



GCC Pharma Regulatory Affairs Award 2022 for Pharmacovigilance Achievement

Nominee's name & title:

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PV achievement summary:

Establishment of a high quality and compliant PV system in the META region with 31 countries and around 38 business partners. Taking into consideration EU standards and GVP for Arab countries.

PV achievements work:

Leading the establishment of the PV system from scratch for Acino in the Middle East, Turkey, and Africa region after establishment of the META affiliate. Following different acquisitions within the company, the PV system has been put in place in line with the highest EU standards and it has been integrated into the Acino Global PV system. The following core elements of the PV system have been established within 1 year time and during the pandemic, considering the EU PV guidelines and the GVP for Arab countries:

- Appointment of local QPPVs and LSRs (and back-ups) according to local regulations in the whole region mainly in the UAE, Egypt, KSA, Iraq & Turkey.
- Establishment of company SOPs, PSMF/local PSSF.
- Introduction of KPIs (Key Performing Indicators) to measure the compliance of the PV system of the company and the business partners in the region (in total 38 business partners). Put in place a risk assessment plan and annual audit plan for business partners (including service providers).
- Increased the safety awareness in the company: developed PV training materials in 3 languages (English/French/Turkish) and rolled-out as onboarding and annual refresher training for all employees.
- Improved the safety culture and the reporting of adverse events: implemented a digital tool on iPads for electronic reporting of adverse events, to simplify and increase reporting. Tool has been launched in 3 languages: English, French & Turkish.
- Organized an annual safety awareness day to promote a safety and compliance culture within the organization on global and regional levels.