Position: Associate Director – Pharmacovigilance

TARIS Biomedical is a unique therapeutically-focused urology company developing drug-device combination products for the treatment of genitourinary diseases.

The individual will be responsible for the development, implementation and maintenance of all pharmacovigilance activities to ensure sustained compliance with Global safety reporting obligations. This position will serve as the Pharmacovigilance Lead for TARIS-sponsored programs and will have a close working relationship with the Safety Physician, Clinical Development, Clinical Operations, Biometrics, and Regulatory Affairs.

Working closely with the TARIS Safety Physician, this position will lead this position will lead the scientific elements of safety evaluation and risk management for TARIS programs throughout all stages of development, including implementation of safety strategy and evaluating the clinical implications of safety data from pre-clinical studies, clinical studies, literature and other information sources in order to predict / establish the safety profile of TARIS products in clinical development.

Principal Responsibilities:

- Lead and/or conduct proactive pharmacovigilance and risk management planning for all TARIS supported clinical trials;
- In collaboration with the Safety Physician, provide safety input into Clinical Development planning activities including but not limited to protocols, site training materials, IB, RMP, informed consent, CSRs;
- Maintain the Company Core Safety Information and other Reference Safety Information;
- Manage, in collaboration with the Safety Physician, the data monitoring committee (DMC) process including authoring the charter, oversight of meeting planning and ensuring that data outputs are provided as specified;
- Oversee coding reviews in collaboration with the Safety Physician and SAE reconciliation activities;
- Represent pharmacovigilance on cross-functional teams;
- Provide input on cross-functional ad-hoc teams to address urgent and important safety issues.

Signal Detection and Evaluation

- Manage routine signal detection processes in partnership with the Safety Physician;
- Identify and use appropriate sources of information and database searches to retrieve relevant data for evaluation of signals;
- Present in collaboration with the Safety Physician safety data to the Safety Review Committee (SRC);
- Author accurate and fit-for-purpose evaluation documents with clear conclusions in response to internal or regulatory authority requests for safety data;
- Coordinate device investigation or other health hazard evaluation in conjunction with the Safety Physician, biostatistics or others in response to device or product complaints.

Regulatory Reports and Submissions

- Author and/or provide input and/or review for periodic regulatory documents (PADERS, DSURs) according to the agreed process and timelines.
- Author and/or provide input to the patient safety contributions for new product regulatory submissions (IND, NDA/BLA, CTA, MAA), in partnership with the Safety Physician and with other functional groups.

Other Activities

- Contribute to and/or review the pharmacovigilance component of contracts/agreements with third parties (e.g. collaborators, development partners) and escalate any deficiencies to the Safety Physician and Quality Assurance to ensure quality and integrity of agreement.
- Assist, as requested, in due diligence activities.
- Maintain state of readiness in response to internal audit or regulatory inspections.
- Contribute to advancement of methodology and process by generating new ideas and proposals for implementation.
- Mentor and/or train new or junior team members;
- Author and/or review current SOPs and identify gaps for development of new procedures/guidelines or training tools.

Qualifications

- Bachelors/Advanced degree preferably in life science, nursing, pharmacy or other healthcare related profession (RN, PharmD, NP, PhD, MPH, etc.). 7-10 years of relevant work experience. At least 5 years of direct pharmacovigilance work experience in the pharmaceutical industry;
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- Oncology and combination product/device experience preferred; (immuno-oncology a plus)
- Working knowledge of relevant FDA, EU and ICH guidelines, initiatives, and regulations and a comprehensive understanding of Global Pharmacovigilance regulatory obligations;
- Demonstrable leadership skills, able to resolve conflict and think/influence strategically;
- Able to work autonomously and effectively as a member of a cross-functional team;
- Excellent oral and written communication, presentation skills;
- Working knowledge of MedDRA, WhoDrug Global, CTCAE, ARGUS;
- Experience with CRO selection and oversight of contract services for database development, life-cycle management and case processing.

To apply, please send your CV to careers@tarisbio.com