

QA/QC Requirements: Ensuring Staff Compliance

A Q&A with Patricia C. Kienle, RPh
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Q. Now that JCAHO's July 2005 deadline for establishing a QA plan has passed and the January 2006 deadline for finalizing and assuring the monitoring of a QA plan is rapidly approaching, what steps should pharmacy be taking?

A. What people need to do is take a look at their processes in the sterile preparation area and develop a QA plan around all of those pieces, including the equipment, air quality, and microbiological monitoring. Personnel competence also needs to be addressed through initial orientation, written documentation of their activities, observation of their aseptic technique, and their ability to pass a media-fill test as described in <797>. Those are the big pieces. The requirements of each hospital's infection-control committee also need to be incorporated into the plan.

Q. What is the most challenging QA requirement to meet from a staff-acceptance perspective?

A. I think the most challenging issue is the garb requirements. People have been very slow to adopt the requirements of <797>; they think, "We've always done it this way, so why do we have to change?" However, appropriate garb is described in <797>, and it is the standard of practice. It just has to happen. To overcome this reluctance on the part of the staff, the pharmacy manager has to insist that appropriate garb is a job requirement. Compare your IV room's garbing requirements to those in the other sterile areas of the hospital, like the OR and central supply.

Q. What other strategies can you use to ensure staff compliance with QA policies?

A. The hospital's infection-control nurse is probably one of your best resources, because he or she oversees those situations in other areas of the facility and sees the broader human-resources picture. The infection-control nurse can act as a buffer; if people don't immediately respond to the director of pharmacy, bring in another person who can support the appropriate practices.

Q. How do you ensure that your staff is continually adhering to the QA policies you have established?

A. That's a big piece. I have talked to pharmacy directors who admit that their facilities' procedures are not followed on a regular basis. That is obviously not appropriate. It is our job as managers to make sure our folks fulfill their requirements. People need to understand the reasons behind the policies. If your staff in the trenches understands the issues behind proper garbing and the reasons makeup can't be worn in the cleanroom, they will have a greater appreciation for those policies and procedures. They'll know it's not just because their director said so.

For more information on cleanroom garb, circle #60 on the reader service card.

Q. Even though the CDC is very clear in its policy on cosmetics in sterile environments, is everyone aware that cosmetics aren't appropriate in the cleanroom?

A. <797> says that makeup must be removed, so it's pretty evident, but not well complied with. Pharmacy has flown under the radar regarding some of the CDC's requirements for sterile areas, including the requirements for nail care. For instance, artificial nails are not appropriate for sterile areas, as they are breeding grounds for bacteria, fungus, and other contaminants. Every nurse, every lab tech, and every central-supply employee in a hospital gets indoctrinated in this, but somehow pharmacy has been missed. So while the information may be new to pharmacy, it's certainly not new to the hospital. This is another area where the infection-control nurse can bring the pharmacy up to speed. Ask him or her about requirements for hand hygiene, nail length, artificial nails, and so on. **R&P**



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Appropriate cleanroom garb, as outlined in <797>, should be a standard of practice for the staff working in your facility's controlled environments.

An employee of Cardinal Health since 1999, Patricia Kienle assumed her current position in July 2004. The recipient of an MPA in health service administration from Marywood College in Scranton, Pennsylvania, and a BSc in pharmacy from Philadelphia College of Pharmacy and Science, Kienle has more than 30 years' hospital pharmacy experience.

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