

PROJECT CASE STUDY: QUALITY CONSULTANT (GXP)

Client: A publicly-traded, clinical-stage biotechnology company focused on the development and potential commercialization of medicines to treat rare diseases. This organization has several clinical and nonclinical programs in their pipeline.

OBJECTIVES:

- Develop overall Quality strategies and plans for the Quality Management System
- Serve as the Quality (GxP) expert to executive leadership and authorities
- Overseeing all Quality activities to ensure they produce the desired results and are consistent with the overall strategy and mission
- Assure all quality systems are in place to support upcoming regulatory filings and meet strategic milestones to help move this late phase company from clinical to commercial

SUCCESS FACTORS:

By partnering with our client's leadership team, Prestige Scientific was able to quickly identify candidates with significant GxP Quality expertise. Prestige presented candidates with past successes and experience designing overall Quality strategies and laying the groundwork for Quality Management Systems, who have the skills to meet the company's short and long-term objectives. This critical hire will help this organization by representing the Quality function to Regulatory Authorities and reach their next strategic milestone.