Quality Services Associate

Note: The use of the masculine gender includes the feminine and is employed solely to facilitate reading.

Can you imagine a career that touches the lives of people everywhere? Can you imagine yourself working in a fast paced and dynamic workplace where rapid decision making, entrepreneurial initiatives, customer service and community become your new vision? A vision that drives our growth and success…if so, then Paladin is the place for you!

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. Paladin has a focused marketing and sales organization that has helped it evolve into one of Canada's leading specialty pharmaceutical companies. Paladin Labs is an operating company of Endo International plc, a highly focused generics and specialty branded pharmaceutical company.

We are a dynamic and fast growing organization. Paladin is constantly looking for great people to contribute to our growing business. We believe in empowering our employees by giving them the freedom to raise new ideas and encourage decision making in an environment that fosters the growth and development of each individual. Paladin's culture is committed to building our business as well as our community, helping others, encouraging integrity and inspiring people to make a difference.

Position Summary

The Quality Services Associate is Member of the Quality group providing support for various aspects of GMP documentation, release, and support of the quality systems. The Quality Services Associate, initiates, coordinates and assesses change control. He assists with internal and external quality operations and systems, such as audits, complaints, training, release, change control, deviations, and general compliance as applicable, and helps assure compliance with current GMPs and regulatory agencies.

Reports To

Manager, Quality Services

The successful candidate will be responsible for:

- Initiate, review and assess change control.
- Prepares and/or reviews controlled documents (e.g. SOP's) required for compliance.
- Completes assigned duties and responsibilities (filing, etc.).
- Assists with documentation related to change request and deviation management.
- Documentation management in Master Control.
- Manage all quality aspects related to change control process.
- Assist with various aspects of validation activities, such as review and assess validation protocol and report related to analytical method and manufacturing process.

- Initiates communication of due dates for Quality Systems (CRs, CAPA, Complaints, etc.) to ensure they are completed on time.
- Assists with various aspects of development, management, harmonization and improvement of quality systems and procedures to ensure compliance with all applicable laws, regulations and company quality standards in support of cGxP activities.
- Contributes to various aspects of quality systems, such as Change Control, Deviations, Investigations, and APQR systems to assure compliance and timely and accurate completion of reported events.
- Monitor the performance of the change control process and provide Metrics to management as required.
- Initiates self-audit checks and evaluates CAPA effectiveness checks.
- Prepares materials for inspection readiness and management review.

Knowledge/Skills & Abilities

- Strong verbal and communication skills required.
- Attention to detail required.
- Demonstrated excellent interpersonal skills and flexibility.
- Ability to handle multiple priorities in a fast paced environment.
- Good writing skills.
- Strong organizational skills.
- Ability to build peer relationships.

Candidate Profile

Experience, Training and Education

Required

- Bachelor's degree in Science with 3+ years' experience in pharmaceutical / biopharmaceutical industry.
- Working knowledge of all current state, federal and local standards and regulations, e.g., cGMP, ISO 13484.
- Technical and quality background related to pharmaceuticals.
- General understanding and knowledge of cGMP regulations
- Proficient in Word advanced Excel functions and Access.
- Excellent interpersonal and communication skills.

Asset

- Master's degree in sciences with 1+ years' experience in pharmaceutical / biopharmaceutical industry.
- Experience with validation and tech transfer is an asset

** To apply, please send your resume: hr@paladinlabs.com*
Only selected candidates will be contacted.