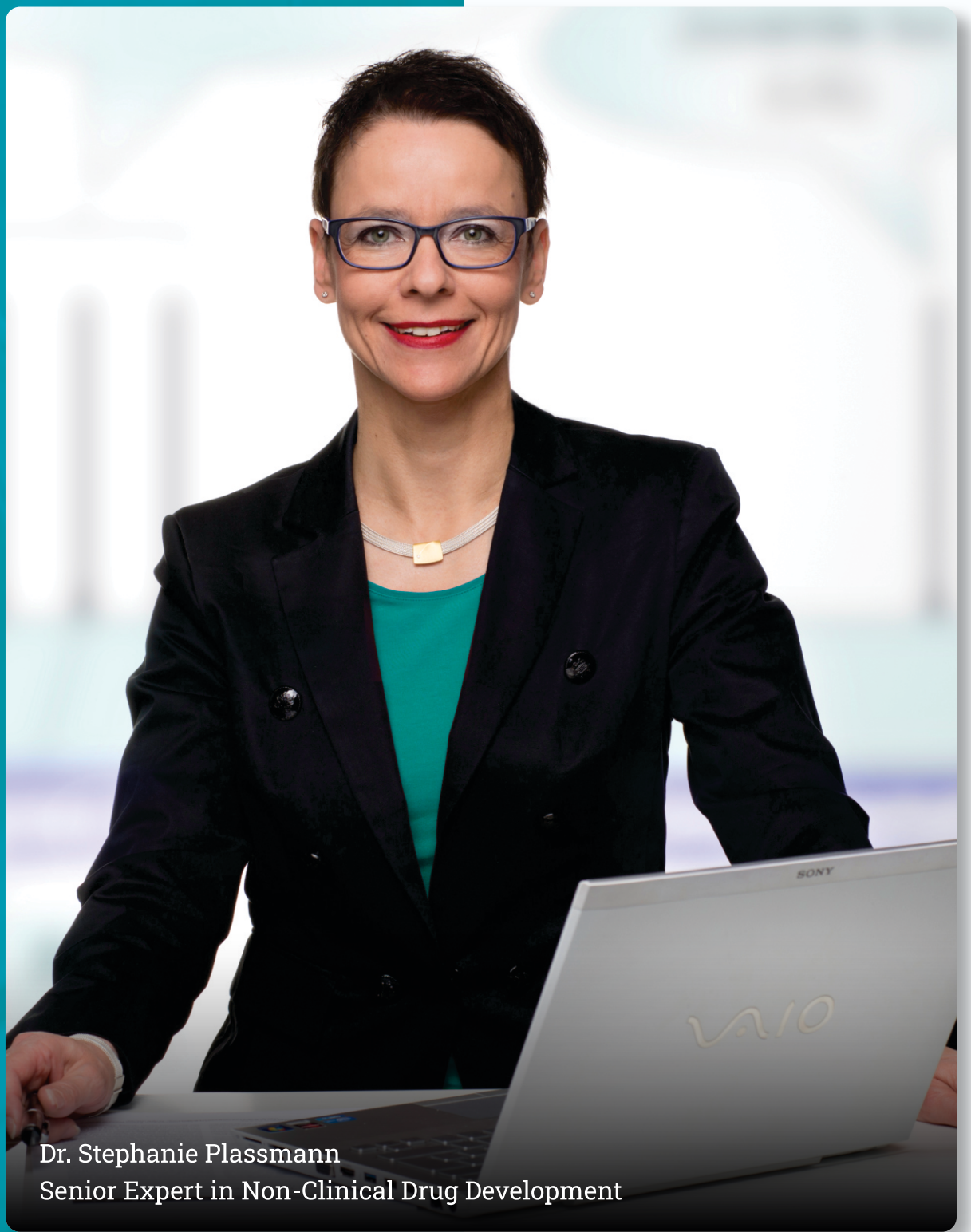

Dr. Stephanie Plassmann
Senior Expert in Non-Clinical Drug Development

PreClinical Safety (PCS) Consultants Ltd

Supporting the customer's complex decision-making process with strategic and operational scientific input

PreClinical Safety (PCS) Consultants Ltd is one of the leading drug development companies, which offers sound strategic and objective scientific input. It provides successful operational implementation through testing programs to ultimately build up a comprehensive basis for a robust risk-benefit assessment. Having long-standing operational experience and strong regulatory background enables PCS to offer independent expert advisory services in non-clinical drug development which makes it a distinguisher amongst the other players in the industry. At the outset, PCS focused on delivering consulting services in histopathology and toxicology. Since Dr. med. vet. Stephanie Plassmann took over, she developed the company further in the areas of drug metabolism and pharmacokinetics, non-clinical pharmacology and quality assurance (GLP), and later to include even clinical pharmacology on a case-by-case basis.

Dr. Stephanie Plassmann is a board-certified specialist in veterinary pharmacology and toxicology and acts as an independent consultant for international companies and institutions since 2004. As a scholar, she holds expertise in pharmacology, non-clinical safety, and drug development, both from a strategic as well as a hands-on operational perspective comprising a broad spectrum of indications from early to late-stage development. She has been a part of the industry for nearly three decades and held positions in senior management for leading companies in the pharmaceutical industry. Dr. Stephanie Plassmann took over PCS (Basel, Switzerland), in 2011 and since she joined the company her efforts have been dedicated to expanding the expertise of PCS. Today the company comprises a dedicated team of senior experts each having more than 25 years of continuous hands-on experience and expertise in the field of preclinical drug development, including preclinical pharmacology, toxicology, toxicopathology, DMPK, and GLP. PCS has established experience in a wide 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.

We encountered a recent opportunity to talk with the scholar Dr. Stephanie Plassmann and understand how she expanded the company's operations making PCS one of the leading companies of the year 2022.

Since the establishment, has digitalization brought any major transformations in the company?

PCS is a front-runner in providing integrated drug development services using digitalized formats since the beginning. Because we strongly believe in involving the most senior experts, our team members work from different areas in the world (including Europe and USA). We never believed in the concept that people can only work successfully as a team when physically sitting in one building. Not only does that allow us to expand our services on a need basis, but on top, we can interact with

QUOTE

PCS strongly believes in the concept of close and mutual interaction with all disciplines along the way and from a scientific perspective, preclinical development builds the bridge from bench to bedside. PCS has seen the best outcomes for projects where all contributing disciplines and parties worked closely together involving not only sponsors but also regulatory agencies, which also support the complex process of drug development with their highly valuable experience and expertise. Therefore, PCS encourages clients to interact with regulators proactively and transparently.

international clients and partners and benefit from time differences, which regularly allows us to react proactively and in due course, as and when required.

What company culture do you embrace at PreClinical Safety (PCS) Consultants?

Diversity rocks! We are multi-national and implement ICH-conform concepts, including regulatory interactions around the globe. Our approaches are driven by strategic considerations which are implemented in a hands-on pragmatic process on a day-to-day basis. We are helping clients to robustly implement the process from the start including the selection of the right places, designing the studies, and working with the CROs to run the studies. We also offer to monitor these studies from a scientific and GLP perspective. Additionally, our group of experts truly helps clients write the regulatory documents, defend the programs in terms of development, and accompany them to regulatory meetings, whether it be in the US or Europe, or other places in the world.

According to you, what distinguishes PreClinical Safety (PCS) Consultants from its competitors?

In the last 20 years, the landscape of non-clinical development has changed dramatically, overall resulting in a loss of senior expertise in the pharmaceutical industry. On top of that, the biotechnology sector has developed very dynamically and many innovative products were invented by SMB companies with a focus on research rather than development. Therefore, there is an ever-increasing demand for senior expertise in the field of non-clinical drug development. Our team offers a solution to companies that require this unique expertise, which is lost or much less available in many places today, in a broad range of indications and all relevant areas of preclinical drug development, including DART (developmental and reproductive toxicity) and JAS (juvenile animal) studies. In this field, only a handful of scientists worldwide has senior experience, which the PCS team offers based on our expertise through hands-on experience for well over 25 years. This is a good example for the shortage of available resources, because specifically in the field of pediatric drug development, there is an increasing demand for expertise, although this is only one of many examples.

How has having senior expertise enhanced the offerings at PreClinical Safety (PCS) Consultants?

The main purpose of a preclinical safety program is to adequately characterize potential risks for human patients culminating in a meaningful translation into a sound risk-benefit assessment and risk management and mitigation strategy to support clinical development. There is less and less senior expertise available worldwide to adequately address these complex questions, because of the ongoing drain in this area while facing increasing demand. Our team is highly committed to helping patients suffering from diseases and conditions with a high unmet medical need including rare conditions (orphan diseases), which need to be addressed case-by-case. Long-standing experience is the basis for our sound understanding of how resources are most efficiently used for bringing drugs on the market in the shortest possible time while maintaining highest quality standards.

How will you describe the team of PreClinical Safety (PCS) Consultants?

We are – on purpose – a small and dedicated team because we want to provide high quality rather than "high-

throughput" advice. Therefore, our team members all make very significant contributions to the success of PCS and that is recognized by our partners, clients, and colleagues in the scientific community.

Are there any new updates or offerings underway for PreClinical Safety (PCS) Consultants?

We are further expanding as a team because of the increasing demand for our services. In addition, as there is only a handful of people with good quality experience, we also engage in the development of the field by passing on our expertise through the education and training of fellow scientists.

COVID-19 has majorly affected industries around the world. How did you navigate the challenges put forth by the crisis?

The pandemic has increased the demand for resources in the field of medicine development even further. Amongst other activities, we have contributed through regular workshops on vaccine development offered by the **AGAH (Association for Applied Human Pharmacology)** to promote the understanding of vaccine development from a non-clinical perspective. I serve as a regent for the AGAH since many years. The AGAH also contributes to the development of guidance documents. I participated as a delegate on behalf of the AGAH as a senior expert in non-clinical development in the EMA-meeting for the revision of the European Guideline on Strategies to Identify and Mitigate Risks for First-In-Human and Early Clinical Trials with Investigational Medicinal Products, the revised version of which was implemented in February 2018 following the MAD trial incident with BIA 10-2474 in January 2016.

In the coming 5 years, how do you envision the industry to shape?

There will be an ever-increasing demand for this expertise conflicting with an ongoing drain which we need to face. We are not only contributing as a consultancy but also by developing fellow scientists in the field, both as a company as well as through education and training such as by contributing to the PharmaTrain certified Introductory Course in Exploratory Medicines Development offered every year by the Association of Applied Human Pharmacology (AGAH), as well as by other regular lectures and publications.

Is there any advice that you would like to share with our readers through this article?

Start your research by defining a target drug profile first – i.e. think backward from the end of the process! Your non-clinical development cannot start without knowing the condition the clinicians intend to treat. The indication will define clinical, and therefore, non-clinical development. Non-clinical development is the bridge from bench to bedside – ca. 75% of new molecules in non-clinical development never reach clinical development, often because of untoward adverse effects which cannot be accepted for a given drug profile. However, sometimes, a certain level of adverse effects may be tolerated in another indication. It is of utmost importance to focus on the most promising candidates. Early consideration of non-clinical expertise for any research project helps to shape the development of a new drug according to the requirements of effective medical treatment, thereby streamlining the process and increasing the chances of success. We also advise seeking regulatory guidance early on through well-prepared scientific advice procedures and meetings. The highest scientific and quality standards are crucial and require a multifaceted approach, involving close and mutual interaction between all disciplines involved. GBL

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