



## *Hope Mueller*

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### **Quality oversight of CMO's microbiology investigation**

**Statement of the Problem:** CMO partnerships can be challenging both for the CMO and the product owner, especially when a significant OOS or other microbiology investigation arises. We will be discussing the CMO relationship and best practices that will ensure consistent, reliable, and quality supply throughout a difficult investigation. There are optimal organizational designs for CMO's and product owners that increase the likelihood of a successful partnership and outcome of the investigation. Clearly defined roles, responsibilities, and accountabilities are required. How to take increased action in the event the CMO's performance is suboptimal or represents a compliance risk? Establish short term and long-term corrective actions to ensure regulatory compliance throughout and in response to a critical event. Real world and first-hand examples to be discussed OOS events in products on stability, facility impacting sterility failure, aseptic processing validation failures, and critical system events experienced at the CMO. The discussion will instruct the participants how to effectively partner with CMO to ensure safe and quality product is provided to patients.

### **Biography**

Hope Mueller has over 18 years in Contract Manufacturing or Contract Manufacturing Oversight. She has designed organizations as a Contract Manufacturer and as a Product Owner. She has experience in the pharmaceutical microbiology laboratory and most of her career was within and managing analytical laboratories. She has lead large teams ensuring consistent and reliable supply of quality product. She has managed relationships with virtual and big pharma clients, and overseen multiple vendors. Hopes expertise lies in quality, operations, and continuous improvement. She has hosted, participated and executed hundreds regulatory and client audits. She has expertise in aseptic filling, BFS, oral configurations, topicals, inhalants, and biologics. She has proven success in launching efficient systems and improving operational performance at all levels. She is an exceptional leader proving her skills through the construction, training and mentorship of highly productive teams.

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### **Notes:**