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Getting to Know Eva von Mühlenen: Our latest digital health thought leader

Eva von Mühlenen-Scholten, Andreas Balsiger Betts

On November 1, 2021, after a career spanning 14 years as a civil servant at Swissmedic, the Swiss Agency of Therapeutic Products, Eva von Mühlenen joined Sidley as advisor for our Global Life Sciences practice. We took the opportunity to talk to Eva about herself, her priorities in life, and especially her new role at Sidley.

Q: Welcome, Eva! Before we get to your new role, please tell us about yourself. Who are you, and what makes you tick?

A: I was born in the famous university town of Heidelberg, Germany, and moved to Switzerland in 2005, married in 2010, and have two children, ages 5 and 8. We live in the beautiful old town of Bern. In my free time, I love all kinds of watersports like kitesurfing and sailing in summer and I'm a keen skier in winter.

This said, my work is a very important part of my life, and I am passionate about what I do. I am driven by an intrinsic motivation to improve healthcare provision. And I believe in the many benefits digitalization will bring to drug development, healthcare, and regulatory science. I think we are facing some very exciting times in this regard.

Q: What is your professional background?

A: I am a fully qualified German lawyer by training and was employed in private practice in Germany and Switzerland before joining Swissmedic. I consulted for companies in both the life sciences and food processing sectors, represented clients in court, and gained experience in M&A transactions.

At Swissmedic, I served as Deputy Head of the Legal Advice Department and Lead Counsel in Swissmedic's Digital Transformation Initiative.

Q: What are your special interests in the life sciences environment?

A: As a regulatory lawyer, I have always identified with the purpose of health protection and the broad provision of healthcare. I believe that emerging new technologies like artificial intelligence (AI)/machine learning (ML) — applications, surgical robotics, decentralized clinical trials, and blockchain solutions — are reshaping healthcare, inter alia*, by improving diagnostics, enabling personalized treatments, or ensuring supply chains. I am enthusiastic about digital health and strive to make sure that new technologies are developed in a safe, secure, and trustworthy way so that these opportunities can realize their full potential.*

Q: If you were a GC or a CEO of a company of the pharma or medtech industry, what legal challenges and/or technical developments would keep you up at night?

A: New technologies like AI, robotics, blockchain, and automation are not just hype anymore but being implemented — and do indeed bring newly evolving legal challenges with them. On the one hand, many standards and legal bases are currently missing or are just being created. Therefore, visibility about what is to come is mostly lacking, and it is hard to find the optimal solution from competing options that may be offered to a company. On the other hand, the regulatory ecosystem around digital health is evolving and leads to the emergence of entirely new regulatory areas. What began with the GDPR in the field of data protection is expanding to encompass new regulatory approaches to AI/ML, robotics, blockchain, and virtual CTs. In this context, I am also engaged in a Swiss National Research Project at the Federal Institute of Technology in Zurich working on the development of innovative regulation for digital healthcare. Thus, I can advise clients with knowledge of the latest developments in this regard.

However, as I am an inherently positive person, I would rather be kept on my toes by the developments emerging and the unprecedented opportunities and to constantly observe and assess the technologies and how they can be used most effectively and beneficially for the company.

Ultimately, digital health technologies will benefit from innovation-driven standards and regulations, as this is key to ensuring efficacy, safety, and quality in order to promote trustworthy adoption and use of the technologies. GCs and CEOs should make sure that their companies and industry associations they adhere to are not merely followers of new regulations but take the opportunity to influence the legislative processes so as to optimize the utility of the new technologies for their industry.

Q: Where do you want to add value to Sidley's clients?

A: Thanks to my background with an in-depth knowledge of the Swiss life sciences regulatory framework and insights into corporate law, I will be guiding Sidley's clients through the regulatory challenges we face. My complementary professional experience in information and communication technology law and the digital transformation in healthcare give me the unique insight to connect the dots, see the business needs, and help clients understand mission-critical regulatory perspectives.

Q: When will Sidley clients be able to meet you in person? Do you plan a "Tour de Suisse"?

A: I am greatly looking forward to speaking at Sidley's first mtlegal event on November 16 in Bern on the regulatory framework for AI/ML. On the same day, also in Bern, I will be chairing a panel on Digital Medtech at the Sidley/ISS Medtech event. On November 17, I will have the pleasure of participating in Sidley's Women Life Sciences Network (WLSN) event, held in Zurich, for which my colleague Josefine Sommer has lined up an amazing panel. And of course, I can't wait to get to know the Sidley clients at in-person meetings in the near future.