



Chiesi – founded in 1935 – is a mid-size, family owned pharmaceutical company with an international presence. Our headquarters are located in Parma, Italy.

*Respiratory is our company's DNA. We aspire to be a point of reference for patients affected by chronic respiratory disorders. Beside that we also specialize in **neonatal pathologies, rare diseases** and other health conditions which are difficult to treat. **Our patients are put in the forefront of everything we do.** We commit to offer patients, and those who take care of them, innovative solutions in the management of their needs, even exploring new frontiers in treatment and care. Therefore, **we invest continuously in Research & Development.***

PHARMACOVIGILANCE & INFORMATION OFFICER

Department: Pharmaceutical Affairs

Main Responsibilities:

1. Pharmacovigilance

- **Mailbox and literature screening:** continuously monitor the PV mailbox for incoming safety and/or Pharmacovigilance data, Perform screening of local scientific journals, Perform screening of local health authority websites.
- Adverse **event handling**, reporting and archiving
- **Reconcile** Pharmacovigilance, Product Complaints and Medical Enquiries Registers, Performs periodic case reconciliation with GPV and partners.
- **Prepare and provide training** to (new) Chiesi staff and yearly refresh of all Chiesi staff members
- Contribute in the **preparation of Safety Agreements** with contractual partners
- Maintain the relevant sections of the PSMF
- Act as back-up for the Local Contact Person for Pharmacovigilance.

2. Information

- **Contract management:** prepare positive list of speakers
- **Prepare listings** on direct and indirect transfers of values to healthcare professionals and/or organizations in compliance with the legislation (Sunshine Act) and corporate guidelines in close collaboration with the Legal & Compliance Manager.

- **Promotional activities:** evaluate and approve/reject regulatory/compliance aspects of HCP/HCO interactions
- **Evaluate promotional materials** in close collaboration with the responsible person for pharmaceutical information (RIP) and the Legal & Compliance Manager.
- Prepare **Mdeon submission** and **follow-up**
- **Perform checks** on forms and requests in compliance with the legislation on medicinal samples
- Perform quarterly compliance **check on gifts**

3. Quality Assurance

- **Quality management:** maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.
- **Capa, deviations, change control:** prepare the documents in accordance with applicable procedures and report to Responsible Person
- **Audits:** maintain the internal and external audit plan & provide the necessary support to audit preparation & audit reporting
- **Maintain the training plan of employees,** file & archive training materials, support to prepare and provide GDP training to Chiesi staff.

4. Policies & Procedures

- **Screen corporate Pharmacovigilance policies and procedures** and indicate the applicable ones to the pharmaceutical affairs department.
- **Prepare local Pharmacovigilance policies and procedures** in compliance with regulatory and corporate guidelines.
- Adhere to Chiesi standard operating procedures

5. Interaction with internal/external stakeholders

Education:

- Pharmacist
- Agreement number as RIP is a plus

Knowledge/ Experiences:

- Experience in a similar position/environment, preferably within the pharmaceutical industry
- Experience in archiving and documentation management is a plus
- French or Dutch mother tongue with a very good level of the other language; good English
- Excellent command of MS office (Powerpoint, Word, Excel), Outlook and telephone protocol
- Experience with databases on document management such as Hermes and tracking systems such as Trackwise is a plus

Behaviour/ Skills:

- Open minded / listening attitude with focus on detail
- Punctual but with a broad “total” company-oriented vision
- Ability in dealing with both internal and external stakeholders
- Able to manage different tasks at the same time
- Flexibility
- Autonomous, assertive and motivated

Place of work: Diegem

Interested?

Please send your CV and motivational letter to jobs.be@chiesi.com