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CMO's challenges and strategies in sterile manufacturing

Jixing Wang
Dalton Pharma Services, Canada

CMOs are facing several major challenges in today's competitive pharmaceutical marketplace. While meeting the increasing demands in GMP and regulatory compliance, CMOs are expected to provide cost effective and responsive, timely services to support various stages of drug development and manufacture. In the case of sterile products, the validation of aseptic processing for investigational medicinal products are very similar to the standards for products theorized for marketing. Compared to commercial products, clinical drugs are usually produced in small quantities with infrequent demands. Several technical and business strategies are developed and implemented to decrease the up-front costs for aseptic process validation and to reduce the manufacturing cycle time. In this presentation, the unique strategies and approaches will be presented and discussed.

Biography

Jixing Wang is the Director of GMP Operations at Dalton Pharma Services, a Toronto based CMO specializing in drug discovery, development and manufacturing. Wang has 17 years of experience in the pharmaceutical industry. He has directed R&D and Quality Control operations, as well as led the development, scale-up and commercialization of new Drug Products. Since joining Dalton in 2013, Wang continues to lead and solve complex technical, operational and regulatory challenges facing CMOs today. Wang completed his PhD in Chemistry at Nottingham University, England. He also holds a MBA degree.

JWang@dalton.com