



Supporting Quality Health Care Services at Home

Via FedEx

December 2, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket No. 2004D-0443: Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, Availability**

Dear Sir or Madam:

The American Association for Homecare (AAHomecare) would like to make the following comments on the "*Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations*", Docket No. 2004D-0443. The Notice of Availability for comment on the referenced draft guidance appeared in the Federal Register on October 4, 2004 at page 59256. It appears that AAHomecare's October 8, 2004, request to have the agency extend this docket's comment period for ninety days has not been granted.

AAHomecare represents approximately 3,000 health care providers, manufacturers and suppliers who furnish home health services, rehab and assistive technologies, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to millions of Medicare and other government and private payors' beneficiaries. A significant percentage of our members provide medical gases, primarily oxygen (classified as a pharmaceutical subject to 21 CFR Parts 210 and 211 and impacted by the provision of this draft guidance), to respiratory care patients at their residences. AAHomecare will limit its comments to those issues affecting the manufacture and/or distribution of medical gases provided to patients at their residences.

We understand and appreciate the goal and scope of the guidance as stated in sections B and C of the draft guidance, and we totally agree with the overarching philosophy articulated in both the CGMP regulations and quality systems, that quality must be built into the product. However, contrary to lines 538 and 539 of the draft guidance that state that the "...language...has been tailored to the pharmaceutical manufacturing environment," it has not been tailored in our

2004D-0443

C 12

opinion, to account for the uniqueness of many aspects of the medical gas segment of pharmaceutical manufacturing. Throughout the guidance the terms “robust” and “modern” are associated with the words “quality system,” and in line 353 it states, “Implementing a robust quality system can help ensure compliance with regulations.” One could infer, although is not explicitly stated in the guidance, that failure to employ the recommendations put forth in this guidance may hinder ones ability to comply with regulations and that the organization failing to implement them is archaic in its thinking. We recommend that the words “robust” and “modern” be dropped as adjectives for the words “quality system.” If an adjective were deemed necessary, the word “current” would be acceptable.

Although granting the extension of the comment period that AAHomecare had requested in its October 8, letter would have permitted us an opportunity for a more thorough review of the guidance, we offer the following comments related to two areas of the draft guidance, (1) The Quality Unit, and (2) Audits.

1. Quality Unit; Pages 5 and 6 Lines 200 through 238

In our response to the Docket No. 03D–0165: “Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases” we provided several comments regarding the structure of the Quality Unit which we believe are equally appropriate for the agency’s consideration in this guidance.

The Medical Gases draft guidance recommended “...that the Quality Control Unit perform more than a testing function, be independent of the production process, and have both quality assurance and quality control responsibilities.” We proposed that the Medical Gas guidance be modified to, “A firm may comply with CGMPs by having the Quality Control Unit’s function be independent of the production process being reviewed.” Our proposed change was based on the medical gas industry’s long standing practice of utilizing qualified manufacturing personnel to perform testing of in-process and final product to ensure established specifications have been met (the quality control function), and utilizing the “QCU” for among other things record review and approval (the quality assurance function), including review and approval of test results. This practice has historically been accepted provided there are appropriate controls and safeguards to prevent conflict of interest situations (i.e. individuals are not permitted to review their own work.) We propose that lines 204 through 212 of the draft QS Guidance be modified to reflect a similar option.

Lines 234 through 238 of the draft QS Guidance appear to key on the “independence” of the Quality Unit. These lines also discuss the Quality Unit in “small operations”. The Medical Gases draft guidance indicates, “In a well-structured and well-defined corporate structure, the QCU would be included as a separate unit”, and further states, “A small medical gas manufacturer can designate a single individual as the QCU.” Historically, independence of the QCU in the medical gases arena has meant that the individual performing the QCU (QA) function at the time of its performance is independent of the manufacturing and quality

December 2, 2004

Page 3

control process he or she is reviewing. Regarding the size of the QCU, we proposed that the Medical Gases draft Guidance state, "The size and complexity of a Quality Control Unit varies greatly with the size of the operation and tasks assigned. (Medical gas) manufacturers may operate one or more locations where a single qualified individual may be appropriately designated as the QCU at each location. Other locations may require more than one qualified QCU individual." We believe that the size of the manufacturer should not dictate the setup of the QCU. We believe the QCU must be adequately staffed with personnel qualified to perform its operations, and while performing these operations, independence must be maintained. We propose that lines 234 through 238 of the draft QS Guidance be similarly modified.

2. Conduct Internal Audit; Page 21 Lines 801 through 819 and the table on page 23

Although we acknowledge the significant benefits of internal audits for larger organizations, including our members with multiple locations, many of our members are small businesses with the owners of the businesses intimately involved in their day-to-day operations. The table on page 23 of the draft guidance infers that there is a regulatory requirement for conducting internal audits as part of the annual review specified in § 211.180(e). We find no specific requirement in the Pharmaceutical CGMP regulation and therefore we recommend the agency remove "Annual Review: § 211.180(e)" from the second row in the Regulatory Citation column in the table on page 23.

We also disagree with a commenter who has suggested the agency include the concept of third party audit and certification under "Evaluation Activities" in this guidance.

We appreciate the Agency's consideration of our comments. If you have any questions, please do not hesitate to contact Penelope Solis, Director of Government Affairs, AAHomecare, via email at penelopes@aahomecare.org or via phone at (703) 535-1893.

Sincerely,



Kay Cox
President and CEO
American Association for Homecare