

Project Manager, Quality Services, Montreal, QC

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 is an operating company of Endo International plc, a global specialty healthcare company focused on improving the lives of patients while creating value.

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 Project Manager Quality Services is responsible for providing oversight and support to Tech Transfer validation initiatives. This role is involved in the validation, tech transfer and stability activities for all products at Paladin. This role acts as lead Quality support on project(s) assigned by managers to support the evaluation, introduction and change to any product requiring validation and technical transfer for Paladin products. The Project Manager will be involved in the Change Control System at the Endo Malvern location and will manage internal changes required to support Paladin Quality Systems. This role will work with cross-functional departments to resolve complex quality issues relating to documentation and change management.

Reports To

Manager, Quality Services

The successful candidate will also be responsible for:

- Supports validation and tech transfer activities from a quality perspective.
- Establishes best practices for tech transfer/validation activities.
- Provides QA oversight and participates in the development of validation documentation and execution as needed.
- Manages Change Controls related to validation and tech transfer activities
- Coordination for Change control and assessment.
- Monitors Paladin Change Controls and supports changes related to validation and tech transfer activities.
- Generates and reports performance metrics for the Change Control process and all changes being implemented for branded products.
- Monitors the performance of the Change Control process and provide metrics to management as required.



- Collaborates with cross-functional departments to resolve complex quality issues relating to documentation and change management.
- Resolves questions and issues related to tech transfers and validation activities.
- Participates on and provides QA guidance to integration/migration teams and validation efforts as assigned by management.
- Escalates issues to management.
- Responsible for supporting Annual Product Review System.
- Perform internal and external audit functions and other tasks related to the quality systems.

Knowledge/Skills & Abilities

- Demonstrates a thorough understanding of fundamental GXP terminology, concepts, regulations and industry standards.
- Technical knowledge related to tech transfers and validation.
- Knowledge of records and data management systems/processes and tools.
- Demonstrates a thorough understanding of change control process and associated regulatory requirements and their application.
- Knowledge of Good Documentation Practices required.
- Strong attention to detail.
- Demonstrates excellent interpersonal skills.
- Ability to establish and maintain effective working relationships with customers; gain trust /respect and ensure service levels are maintained; and ensure cGMP compliance and adherence to established procedures.
- Ability to effectively communicate using a variety of styles to ensure that service levels are maintained.
- Plans, prioritizes, and negotiates concurrent assignments and completes within agreed upon timeframe.
- Ability to identify and troubleshoot routine technical problems.
- Works independently or within a cross functional project team as required.

Candidate Profile

Experience, Training and Education

Required

- BA/BS or equivalent relevant experience.
- Minimum of 4 years' experience working in a Quality role in a GXP environment in the pharmaceutical or medical device industry.
- At least 2 years of experience in validation or production. Fluently bilingual (written & oral).
- Proficient in Word advanced Excel functions and Access.
- Excellent interpersonal and communication skills.
- Strong technical writing skills in addition to strong command of general grammar and usage principles.

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