

The key to success in integrated drug development

Switzerland has thriving science-based industry, comprised of world-class firms in the pharmaceutical, chemical and biotechnology sectors. It is estimated that the Swiss pharmaceutical industry alone accounts for over 11% of the country's exports and for nearly 6% of its GDP. These high-value industries are backed by a strong R&D sector, which currently benefits from one of the world's highest governmental budget allocations. Basel-based PreClinical Safety (PCS) Consultants Ltd. is a successful player in this field.



Dr. med. vet. Stephanie Plassmann of PreClinical Safety (PCS) Consultants Ltd., Board Certified Specialist in Veterinary Pharmacology and Toxicology and Senior Expert in Non-Clinical Drug Development

PCS was founded in 1989 with the aim of providing independent expert advisory services and preclinical safety evaluations for the pharmaceutical, agro-chemical and chemical industries. Initially, the company had its main focus on advice in histopathology and toxicology and was regarded as a pioneer in the field. Later on, the expertise was expanded to comprise the areas of pharmacology, drug metabolism and pharmacokinetics, quality assurance, pharmaceutical development, clinical pharmacology, and, last but not

least, regulatory services including the preparation of regulatory documentation such as IBs, INDs, Briefing Documentation and CTD writing covering a broad range of indications. PCS has long-standing experience with the full range of test items used in drug development, including small molecules, herbals or biotechnology-derived products, but also with other materials such as food supplements, chemicals and impurities. Ultimately, the aim for any test item is to arrive at a robust risk-benefit assessment for the intended use in humans, which



Like pieces of a puzzle, the services offered by PCS fall into place

provides the client with a sound basis for further decision-making as the process continues.

The company offers its services to any potential customer who is concerned about the safety and efficacy of test items including medications in development, food supplements, chemicals or others. "Independence is important. Sound strategic and objective scientific input and quality assurance, and their successful operational implementation through testing programmes to ultimately build up a comprehensive basis for a robust risk-benefit assessment are key services we provide," states Dr. Stephanie Plassmann, who is assuming leading responsibility for PCS in these areas. She explains the essential factors involved in achieving a solid reputation in this sector: "In our industry, the highest scientific and quality standards are crucial and require a multifaceted approach in the complex multidisciplinary process of integrated drug development. This is why our team consists of pharmacologists, toxicologists, toxicopathologists, pharmacokinetic, clinical and regulatory experts, pharmacists/CMC experts, chemists and GLP experts, all of whom have long-term hands-on experience and came on board to guarantee that the implementation and development of every project is up to standard," she explains. "In the pharmaceutical industry, the current

trend to reduce in-house resources with concomitantly increasing challenges associated with the development of new medications may lead to a limitation of the available manpower in situations where hands-on expertise is urgently required. On the other hand, small and mid-sized companies may be in the process of building up their teams, but meanwhile often have a critical need for the kind of expertise PCS can provide to them." Therefore, typically, PCS works together with very different teams in small to large companies in short, ad hoc projects as well as over extended periods of time from early development to marketing applications. Moreover, PCS not only provides these services to its clients, but also actively gets involved in the training and development of fellow scientists through a range of voluntary activities in the scientific community. Dr. Plassmann considers it mandatory to encourage young scientists to get involved in this important, interesting and challenging scientific field. ■

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