April 24, 2025

CAPS 503B Remediation Update

We would like to provide you with an update on the transformation of the CAPS 503B business and the remediation efforts we have undertaken at our Lehigh Valley and Phoenix 503B sites. We appreciate your patience in learning more about our remediation efforts and the big changes being made at CAPS over the last two years. Despite our silence, we have been diligently working to transform the CAPS 503B business to ensure the standards that you and our regulators expect are met. Our CAPS 503B facilities are in full production and are ready to meet your needs.

Over the past two years, we have worked closely with the FDA, state regulators, our enhanced internal teams and third-party experts to address the issues raised in the FDA Warning Letters and inspection findings. CAPS acknowledges the seriousness of these findings and apologizes for the inconveniences that we may have caused you. CAPS has been committed to the transformation of its quality culture as demonstrated through the dedication of both human and capital-intensive resources. To date, CAPS has spent over $25 million in remediation activities at its Lehigh Valley and Phoenix outsourcing facility sites. CAPS is now operating within full cGMP compliance and remains fully committed to completing all of its remediation activities. We want to tell you more about this new CAPS.

New CAPS Leadership

CAPS has undertaken a complete transformation of its operational, site and quality leadership with a focus on cGMP pharmaceutical manufacturing expertise. As follows are more details on these changes.

Executive Leadership

Change starts at the top and to help guide CAPS through these challenges we have installed two seasoned cGMP leaders

- Jim West has been appointed the new President of the organization. Jim has more than 40 years of experience in the manufacturing sector, with deep expertise in FDA's cGMP regulations and drug manufacturing.
- Michael Galleno recently joined the company as Corporate Vice President & General Manager, CAPS. He brings significant experience driving transformation in end-to-end global business, supply chain and manufacturing operations within life sciences industries. In this role, he will be responsible for the operational leadership of the CAPS 503A and 503B businesses.

Site Leadership

We have continued to invest in local leadership at our two main 503B locations, Phoenix and Lehigh Valley, by bringing on seasoned leaders from the medical device and pharmaceutical industries.

Quality Leadership

CAPS has transformed our Quality leadership to a cGMP-experienced team with oversight independent from Operations, including the involvement of key Quality leadership from the B. Braun of America Inc. group of companies - Senior Vice President and Chief Scientific Officer and the pharmaceutical CGMP-experienced Quality Vice President. CAPS has also hired a new Quality Senior Director for CAPS 503B, as well as new Quality Directors for both the CAPS Phoenix and Lehigh Valley sites to provide additional on-site cGMP-experienced Quality leadership.

Comprehensive Quality and Operational Changes

CAPS has undertaken a comprehensive transformation of its quality system and has made significant operational changes to fully address all of the regulatory observations. Some of the key actions CAPS has taken to ensure compliance and our return to full manufacturing capacity include:

- For the last 2 years, CAPS has engaged dozens of third-party experts to provide training, remediation assistance, and CGMP and aseptic processing consulting services concerning all areas of site operations.
- CAPS developed a comprehensive Quality System Compliance Plan with the assistance of external consultants. CAPS's plan includes the integration of the CAPS Quality System into the well-established and 21CFR 210/211 compliant B. Braun Medical Inc. (BBMI) pharmaceutical Quality System pursuant to intercompany service agreements. As part of the integration, Nonconformances, CAPAs, Change Controls, Quality Events, audits and Supplier Qualification systems have been integrated into BBMIs Trackwise system (eQMS).
- CAPS has changed its sterility testing process to meet USP<71> compendial sample size requirements.
- CAPS engaged with recognized sterilization research and aseptic process experts to provide strategic advice on sterilization operations and improvements at each of the facilities.
- CAPS created and operationalized a Quality Governance Steering Committee and has made additional Quality program enhancements using broader internal and external expertise.
- We have established a remediation program with a focus on fully integrating our operations into the B. Braun Medical Inc. manufacturing and quality systems.

B. Braun and CAPS value your business greatly and sincerely regret the disruption to your business and the frustrations these findings may have caused you. CAPS is eager to regain your full trust in our 503B products to provide quality for life to your patients.

CAPS strives to continuously advance its quality assurance program to ensure that its life-sustaining and lifesaving compounded therapies are prepared to the highest standards of safety so that our providers can continue to treat millions of patients across the United States who depend on CAPS compounded sterile preparations. Reach out to your local sales rep to schedule an appointment, visit our website and check us out at ASHP Pharmacy Futures in June.