



Senior Quality Manager

Job requirements:

- BS/BA degree or equivalent experience in a CMC QA decision-making capacity with 10+ years in a FDA regulated industry, preferably in drugs or biologics.
- Must possess a good working knowledge & hands on application of GMPs & a basic working understanding of GCPs & GLPs.
- Knowledge of quality systems & regulatory compliance requirements within a commercial drug manufacturing operation is necessary as is experience with domestic & /or international drug development & approval process.
- Must have up to date knowledge of domestic & international regulatory compliance requirements & experience with active pharmaceutical ingredient & drug product formulation & manufacturing.

Job description:

The Senior QA Manager, CMC will be responsible for reviewing, preparing, & overseeing all aspects of CMC quality compliance, & will also be responsible with the overall implementation of quality systems, processes & procedures within Chemical Development, Pharmaceutical Development, Preclinical Development & Commercial Operations functional areas. The Senior QA Manager, CMC will also be responsible for performing batch record review, coordinating all internal & external GMP & GLP audit programs, providing disposition of & implementing corrective action to out of compliance situations, writing detailed audit plans & reports, performing training based upon regulations, & working closely with QA Management to ensure that the company meets & maintains its regulatory compliance obligations & also its strategic goal & objectives. Travel required.

Please submit a cover letter and your resume along with salary requirements to:

CBR International Corp.

Director of Operations
2905 Wilderness Place, Suite 202
Boulder, CO 80301

Or email an electronic copy (MS Word format) to info@cbrintl.com

Or Fax to: Human Resources (720) 746-1192