Stephanie Krumholz, Pharm.D./Dr. rer. medic

Dr. Stephanie Krumholz is Founder and CEO of therainnova AG, Switzerland. Dr. Krumholz is an entrepreneur and a regulatory leader with about 20 years of experience in developing and implementing regulatory strategies focusing on EU, Switzerland and certain ROW countries. She supports companies in shaping the regulatory environment across therapeutic areas from early development through filing submissions and up to providing post-marketing support in those markets.

Dr. Krumholz has served as EU regulatory lead, US regulatory lead, and Global Regulatory Leader in various NDA /BLA / MAA submissions across several jurisdictions. Her experience includes providing international strategic development plans, labelling analysis, paediatric programs, as well as leading Health Authority meetings with EU, Swiss, US and certain ROW Health Authorities including managing two FDA Advisory Committees and several EU Scientific Advise meetings. In addition, Dr. Krumholz has successfully managed critical issues and safety related changes across a variety of projects. She supports companies in Switzerland to gain marketing approvals through identifying the most optimal filing pathway while within Switzerland, in parallel, advising the clients in the local requirement (QMS) when acting as Swiss Marketing Authorisation Holder. She also acts as legal representative for clinical trials in Switzerland.

Dr. Krumholz has a huge passion in developing global filing strategies to enable parallel submissions of MAAs, NDAs and BLAs in several jurisdictions across the world. When Project Orbis was set up as a pilot project by the US FDA, Dr. Krumholz led more than 4 Project Orbis Submissions in Switzerland, as well as in Canada and Australia with support of her existing network.

Dr. Krumholz `s experience also includes assessing global due diligence projects from a regulatory perspective and managing them as a project leader ensuring all parts of the due diligence key considerations are brought together.

Prior to setting up her own company therainnova AG in 2021, she was the founder of NDA Switzerland (2015). Before joining NDA, Stephanie held EU, US and Global Regulatory Affairs positions at F. Hoffmann-La Roche Ltd, Roche Inc, Cytos Biotechnology AG and led projects in various rare diseases and in therapeutic areas such as renal, gastrointestinal, cancer, metabolic or CNS disorders. Stephanie has a degree in Pharmacy and a Dr rer. medic title from the University of Berlin, Charité University Hospital, Department of Obstetrics and Gynaecology.

Dr. Krumholz is the speaker at different conferences, acts as Coach for Start- Up companies and provides operational and strategic support to Start-Ups, Biotech Companies and Big Pharma.

Dr. Krumholz's key areas of expertise include:

- Extensive experience in designing and executing regulatory strategies in several markets (EU/US/Global, including Project Orbis)
- Early and late-stage development of small molecules, biological, orphan, and non-orphan medicinal products
    - Provide regulatory roadmaps, strategic and operational support through the development phase, advise on impact of key claims process
    - Advise on and submit NDA/BLA/MAA filings in EU, CH, ROW countries
    - Engage with Health Authorities in EU, CH, US and certain ROW countries (Scientific advice, IND interactions with FDA, interactions with Swissmedic etc.)
    - Lead due diligence processes
    - Strategically advise and operationally submit Swiss MAAs submission including life cycle management
    - Act as legal representative for clinical trials in Switzerland
    - Set up QMS for Switzerland
    - Set up new business areas, e.g., international filings in China, Canada, Australia, Singapore
- Overseeing and advising a team of regulatory professionals from early to late-stage development/marketing