Acino is a Swiss pharmaceutical company, leader in advanced drug delivery technologies. We have a clear focus on selected emerging markets in the Middle East, Africa, the CIS Region, and Latin America, and we operate in some of the most dynamic countries of the world. We value courage, commitment, trust, and empathy and provide an environment that supports initiative and effort. We are proud to be action-oriented and open-minded, with a strong focus on quality and product availability, even in remote and hard to reach areas of the world.

This is a once in a lifetime opportunity to become our

Labelling Specialist (f/m) 100%

This new position is based in Miesbach, Germany.

Your main responsibilities include:

- Manage and maintain core reference SmPC / core reference PIL of medicinal products in EU and CH reference markets
- Manage the internal labelling review and approval processes to ensure alignment with EU or CH reference product information according to established process and assure conformity with applicable labelling guidelines/regulations
- Lead the creation and maintenance of regulatory compliant documents to match originator's labelling) and up-to-date labelling documents (SmPC, PIL, Labelling) for an assigned portfolio of brands/ products
- Provide medical relevance assessment and labelling guidance (medical evaluation and text proposal), Text comparison (originator, reference vs generic) and medical writing of Acino labelling-related documents (PIL, Abridged SmPCs, updates of SmPCs) as needed
- Managing the Labelling Deviation request process as per Global core labelling SOP for the assigned portfolio of brands/products
- Documenting and monitoring of all global and local changes for the assigned portfolio of brands/products
- Contribute to labelling process improvement initiatives
- Cross-functional collaboration (regional RA, GRA responsible person for the products under responsibility, Commercial, GMA, GPV, GSLC, others)
- Guide and support the local/market RA teams for local labelling-related Health Authority (HA) queries
- Contribute to responses to Health Authority queries related to labelling together with GRA/LRA person
- Ensure that key regional/market RA input is sought and incorporated into country labelling creation
- Monitor HA safety updates for assigned portfolio as well as legislative updates

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Your profile:

- Degree in life science (Pharmacy, human or veterinary medicine, “Medizinischer Dokumentar”)
- 3-5 years' labelling experience within the Pharma industry or experience in Regulatory Affairs
- Understand urgency of required labelling changes
- Solid knowledge of labelling guidelines and regulations
- Understanding of PV requirements in EU and CH
- Expertise in managing labelling processes and content
- Excellent project management and organizational skills together with experience in cross-functional team collaboration in an international environment
- Specialist in documentation and archiving with excellent computer skills – MS Office applications exp. Word and Excel, eCTD / Document Management Systems (experience with docuBridge is an advantage)
- Team player with good communication skills
- Strong analytical skills with attention to detail, process adherence and quality drive
- Capability to prioritize tasks and adhere to timelines
- Solution oriented personality with solid negotiation and decision-making skills
- Excellent written and verbal communication skills. Fluent in German & English (written and oral) is a must; any further languages are an advantage

This is the opportunity to join a very dynamic organization, where decisions are taken fast and where you can actively participate in shaping our future. If this sounds exciting, we would love to hear more about you!

Please send us your complete application to - **preferably via e-mail into one PDF document** - Ms. Sandra Gamboni.

Sandra Gamboni
HR Site Head
hr.international@acino-pharma.com

We are looking forward to the opportunity to get to know you.
Only direct applications are considered.

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