LOGO

PPD HRVATSKA d.o.o.

Country Approval Specialist (m/f)

As a Country Approval Specialist, you are responsible for pulling regulatory Country Submissions together in order to activate investigative sites. You have a strong attention to detail, taking ownership of the accuracy of these documents while holding yourself and others accountable.Essential Functions of the role also include:- Prepares, reviews and coordinates, under guidance, local regulatory submissions (MoH, EC, additional special national local applications if applicable, e.g. gene therapy approvals, viral safety dossiers, import license) in alignment with global submission strategy- Provides, under guidance local regulatory strategy advice (MoH &/or EC) to internal clients- Provides project specific local SIA services and coordination of these projects- May have contact with investigators for submission related activities- Key-contact at country level for either Ethical or Regulatory submission-related activities- Coordinates, under guidance, with internal functional departments to ensure various site start-up activities are aligned with submissions activities and mutually agreed upon timelines; ensures alignment of submission process for sites and study are aligned to the critical path for site activation- Achieves PPD's target cycle times for site- May work with the start-up CRA(s) to prepare the regulatory compliance review packages, as applicable- May develop country specific Patient Information Sheet/Informed Consent form documents- May assist with grant budgets(s) and payment schedules negotiations with sites- Supports the coordination of feasibility activities, as required, in accordance with agreed timelines- Enters and maintains trial status information relating to SIA activities onto PPD tracking databases in an accurate and timely manner- Ensures the local country study files and filing processes are prepared, set up and maintained as per PPD WPDs or applicable client SOPs- Maintains knowledge of and understand PPD SOPs, Client SOPs/directives, and current regulatory guidelines as applicable to services provide
Izvor: www.moj-posao.net

Lokacija: Zagreb

Datum objave: 24. Dec 2020.

Datum isteka: 07. Feb 2021.