B&R Compliance Associates LLC

Regulatory Update Bulletin

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Conducting & Documenting Management Program Reviews

It is important that every medical gas firm conduct and document an annual management program review, which is a § 21 CFR requirement. An annual program review is different from a compliance audit. This management technique is a tool to identify weakness in your compliance programs, and help you decide where to focus time and resources towards improvement.

We find that the firms who adopt continuous improvement of their quality systems into their business philosophy, typically not only do well with compliance audits, they usually are very efficient businesses as well. These companies have become adept at finding and correcting their own problems. Managers of these firms are willing to take the time to analyze problems, and implement appropriate remedial actions that ensure the same problem does not crop up again. These firms take this internal problem solving capability and apply it to the non-FDA elements of their business portfolio to eliminate waste and improve quality & customer satisfactions, becoming more competitive as a result.

What elements should be included in your management review procedures?

- A statement that management reviews will take place on a periodic basis.
- Schedules including the requirement for reviewing and adjusting the frequency based on findings.
- A description of the level and scope of authority of the people who will attend the reviews.
- A description of the data which will be covered in the review.
- A requirement for initiating, documenting, and follow-up on corrective and preventative actions.
- A requirement to ensure that the minutes of the reviews are accurate and contain appropriate language.

Program reviews should look at the following data:

- Internal Compliance Audits
- Supplier (Vendor) Audits
- Customer Complaints
- Incoming Materials Inspections
- Investigations of Process Variations & non-conforming product

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.

Documentation of Annual Management Program Review & Internal Audits

The Quality System Regulation provides that the requirement to make records available for inspection and copying by FDA officials does not apply to management reviews, quality audits, and supplier audits. An FDA employee may request under the requirements of the regulations, "management with executive responsibility" certify in writing that management reviews and quality audits have been performed and documented, the dates on which they were performed, and that "any required corrective action has been undertaken". If an FDA employee makes this request, we recommend that you seek the assistance of legal counsel before providing this certification.

Sample Language for the memo you prepare to share with the FDA would be something like below:

(Insert Facility Name) conducted an annual management program review to assess their Quality Systems on: (insert date)

Persons in attendance: (A list which should include senior management)

During the meeting the following areas were reviewed:

- Any Compliance Audits (Internal, External Agencies, and Supplier/Vendor) conducted since last review
- Any complaints received since last review
- Any investigations of process variations & non-conforming product since last review
- Any Agency documents regarding changes in regulations (Proposed regulations or guidance documents) since last review
- Any association bulletins (CGA or GAWDA) regarding enforcement trends in the industry

Based on the above review any required corrective action to address findings has been undertaken.

Insert Signature & Date of "management with executive responsibility" sign off certification

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