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QuVa PHARMA

How 503B outsourcing can reduce hospital pharmacies' regulatory burden — 5 Qs with QuVa Pharma CEO Stuart Hinchen

Written by Maia Anderson

The FDA's requirements for compounding sterile drugs have become more stringent in recent years, especially since 2016, following the addition of section 503B to the 2013 Drug Quality and Security Act.

Stuart Hinchen Beckers QAStuart Hinchen and his business partner Peter Jenkins founded QuVa Pharma in August 2015 after noticing hospital and health system pharmacies were having issues meeting the new regulatory requirements.

"It was clear that the FDA was speaking a different language, and the incumbent players just didn't have the people or the tools to deal with them," Mr. Hinchen told Becker's Hospital Review.

QuVa's mission is to take the burden off of hospital and health system pharmacies by providing sterile, compounded drugs to pharmacies quickly and cost effectively. Doing so allows pharmacies to spend their time and resources on improving patient care rather than on adhering to strict FDA regulations to compound their own sterile drugs.

Mr. Hinchen recently spoke with Becker's Hospital Review about QuVa's mission and how outsourcing drug compounding can help hospital and health system pharmacies reach their goals.

Stuart Hinchen
CEO, QuVa Pharma

Editor's Note: Responses have been lightly edited for length and clarity.

Question: What new regulatory and compliance standards should hospital pharmacy leaders keep a keen eye on?

Stuart Hinchen: There will be a real awakening within health system leadership, both on the pharmacy side and the C-suite side, regarding increased FDA influence on their hospital operations forcing an increase in standards of sterile compounding operations. By working in conjunction with USP on revising section 795, 797, and 800, and with State Boards of

Pharmacy on audit compliance standards and the draft MOU over reporting adverse events in the 503A settings, the FDA is surrounding the entire sterile compounding setting. Hospital pharmacy leaders should not be in denial that the FDA is a big influencer and should look for the common threads in emerging draft guidelines as a clear direction of where future standards and regulations are heading.

Q: What advice would you offer hospital and health system pharmacies searching for a 503B outsourcing partner?

SH: Hospitals and health systems really need to understand what their own needs are now, and how those needs might evolve as their own business plan evolves. When they consider partnering with a 503B, they should do so with one that can address their current needs and their longer-term needs as well. It's important for them to understand how well a 503B is positioned for the longer term to meet the regulatory changes occurring within the 503B space. We actually have developed an evaluation checklist for hospitals and health systems that helps them assess potential 503Bs in relation to cGMP knowledge and their compliance status with respect to the FDA. I would recommend them to use our checklist as a guide, in conjunction with the American Society of Health-System Pharmacists' checklist, as ours has a more robust cGMP focus.

Q: What is the biggest misconception when it comes to outsourcing drug compounding?

SH: There's generally a ot of misconceptions as to how readily available products are to be ordered and shipped. The industry had been spoiled by expectations that were set prior to the New England Compounding Center disaster back in 2012, and for a few years thereafter, when it was very easy for a hospital, at any frequency of ordering and without notice, to place an order and get a compounded preparation made for them on the same day, and sent to them the next day. The new rules associated with cGMP adherence, and the necessity to do full finished product testing, make that spontaneity impossible in the 503B setting. Same day ordering may very well be possible for highly individualized named patient compounding. However, for commonly used products for general office use, there is more onus now on hospitals and health systems to work with their 503B provider in projecting their needs so products can be produced in anticipation of orders arriving.

Q: What steps can hospital and health system pharmacies take to ensure compliance with the new guidelines?

SH: One thing that hospitals and health systems should do is engage more with 503B providers than undertake it all themselves. Find a 503B provider in good standing with the regulatory authorities and look to see how the hospital can have that 503B provider as an extension of their own pharmacy. By shifting volume and hence production risk out of their pharmacy, it actually does raise the efficiency and quality of their pharmacy operations while reducing the complexity of having to do everything themselves.

Q: How can compound outsourcing help pharmacies reach their goals?

SH: I see it very much as a partnership. 503Bs don't need to necessarily solve all of the problems of today, but should be able to look ahead and see what the emerging issues and the risks for the coming few years are. We've got to work ahead of the risk profile of hospitals and health systems so we're ready to meet those needs when they come to fruition. I think the future benefit will come from us being a part of the partnership so hospitals and health systems can look toward us and figure out how to fit us into their overall initiatives when they're laying out their own strategic plans. We need to move from being a transactional partner to a strategic one.