Job Posting – CPTR Regulatory Consultant

Critical Path Institute

Critical Path Institute (C-Path), Tucson AZ, is a leading organization working at the forefront of numerous innovative advances to improve drug development and regulatory processes to facilitate getting new products to patients quicker and at more affordable price points. Although we do not develop drug products, C-Path's consensus driven science, using a pre-competitive consortia model, improves medical product development by identifying pathways that integrate new scientific advances into the regulatory review process. As a trusted, independent third party, C-Path works closely with the FDA, EMA and other regulatory agencies to ensure relevant regulatory input is incorporated into the new science being developed. When formal regulatory decisions are desired (e.g., qualification of a biomarker, fit-for-purpose determinations), C-Path gathers the necessary evidence. This involves the development of standards for data, measurement and methods, the aggregation of large volumes of data, doing the statistical analysis, and the preparation of regulatory documentation of the evidence. The results of C-Path's efforts are regulatory-endorsed tools and processes that improve efficiencies and reduce the time and effort needed to bring safe, effective medical products to market.

The CPTR program

C-Path has consortia that work on specific disease areas of high unmet medical need with the goal of improving the failure rate of testing new drug therapies. The Critical Path to TB Drug Regimens (CPTR) initiative is one of the largest public-private partnerships within C-Path with funding from the Bill & Melinda Gates Foundation. The CPTR initiative is dedicated in delivering a safer, more efficacious, and faster-acting tuberculosis (TB) drug regimen(s) by developing and promoting innovative regulatory pathways, pharmacological tools, and rapid drug-susceptibility tests which are essential for supporting and deploying new drug combinations. In collaboration with our partners including the World Health Organization, the Foundation for Innovative New Diagnostics, StopTB Partnership, industry, academia, regulators, nonprofit organizations and patient advocacy groups, CPTR works in the non-competitive space to maximize data sharing initiatives that will ultimately benefit patients.

Position Description

C-Path is seeking an experienced regulatory professional to work on a consulting basis, preferably with infectious disease experience, to assume the following responsibilities in a consortium environment. The primary responsibilities of this role are:

1. Provide regulatory strategy and support to the CPTR working groups as follows:

    - Drive project team's thinking beyond the scientific research to identify desired regulatory outcomes, see regulator perspective, and develop objectives and action plans for regulatory pathways the team will pursue.
    - Advise on regulatory timing and procedural steps for projects.
    - Help resolve regulatory problems and identify responses and corrective action if needed.

- Provide direction on and interpretation of regulatory guidance/policy requirements, regulatory intelligence; representing the regulators perspective on project goals and objectives as well as scientific data generated

- Communicate regulatory engagement and experience with regulatory agencies across the CPTR working groups to promote learning and strategic approaches to issue avoidance and/or resolution within CPTR's many working groups

2. Effective regulatory communication
    - Lead/contribute to on-going communications with regulatory agencies involved on the project
    - Develop/contribute to regulatory focused sections of a briefing package (e.g. Questions to Regulators, Regulatory History of the project, Executive Summary and Conclusions).
    - Coordination and preparation of responses to regulatory inquires or request for information from regulatory agencies.
    - Overall regulatory review and editing of all documents for submission to regulatory agencies to improve overall organization, flow, and consistent messaging.
    - Preparation, editing and review of slide sets used for regulatory meetings for clarity and consistency of messaging to regulators.
    - Help prepare teams for meeting with regulatory agencies (e.g. develop clear agendas, manage meeting preparation sessions for meeting attendees, provide regulator's perspective on potential reactions/questions on the project).

The following are characteristics of the candidate:

- Positive, achievement- and goal-driven experienced regulatory professional (consultant) with an advanced degree in life sciences, chemistry or biology
- Experience, ideally recent, in providing regulatory support in the anti-infective therapeutic area and previous interactions with anti-infective divisions of FDA and EMA
- Previous experience providing regulatory leadership in a consortium environment, composed of academic, pharmaceutical, governmental and advocacy members
- Interacts well in a matrix organization, with ability to positively influence and direct internal and external stakeholders
- Effective multi-tasking across several working group projects
- Effective and influential communicator, with ability to appreciate and understand cross-cultural communications and differences
- Ability to travel domestically and internationally for meetings with regulatory agencies and to consortium meetings
- Can commit to an average of 20-30 hours / month on CPTR related activities, preferably over a multi-year period