Personal data:

Name	Aude Leroy-Gallissot
Position	Senior Consultant, Quality and Regulatory Affairs
Education	M.Sc. Bioengineering, Clemson University, SC, USA Biomechanical Engineering, UTC, Compiègne, France
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Citizenships	Swiss and French

Core competencies:

Regulatory Affairs	MDD 93/42/EEC, MDR EU Reg 2017/745, IVDD 98/79/EC, IVDR EU Reg 2017/746, CE technical files, 510k submissions
Quality Management	QMS assessment, audits, GMP, quality compliance, quality engineering (internal & with suppliers), ISO13485, 21CFR820, notified body audits, FDA QSR and inspections, training
Design & project management	20 years of experience: product development life-cycle, design controls, risk management, DHF & DMR requirements, combination products
Multidisciplinary and intercultural settings	Worked in USA, France, Switzerland with international teams; fluent in French and English, proficient (C1) in Spanish, advanced (B1) in German

Professional career:

Since 01/2019	Senior Quality and RA Consultant, meditec Consulting GmbH, Switzerland Activities: ensuring compliance of quality systems and technical files, compliance training
01/2015 to 10/2018	Senior Quality and RA Consultant, Exco Consulting GmbH, Switzerland Activities: ensured Design Controls compliance on combination product projects (including legacy products); conducted remediation gap assessments on DHF and QMS and supported the remediation implementation; negotiated Quality agreements with key suppliers
06/2013 to 04/2014	R&D Manufacturing Director, Bracco Injeneering, Lausanne, Switzerland Activities: responsible for the R&D department and its strategies
10/2010 to 01/2013	Senior Quality Manager, Greatbatch Medical SA, Orvin, Switzerland Activities: responsible for the Swiss quality team: Quality System, Quality Engineering, Supplier Quality Engineering, Metrology and Inspection (7 direct reports - 26 people in total), performed strategic gap analyzis of the QMS and implemented the action plan; coordinated the CE Technical File remediation task force Internal support mission for Greatbatch Medical SAS in France for 9 months (2010-2011): managed customer requirements for Class III device projects; headed the site preparation for an FDA inspection
10/2004 to 08/2009	Development Project Manager, Zimmer GmbH, Winterthur, Switzerland Activities: managed hip projects between the production sites in the USA, Switzerland and France; selected and validated outsourced technologies; supported Regulatory Affairs with CE-marking and 510K submissions; provided technical and quality assistance to the French production site.
03/1999 to 10/2004	Product Development Eng. & Project Manager, Zimmer Inc, IN, USA Activities: in Traumatology (1999-2003): responsible for the design, development, and processing of implants and instruments, including generating Design Controls documentation and product evaluations with surgeons. In Computer Assisted Surgery (2003-2004): led the integration of a third-party software platform with Zimmer instruments between three international manufacturing sites.