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13 Creating Pharmacovigilance Quality Assurance

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Regulatory authorities throughout the world heavily regulate activities of drug safety and pharmacovigilance. As a consequence of recent drug safety-related regulatory actions and revision of the Rules Governing Medicinal Products in the European Union, regulatory agencies have substantially increased their focus and investment for drug safety surveillance activities – not only of internal processes, but also in regard to supervision of industry. Failure to comply with these requirements may result in significant negative regulatory, legal, and public opinion impact.

In 2007, UCB created a Quality Assurance department (GCS&P QA) dedicated to supporting the activities of the company's global pharmacovigilance system. These activities include but are not limited to UCB's internal drug safety group, Global Clinical Safety and Pharmacovigilance (GCSP), the company's Affiliate offices located in forty-five countries around the world, and UCB's contractual partners.

GCS&P QA drives quality into drug safety activities in three main ways; by partnering with GCSP and key stakeholders (Research, Development, Global Medical Affairs, Regulatory Affairs, and Commercial Operations), by providing direct compliance and investigative support to areas which are impacted by local and/or international regulations pertaining to Good Pharmacovigilance Practices (GPvP), all applicable local and/or international regulations, and by developing and implementing a risk-based GCS&P QA surveillance program.

The risk-based surveillance program includes key areas such as SOP review and approval; set up and continuous assessment of the Affiliates' local pharmacovigilance quality systems; assessment of clinical safety and pharmacovigilance processes of distributors and licensing partners; and a multi-component routine auditing program, including follow up of corrective and preventative action plans. Additionally the surveillance program includes root-cause investigations for late reporting, and coordination of inspection readiness activities and hosting of pharmacovigilance regulatory inspections at UCB Headquarters and major Affiliates. Critical Quality Indicators have been established as a continuous monitoring of the quality and compliance status of the areas impacted by GPvP.

By pro-actively driving quality into GCSP processes through partnership with key stakeholders in the organization, provision of direct compliance and investigative support and implementation of the risk-based surveillance program, UCB has established a system to continuously assess and improve the quality of its pharmacovigilance system, thereby ensuring patient safety and improving overall compliance.

Conflicts of interest: None declared.