Biopharmaceutical Method Transfer as Part of the Quality System

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Approaches to non-compendial biopharmaceutical analytical method transfer often focus on a point-in-time comparison between a Sending Unit (SU) and Receiving Unit (RU) without fully integrating the method transfer process into the larger Quality System (QS). Many components of the QS that should be comprehended for a transfer include risk management, analytical lifecycle management, documentation, and contractor management. Confidence in a test method initially comes from method validation but ongoing confidence in the method depends on other components of the QS including managing the analytical method lifecycle process. The purpose of a method transfer is to provide assurance that the validated method post-transfer provides results consistent with the existing product control strategy needs by leveraging method transfer as part of a larger QS. A simpler way of stating this is that a method transfer should have no, or negligible, adverse impact on drug safety or efficacy risk.

This talk will focus on using a risk-based approach for method transfers and integration of method transfers into the analytical lifecycle management process. Utilization of a risk-based approach requires evaluation of current method performance relative to the specifications/targets established or the method rather than reliance on a standard equivalency testing approach. In addition to the point-in-time transfer ongoing method monitoring of results at the RU is critical to maintain method performance.