criticalpoint

March 17, 2016

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IOWA BOARD OF PHARMACY

Andrew R. Funk
Executive Director
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, IA 50309-4688

Dear Andrew,

Peter and I are writing to you to address a letter we believe you recently received from Hank Rahe of Containment Technologies Group (CTG) containing false accusations against CriticalPoint LLC. We understand that Mr. Rahe sent this letter to board members and staff at every state board of pharmacy and to the National Association of Boards of Pharmacy. Because you, your staff and inspectors have been using CriticalPoint training, we wanted you to hear the truth from us directly.

Mr. Rahe's letter to you and the other state boards of pharmacy is part of an ongoing campaign to claim – incorrectly, we believe – that CTG's MIC family of isolators comply with all requirements of USP Chapter <797>-Pharmaceutical Compounding-Sterile Preparations, and further, to silence anyone who disagrees.

The claims in Mr. Rahe's letter are demonstrably false and are disparaging to CriticalPoint and to us. The core of CTG's complaints are the following statements in CriticalPoint's training materials: "In a Static Pass-Through, there is no HEPA filtration so this type of pass-through must be used within a cleanroom" and "CAI/CACIs with static airlocks are required to be placed into an ISO 7 cleanroom." These statements are completely accurate interpretations of the requirements of USP <797>, including specifically the provisions on Placement of Primary Engineering Controls. That provision requires that:

> "CAIs and CACIs shall be placed in an ISO Class 7 buffer area *unless* they meet all of the following conditions:
>
> - The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components and devices into and out of the isolator and during preparation of CSPs
> - Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations
> - Not more than 3520 particle per m^2 shall be counted during material transfer, with the particle counter probe as near to the transfer door as possible without obstructing the transfer[1]."

Simply put, CAIs and CACIs which deploy a static pass-through, have no means to provide isolation from the room during material transfer. There is nothing in the training slides, or in any of the CriticalPoint training, that is incorrect or needs correction.

One reference for this requirement comes from the following passage regarding static transfer devices (pass-throughs) from a book written by Brian Midcalf, et al. (Pharmaceutical Isolators, A guide to application, design, and control, Pharmaceutical Press, 2004). It states: "The main application is where the transfer in or out of potentially contaminated air during transfers of material in or out is either non-critical or can be dealt with by other means." Since sterile compounding is a critical activity, static pass-through systems are not appropriate for sterile compounding applications.

[1] US Pharmacopeial Convention, Inc. United States Pharmacopeia 38. Chapter <797> "Pharmaceutical Compounding–Sterile Preparations." Rockville, MD: US Pharmacopeial Convention, Inc.; 2016

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While CriticalPoint training does not directly mention any specific brand or line of isolators, and does not, as Mr. Rahe claims, make any statement about "the application of USP <797> to CTG's MIC isolators in particular," based on our testing, and in light of the requirements of USP <797>, we do not recommend MIC isolators to clients who seek our recommendation.

Please know that neither Clinical IQ nor CriticalPoint sell or receive commission on the sale or installation of any equipment. We are not competitors with CTG or any equipment manufacturer. Clinical IQ, our consulting associates and affiliates along with CriticalPoint, LLC have been offering consulting, educational and training services that meet or exceed the requirements of the chapter. One of the key tenets that we have been teaching involves the use of robust testing standards to ensure that the critical engineering environments can meet the requirements of USP <797>. Our teachings focus on the performance standards described in the chapter. We have tested many of the available isolators, including equipment manufactured by CTG, for performance against the standards, and the results of that testing informs our opinion. That CTG views our training as a threat to its business should highlight for the Board a serious concern about the ability of its MIC family of isolators to conform to the requirements of the chapter when operated outside an ISO 7 cleanroom.

This is not the first instance of CTG attempting to silence others. In 2007, The American Journal of Health-System Pharmacists (AJHP) published an article titled: Potential for airborne contamination in turbulent- and unidirectional-airflow compounding aseptic isolators[2]. It was a peer-reviewed article and when it was published, the Journal and ASHP incurred the ire of CTG. The paper demonstrated that the isolator from this manufacturer did not pass critical testing procedures, similar to those described in the CETA Isolator Testing Application Guide. One of the two major points of failure involved the lack of unidirectional airflow. CTG sued ASHP, its journal, the authors and the peer reviewers, seeking damages and a retraction. Instead, the court dismissed the charges and ordered CTG to pay damages for bringing a frivolous lawsuit.

Clinical IQ, LLC and CriticalPoint, LLC have been working diligently since 1999 and 2006 respectively to provide the highest level of consulting, training and educational services for the compounding industry. We respect our very important relationship with you, your staff and your colleagues NABP, and we thank you for taking time to read this response.

Very truly yours,

Eric S. Kastango MBA, RPh, FASHP
Principal and Chief Executive Officer
Clinical IQ, LLC & CriticalPoint, LLC

Peter A. Cantor
Managing Partner, Chief Operating Officer
CriticalPoint, LLC

[2] Peters GF, McKeon MR, And Weiss WT. Potential for airborne contamination in turbulent- and unidirectional-airflow compounding aseptic isolators. Am J Health Syst Pharm, March 15, 2007 64:622-631. Abstract available at http://www.ajhp.org/content/64/6/622.abstract