

Principal Scientist, Pharmaceutical Sciences

Req# 2025-000015

Company: MedPharm Manufacturing Services, LLC

Location: 4018 Stirrup Creek Dr, Durham, NC, 27703

Position Title: Principal Scientist, Pharmaceutical Sciences

Hours: Monday – Friday, 8:00 am to 5:00 pm

Summary of Duties: Develop and execute topical drug development strategies leading to regulatory submission. Act as chemistry, manufacturing, and controls (CMC) lead to project teams. Mentor scientists in semi-solid product development. Support Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) manufacturing, including provision of process instructions, batch record review, and hands-on resource. Point of contact for external contract research organizations as related to Form Dev activities. Responsible for the review and approval of formulation related study protocols, study reports, specifications for raw materials, and finished drug product. Ensure lab compliance and safety practices. Project tracking and updates as requested of assigned projects. Maintain data packs for assigned projects. Peer review of laboratory notebooks and batch records.

Qualifications: Position requires a Bachelor's degree in Pharmaceutical Sciences, Chemistry, Biology or related field of study plus seven (7) years of experience in the job offered or seven (7) years of experience as a Research Associate, Research Officer, Manufacturing Supervisor, or related occupation. Alternatively, the employer will accept a Master's degree in Pharmaceutical Sciences, Chemistry, Biology, or related field of study and five (5) years of experience in the job offered, Research Associate, Research Officer, Manufacturing Supervisor, or related occupation; or a PhD degree in Pharmaceutical Sciences, Chemistry, Biology, or related field of study and two (2) years of experience in the job offered, Research Associate, Research Officer, Manufacturing Supervisor, or related occupation.

Requires experience as a subject matter expert for CMC-related activities, including formulation development, process development, and container/closure. Requires skills in drug delivery optimization, using Design of Experiment (DOE) where applicable. Requires experience in semi-solid dosage form development for topical drug delivery. Requires experience with dermatology therapeutic area. Requires experience with Chemistry, Manufacturing and Controls (CMC) and regulatory filing requirements. Requires experience with regulatory requirements for New Drug Applications (NDAs) in U.S., Europe and Asia. Requires experience with eCTD format for regulatory filings. Requires familiarity with International Council for Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH) requirements.