National MDR & IVDR Conference 2021
19 October 2021, BERNEXPO, Bern

Karin Ackema, PhD, ISS AG

Senior Quality Consultant and Medical Writer at ISS AG. Studied Biotechnology, followed by a doctorate in cell biology at the Erasmus Medical Centre, and a postdoctoral appointment at the Biozentrum in Basel. After several years of experience in Quality System Managament at DePuy Synthes, she moved to QMS Support, Technical File Remediation and Medical Writing at ISS AG.

Management experience both as a line manager and as a project manager. With the combination of these different areas, Karin Ackema supports the manufacturer with an evidence based technical file with specific focus on V&V, preclinical data and manufacturing control. Key support areas are biological evaluation, sterility, cleanliness, and clinical evaluation.