Guide for US FDA-Regulated Organizations

Submitted by Guest (not verified) on Fri, 05/07/2010 - 12:51pm Veriteq Instruments, Inc.

In such stringently controlled industries as pharmaceutical/biotechnical/medical device development, manufacturing, and warehousing, receiving a list of deficiencies can feel like a heavy blow to your quality system. The following article shows three excerpts from some of the more common “observations” noted in Form 483 Letters during 2008-2009. None of the deviations excerpted here are unique, but all are avoidable. After the excerpts, the reader will find an outline of the best practices of a 483 response, including a 10-point checklist that should make that 15-day time limit more manageable, links for further research, and some ways to simplify and automate monitoring, alarming and reporting on FDA regulated environments.

Click here to access the Veriteq Instruments, Inc. white paper. [1]

Links:
[1] http://www.mdtmag.com/sites/mdtmag.com/files/legacyfiles/MDT/White_Papers/Guide_for_US_FDA-Regulated_Organizations.pdf