performing review and approval operation must be someone who has not previously performed any of the work recorded on the record in question. For example if filler also performs analytical measurements they cannot be the person approving and releasing product. Or, if one individual fills and a second individual analyzes, then a third individual must be the reviewer.
- If, during this review, the Q/A Coordinator (or other qualified individual) finds omissions or errors, they must determine who made the error or omission and ask that person to properly correct it in accordance with the appropriate procedures.

Release of Product

- Only after all records are reviewed and approved will the product be released for distribution.

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