

Descripción empresa

ESTEVE (www.esteve.com) es una empresa farmacéutica internacional con sede en Barcelona. Su misión es impulsar la innovación para mejorar la vida de las personas y, desde su fundación en 1929, su objetivo ha sido aportar soluciones a necesidades médicas no cubiertas. ESTEVE tiene una fuerte presencia en Europa a través de filiales farmacéuticas en España, Portugal, Alemania, Francia, Reino Unido e Italia, y es una organización europea líder en fabricación por contrato (CMO) con centros de producción dedicados al desarrollo y producción de principios activos farmacéuticos para terceros, en España, México y China.

ESTEVE(www.esteve.com) is an international pharmaceutical company headquartered in Barcelona. Its mission is to drive innovation to improve people's lives and, since its founding in 1929, its goal has been to provide solutions to unmet medical needs. ESTEVE has a strong presence in Europe through pharmaceutical subsidiaries in Spain, Portugal, Germany, France, the United Kingdom and Italy, and is a leading European contract manufacturing organization (CMO) with production centers dedicated to the development and production of active pharmaceutical ingredients for third parties in Spain, Mexico and China.

PUESTO DE TRABAJO

Medical Drug Safety Manager

MEDICAL DRUG SAFETY MANAGER

CODIGO DOCUMENTO: MDSM

Departamento/ Department: Global Drug Safety & Pharmacovigilance

Ámbito funcional/ Area: Global Scientific and Medical area

Centro de trabajo/ Job Site: Torre Esteve

1. CONTENIDO FUNCIONAL/ FUNCTIONAL CONTENT

Misión / Main Role

Protecting and improving patient care and safety in relation to the use of medicines and all medical and paramedical interventions; — Promoting the safe, rational and effective use of medicines; — Promoting education, understanding and training in Pharmacovigilance (PV); — Evaluating the benefit, harm, efficacy and risk of medications, carrying out continuous benefit-risk evaluations of medicines; — Ensuring compliance with PV obligations under current legislation on the safety of medicines and PV. — Maintaining a robust PV system for the performance of the PV activities for all the medicinal products of Esteve Group.

Funciones / Roles

Medical Review and Quality check of suspected adverse drug reactions (ADRs) and serious adverse events

(SAEs).

- Review / Preparation of Periodic Safety Update Reports (PSURs), safety documents for renewals and Risk

Management Plans (RMPs), expert reports and Development Safety Update Reports (DSURs).

- Assessing, defining and implementing, where necessary, the PV activities or risk minimization measures for

company products.

- Assessment of signals for company products either marketed or under investigation. Continuous safety profile

review along life-cycle of the company products.

- Collaboration in PV audits and inspections.
- Medical assessment and elaboration/review of the Company Core Safety Information (CCSI) defined as

relevant for the company.

- Review and elaboration of safety sections and Reference Safety Information of the Investigator Brochure and

labellings, in collaboration with Global Clinical Development department. For already marketed products: review

of the safety sections of the product information in collaboration with Medical Affairs.

- Review of clinical study protocols from the PV point of view.
- Review of clinical study reports (safety section) and safety section of the regulatory dossiers.
- Managing external PV providers.

Updating and maintenance of the Pharmacovigilance System Master File – PSMF.

- Preparation, review and updating of Standard Work Procedures (SOPs) and Working Instructions (WIs)

applicable to the drug safety and PV department.

- Medical surveillance of health products, cosmetics, and food supplements.
- Support to any request for information from the competent authorities on drug safety.
- Participation in project teams for the preparation of dossiers for new drug authorizations or new developments

of already authorized products.

- Contributing to the maintenance of an adequate file.
- Participation in due-diligence of new products/companies.
- Promoting and complying with the applicable regulations (for example GVP, GCP, data privacy), operating

regulations in general as well as the procedures in the systems regarding the prevention of occupational risks

and the environment, with the prior and relevant training in the field. All this while ensuring the maintenance of

the confidentiality and security of the information.

- Participating in Scientific Steering Committees and Scientific Advisory Meetings with Competent Authorities.

2. ENTORNO ORGANIZATIVO / ORGANIZATION CHART & JOB RELATIONSHIPS

Superior directo / Line Manager

- Global Drug safety & Pharmacovigilance Head / EU/UK QPPV

Relaciones externas / External Relationships

- Partners/Other pharmaceutical companies
- Healthcare professionals/Patients
- EMA/MHRA/Other Regulatory Authorities
- Regional PV centers in Spain
- Ethic Committees and Investigators
- Asociación de Médicos de la Industria
- Farmacéutica Española (AMIFE)
- Farmaindustria/other pharmaceutical associations
- CRO: Clinical Research Organisation

3. PERFIL PROFESIONAL / JOB PROFILE

Formación requerida / Required Studies

Bachelor in Medicine.

- Excellent verbal and written communication skills in English.
- High organizational and analytical skills.
- Fluent use of office tools.
- Able to work in an environment with changing priorities.
- Ability to work independently as well as in a matrix organization in teams.

Otros conocimientos especializados / Other specialized knowledge

Argus Safety Database or other safety databases

- Knowledge in GVPs and GCPs
- Knowledge in Clinical Trial performance and Clinical Development

Idiomas / Languages

- English
- Spanish
- Catalan

Experiencia profesional / Professional experience

- More than 6 years of experience in the field

4. COMPETENCIAS / Behaviors

Behaviors	Definitions
Proactividad / Proactivity	Capacidad para tomar la iniciativa y anticipar las necesidades del negocio, identificando proactivamente áreas de mejora e implementando soluciones. / <i>Ability to take initiative and anticipate business needs, proactively identifying areas for improvement and implementing solutions.</i>
Colaboración y Trabajo en Equipo / <i>Collaboration & Teamwork</i>	Capacidad para trabajar de manera transversal con los equipos de ventas, desarrollo de negocios y otros departamentos, fomentando un entorno colaborativo. / <i>Ability to work cross-functionally with sales, business development, and other departments, fostering a collaborative environment.</i>
Adaptabilidad / <i>Adaptability</i>	Capacidad para desenvolverse en un entorno dinámico, adaptando los informes y análisis según las estrategias empresariales y la evolución del mercado. / <i>Ability to thrive in a dynamic environment, adapting reports and analyses based on business strategies and market evolution.</i>
Comunicación Efectiva <i>Effective communication</i>	Excelentes habilidades de comunicación escrita y verbal, con la capacidad de articular información compleja de manera clara y concisa / <i>Excellent written and verbal communication skills, with the ability to articulate complex information clearly and concisely.</i>
Pensamiento Analítico <i>Analytical Thinking</i>	Mentalidad analítica sólida, capaz de interpretar datos, extraer ideas y traducirlas en recomendaciones prácticas para los equipos de marketing y ventas. / <i>Strong analytical mindset, able to interpret data, extract insights, and translate them into actionable recommendations for the marketing and sales team.</i>
Atención al Detalle <i>Attention to Detail</i>	Enfoque en el detalle para la gestión de datos y la elaboración de informes, garantizando precisión y fiabilidad en todos los análisis y presentaciones. / <i>Detail-oriented in managing data and reporting, ensuring accuracy and reliability in all analyses and presentations.</i>
Resolución de Problemas / <i>Problem-Solving</i>	Habilidad para identificar problemas y ofrecer soluciones basadas en datos, optimizando procesos y estrategias de negocio. / <i>Ability to identify problems and offer data-driven solutions, optimizing processes and business strategies.</i>

