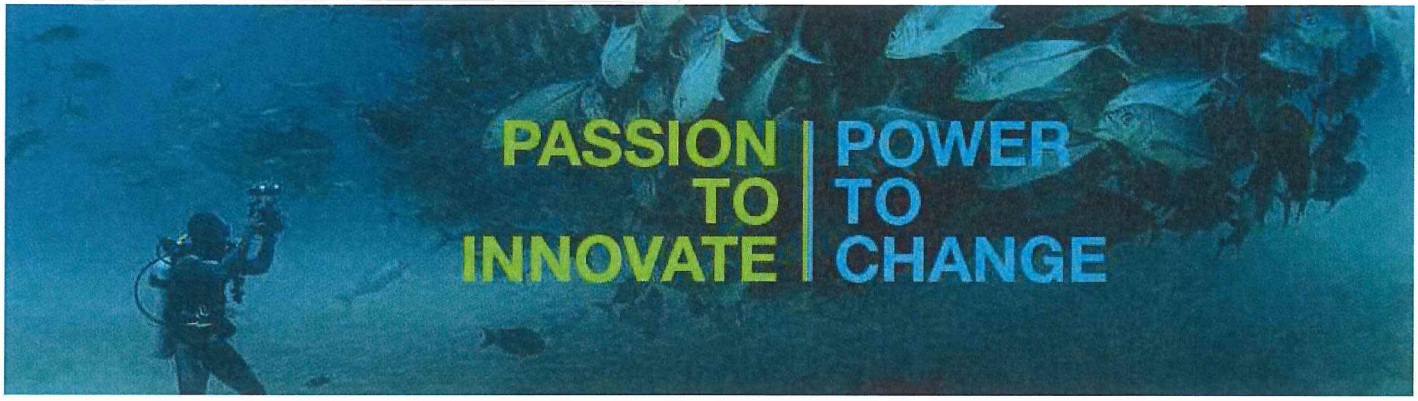
Job Title: Junior Regulatory Affairs and Pharmacovigilance Quality Manager (m/f)



Junior Regulatory Affairs and Pharmacovigilance Quality Manager (m/f)

YOUR TASKS AND RESPONSIBILITIES

- Implement quality management processes for Pharmacovigilance (PV) and Regulatory Affairs (RA)
- Link to R&D quality management within Bayer Animal Health (BAH), other BAH quality functions and PV/RA system audit team
- Provide initial analysis of late single case reporting and late aggregate report submissions for regular compliance report as well as deliver information to PV functions to trigger and support improvement initiatives
- Define, implement and maintain consistent metrics and Key Performance Indicators (KPIs) in close cooperation with QPPV and RA functions
- Support in PV/RA inspections and PV/RA audits and contribute to the overall inspection readiness of PV/RA through compilation of inspection/audit relevant materials and managing front and back office
- Support tracking and implementation of corrective and preventive action (CAPA) related to findings from compliance monitoring, quality management, PV/RA inspections and PV/RA audits
- Maintain the global and head office PV/RA Quality System Documents (QSDs) by supporting the development of selected QSDs referring to PV/RA processes, review of the draft QSDs and management of the implementation process
- Support impact assessments for new external PV/RA regulations, internal regulations and PV/RA QSDs and support the PV/RA business by defining implementation steps
- Define in consultation with Head of RADS and QPPV the global PV/RA trainings, supervise and coordinate monitoring of training success/ performance for all RADS Head Office staff incl. external service provider, regional and local RADS staff

WHO YOU ARE

- University degree in veterinary or other life-science oriented studies (e.g. pharmacy, human medicine, biology or chemistry), preferably with PhD
- Initial experience in regulatory affairs and pharmacovigilance
- Good knowledge of veterinary drug legislation (especially related to pharmacovigilance) and quality management aspects related to GxP requirements
- Very good interpersonal and communication competencies as well as a high degree of persuasiveness
- Good leadership skills and the ability to collaborate effectively within a global, cross-functional team
- Strong analytical skills
- High ability to solve problems and to structure and simplify complex tasks
- Capability to prioritize tasks and to meet deadlines in an independent, proactive and result-oriented manner
- Fluent in business English, verbal and written; German skills would be advantegeous

Passion to innovate | Power to change

Division:	Animal Health	**Reference Code:**	18585
Functional Area:	Regulatory Affairs	**Location:**	Monheim
Legal Entity:	Bayer Animal Health GmbH	**WorkTime:**	Fulltime
Employment Type:	Regular		

Contact Us

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