CASE STUDY

Start-up Injectable (Aseptic) Pharmaceutical Facility

Background

A mid-sized medical device company launched a start-up pharmaceutical division and needed to transfer five injectable products from a Fortune 500 corporation to a new manufacturing facility.

Objective

The primary objective was to obtain MHRA Approval to begin distribution in the UK. Responsibilities included equipment requisitioning, facility qualifications, equipment qualification, and aseptic fill-line development.

Enhanced Compliance Engagement

Numerous consultants supported the launch effort with the following tasks and documentation activities.

- Ensured that all products and processes were adequately characterized and optimally controlled, resulting in a high degree of confidence that product consistently met specified corporate and FDA Quality standards.
- Performed process development, process improvement, and production investigation activities.
- Performed compounding and filling process improvements to meet product specifications and increase product efficiency.
- Worked with QA, manufacturing, and other departments to investigate discrepancies and deviations, identify root cause, and implement corrective and preventive actions (CAPA).

Result

Validation of new facility resulted in MHRA Approval to manufacture and distribute the injectable pharmaceutical in the UK.