Applied Therapeutics is seeking a Manager, MLR to oversee and lead management of the medical and promotional materials review process of for Applied Therapeutics on a contract basis. This individual will serve as the primary contact in the management of all aspects of the advertising, promotional and medical review process and work closely with the Commercial, Regulatory, Legal, Compliance, Medical and Marketing Operations teams. Responsibilities include creating and managing agendas, end-to end process for review and approval of materials and managing forecast and submission of materials for review. Reporting to the Medical Director, the Manager, MLR Review will be a critical member of the Medical Legal Regulatory Review Committee (MLR) and partner to the review and approval process for medical and commercial materials.

This role is remote and may require travel to the Applied Therapeutics office on occasion.

Manager MLR

Job Responsibilities and Duties include, but are not limited to, the following:

- Collaborate cross-functionally with Regulatory, Medical, Legal, Marketing, Commercial, and external Agencies as appropriate
- Lead the coordination of the MLR review committee activities and ensure that the medical and promotional review process is conducted in a compliant, timely and efficient manner
- Lead and manage the end-to-end review, approval and expiration lifecycle of medical and promotional materials in VEEVA PromoMats
- Facilitate, lead and manage MLR meetings, including leading the review of materials, planning agendas and content, ensuring meeting documents are routed to MLR review team prior to meetings, and performing operational tasks such as annotating and accurately capturing comments during live reviews, and performing the final proofing of materials before proceeding to an approved status
- Review and ensure that all material submissions are complete and meet specified quality standards prior to circulation to reviewers
- Create and manage the weekly meeting planning and prioritization and the MLR forecast tracker and provide guidance on submission timelines to meet deadlines and launch initiatives
- Responsible for tracking medical and promotional materials from inception through approval and provide actionable solutions where there are workflow issues, maintain appropriate systems and documentation files, and coordinate any associated regulatory submissions within timelines
- Monitor document lifecycle, including reapprovals and expiry of materials in accordance with MLR SOP

Requirements/Qualifications

- BS or BA degree

- A minimum of 3-5 years of experience in the biopharmaceutical industry with at least 2 years' experience with Promotional Review Committee/Medical Legal Review
- Experience with Veeva Vault PromoMats
- Ability to work remotely 20-40 hours per week as needed on a contract basis.

Language(s):

- Fluent in English

Please apply via LinkedIn or by emailing your resume to careers@appliedtherapeutics.com. Please note the position you are applying for in the subject line.