B&R Compliance Associates LLC

Regulatory Update Bulletin

Bulletin Number

BR10-002

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Issue

This bulletin is being issued to provide current information on the above topic.

What better way to know where you should look for potential FDA violations than to examine your compliance against the most common cGMP violations? B&R assembled this list of cGMP violations that are the most frequently violated. The information comes from monitoring audits conducted by the FDA at member locations.

"10 Most Common cGMP Violations"

1. Failure to establish written quality control unit procedures (staffing & record review) [§211.22 (d)]
2. Failure to establish an adequate training programs (frequency/content/documentation) [§211.25 (a)]
3. Failure to perform finished product testing & follow proper release procedures [§211.165 (a)]
4. Failure to properly calibrate the testing equipment (Reference Standards/Follow Manufacturers Recommendations) [§211.160 (b)(4)]
5. Failure to follow proper laboratory controls (Alternate Test Method Validation & Analyzer Qualifications) [§211.160 (b)(4)]
6. Failure to establish or follow written procedures for production and process control (SOP Manuals not up to current industry standards) [§211.100 (a)]
7. Failure to establish adequate batch production records [§211.188 (b)]
8. Failure to establish adequate labeling procedures [§211.130]
9. Complaint/Recall Procedures (Failure to recognize/investigate/document complaints & adverse events) [§211.198]
10. Validation (Remote Sample Lines/Automated Filling Manifolds/Portable Manifolds) [§211.110]

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 compliance with the above list. Taking steps to ensure compliance with these items will enhance your quality assurance program and be a good step toward overall better FDA compliance.

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.

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.