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# pharma

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# ASPHALION

## Playing Pharmacovigilance Game Strong

**A**s a valuable part of patient care worldwide, pharmaceutical drug safety needs to be monitored and reported from initial testing to everyday use. This is the world of pharmacovigilance (PV). ASPHALION is a leading international scientific and regulatory affairs consultancy founded about two decades ago that has recently launched a new EU Local Contact Network to provide local pharmacovigilance support to any EU country in order to provide its global solutions for the externalisation of pharmacovigilance services, the European Qualified Person for Pharmacovigilance (EU-QPPv) and the Pharmacovigilance System outsourcing. “With our solution, clients can have a single point management of LPPVs across Europe, qualified and validated pharmacovigilance partners, with strong knowledge of local PV legislation and local requirements and know-how, as well as standardised procedure for PV activities, including local literature searches and ICSR management,” says Núria Romero Carol, Managing Director, ASPHALION. Additionally, since ASPHALION has opened its office in London, it can act as National Person for Pharmacovigilance in the United Kingdom. “In this way, no matter what setbacks Brexit may bring, our clients will be able to smoothly keep operating their businesses in the UK.”

ASPHALION has created its own PV system with a validated PV database, audited yearly by its clients. ASPHALION PV System has successfully been audited in the last 15 years, with 0 critical findings and is ISO certificated with yearly renewal without even a minor finding. Alongside its PV system, ASPHALION’s varied services, including risk management system (RMP), Periodic Safety Update Report (PSUR/PBRER), audits, Pharmacovigilance System Master File (PSMF), medical information, Quality system and SOPs, xEVMPD, training, and more, offer a well-developed, comprehensive service base that covers all possible needs of the pharmaceutical industry. Furthermore, apart from its PV services, the company also offers Medical Device vigilance services.

ASPHALION brings its knowledge and expertise in safety

from the very moment a client starts planning clinical studies. ASPHALION provides not only support for the definition of a strategy for safety monitoring but also the experience in preparing the required plans and reports. “As soon as the clients have overcome the challenges of safety during clinical testing, it is our goal to transform all the knowledge gained about the product during this phase into safety plans and actions to ensure compliance with legislation and maintenance of the product in the market,” says Núria. In addition to it, ASPHALION provides global support, both in regulatory and pharmacovigilance, through the whole lifecycle of a medicinal product.

Illustrating an instance, Núria cites the example of a big pharma company, with whom ASPHALION has been working in the change management of their PV database, a challenge for a company that big, with several subsidiaries and with products nearly everywhere all over the world. ASPHALION is carrying out the process in an orderly, sequential and robust manner while enabling the client to carry on with their operational activities. To do this, the company defined a project plan and the different milestones in order to meet the customer’s timetables for implementation and migration, which proved crucial. At the same time, ASPHALION was responsible for all pharmacovigilance activities of the client, which was a double challenge. In addition, Núria says, “Currently, we have more than 100 ongoing PV services collaborations with our clients that demonstrates our strong track record and, more importantly, a very high customer satisfaction.”

Since the company has an international team with more than 120 professionals with more than ten nationalities and offices in different countries, it has a strong track record, knowledge and capacity to deliver the best solutions to clients. “Being passionate is the key to our success: Our passion reflects in everything we do, in every project we undertake, big or small,” says Núria. [Ph](#)



Núria Romero Carol