CASE STUDY

MITIGATE POTENTIAL DELAYS THROUGH FILLING REGULATORY REQUIREMENT GAPS

THE CHALLENGE

A biopharmaceutical company focused on protein therapeutics in Phase 3 mis-interpreted Phase 3 FDA requirements for extractables and leachables testing. The company was at risk for delaying a crucial regulatory submission.

Misinterpretation of testing is a common challenge in the industry as there is no prescription to executing an extractables and leachables evaluation. While working groups like Product Quality Research Institute (PQRI) and guidance chapters from United States Pharmacopeia (USP) provide direction, drug developers must understand these sources of guidance and apply them appropriately to their drug product.

THE CONSIDERATIONS

The customer was very concerned about potential delays to the planned regulatory submission and contacted West for guidance on potential solutions to mitigate delays.

THE SOLUTION

The customer purchased West's VeriSure® technical package for extractables which includes data acquired using multiple solvents, extraction conditions and analytical techniques. The package is a semi-qualitative compilation of results excerpted from years of data and studies for these formulations. The customer was able to use that data in their electronic filing to the FDA, with a commitment to the agency that the leachables data would follow. The VeriSure® package filled the customer's regulatory gap and prevented a delay of a critical submission.