Curriculum Vitae / List of Projects

Holger Landau – Self-employed since 2000

- **QM Specialist (ISO 13485)**
- **Regulatory Affairs Manager**
- **Technical Writer**

Personal Data:

Name:	Landau
Surname:	Holger
Address:	Massragastrasse 3, 8885 Mols (Switzerland)
Mobile:	0041 (0) 793425385
E-Mail:	h.landau@media-tipps.de
D.O.B:	20.01.1962
Own Company:	media-tipps GmbH (ch)
Homepage:	www.media-tipps.de

Professional Experience – Projects (self-employed):

02/2024 – 06/2024	**Maquet / Getinge, Rastatt/Hechingen (DE)** Audit-Manager / Deviation Management / CAPA
09/2022 – 01/2024	**VDW GmbH, München (DE)** RA Manager / Approvals in different countries / MDR
04/2022 – 09/2022	**Weidmann Medical Technology AG (CH)** Compalint Manager and CAPA Manager
10/2021 - 04/2022	**Johnson & Johnson (DE), RA Manager** Swixit, Contracts, Labelling, MDR, Registrations
02/2021 – 09/2021	**BEGO – Bremen (DE) Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG** RA-Manager / Approval for Canada, Russia, China etc.
09/2020 – 01/2021	**medi Gmbh, Bayreuth (DE), QM-Consult** MDR and MDSAP-Consulting, Technical File
11/2019 – 06/2020	**Ulrich Medical GmbH, Ulm (DE), Technical Writer, QA** Updating technical file to MDR including Biocompatility and Labels.
05/2019 –11/2019	**Paul Hartmann AG, Heidenheim (DE), Regulatory Affairs Manager** Development of regulatory strategies for MDR and different products. Including responsible documents.
06/2018 – 04.2019	**Dentsply Sirona, Mannheim (DE), Regulatory Affairs Manager** International registrations of dental implants and instruments USA (510k), China, Russia, India and Brasil). Updating technical file to MDR, including Biocompatility (ISO 10993-1) and Labels.
08/2017 – 11/2019	**KAIA Health, München (DE) – QM Manager (Lead)** External QMB. Managing the QM system, internal and external audits, SOP, supporting all aspects of Supplier QA activities, support projects in Interpretation of Quality Plans, Review, approve and supports issuance of products under Certificate of Conformity. Carry out root cause investigations of non-conformances, Support NPI.
05/2017 – 04/2018	**Trumpf Medical, Pucheim (DE) – QA/RA Manager** Regulatory affairs, international registrations and approvals of medical products (USA, Brasil, China, FDA 510 k). (Application of new MDR, ISO 13485: 2016, PMS). Performance of a GAP analysis for the Medical Device Regulation (MDR) covering Unique Device Identification (UDI) and the General Safety and Performance Requirements. Creation of Technical File Summary Reports, Essential Requirement Checklists and Lists of Applied Standards. Creating and maintaining data sets that support technical file maintenance and sustainability. Remediation of Class 1-3 Instruments under MDD 93/42/EEC including the review of the Clinical Evaluation Report, Risk Management, Biocompatibility

(ISO 10993-1), Labels and Shared Service Documents.

Personal Data:

09/2016 – 04/2017 **Leica Microsystems, Heerbrugg (CH) – QA Manager**
Establish CAPA management in accordance with FDA requirements, process FDA deviations. Accompany FDA Audit. Editing FDA deviations. (Application of new MDR and ISO 13485: 2016) Post Market Surveillance. Ownership for various elements of the quality system including Corrective/Preventive Action (CAPA), Validations, Customer Complaints, Risk Management, Document Control, Management Reviews, ISO:13485:2016, MDSAP. Training, and Internal Audits, party audits. Prepare regular performance reports and metrics for Quality Management Systems, assist other departments in establishing and mining databases to support quality and management objectives

08/2015 – 12/2015 **Roche Diabetes Care, Mannheim (DE) – QA Manager**
Risk Management (60601-x-x), gap analysis, evaluation, FMEA for FDA requirements for an IVDR device. Accompany FDA Audit. Complaint handling, execution of Safety Board Notifications, primary contact person for local authorities in affiliates. Management of Regulatory Submissions under the responsibility of the Local regulatory and safety Officer (LRSO). Establish Quality Management System (QMS), responsible for the setup and the maintenance of the QMS. Key responsibilities: Supervision of Quality Management System: Supporting QMS including documentation management. Implementing Roche Diabetes Care (RDC) Standards in local processes. Ensuring working structures are up to date. Supporting internal and external audits Auditing: Executing internal audits (affiliate oversight audits, management of certification audits.

03/2015 – 08/2016 **Dewimed (DE), QA Manager (Lead)**
External QMB in both companies.
Audits of the Notified Body, the Regional Council and the FDA, development of a new QM system, processing of deviations, conducting of regional council audit, drawing up action plans, analysing and introducing processes. Editing and Creating Clinical Evaluations, CAPA, SOPs, User Manuals, Procedures, Biocompatibility (ISO 10993-1), Labels.
Introduce Post Market Surveillance, Risk Management, Change Management. Create a new QMH, introduce a new Q-System.
Approvals of new products in Europe, Asia and the USA (510 k). Technical documentation according to STED standard.

10/2014 – 01/2015 **Johnson & Johnson (CH), QA Manager**
Technical Editor in the Implants sector for:

- Quality and
- CSV documents and other validation documents. Sterilisation, validation, Cleaning.

Personal Data:

10/013 – 06/2014 **Roche Diagnostic (CH), QA Manager**

Freelance Technical Writer and Quality Manager in the pharmaceutical and medical device industry. Transfer of Blood Analysing Devices from Austria to Switzerland. Responsible for preparation of product and manufacturing documentation according to FDA requirements:

- SAP user
- FDA documents, validation documents, Process Documents, Process Development etc.
- QM-compliant documentation (GMP)
- ISO 13485, ISO 14791 etc.

07/2010 – 09/2013 **TOX, Ravensburg (DE)**

Technical Editor in the Mechanical Engineer industry:

- Preparation of operating instructions, service manuals and all other requires documents
- Support of the internet pages
- Creating brochures and other promotional material
- SAP user.

12/2009 – 06/2010 **Commerzbank AG, Frankfurt (DE)**

Freelance communication manager in the banking industry:

- Create different newsletter for employees and external presentation
- Controlling the communication flow
- Leadership
- Presentations
- Communication planning

06/2006 – 11/2009 **Konstanz (DE), MTS**

Freelance technical writer and Q-Manager in the medical device industry.

- Preparation of user manuals, service manuals and all other required documents such as Marked Components, Work Instructions, Test Instructions, software documents, etc. in English and German.
- Authorization of multiple Class IIb and Class III devices in USA, Asia and Europe. For example, risk analysis, verification and validation documents, instructions for use, specifications, work instructions, labelling and the like.
- Prepare documents for CE approval of multiple Class IIb devices and a Class III (Cardio) device.
- Participation in conducting an FDA audit.
- Participation of several CE certification
- Several 510 k Submission (Lithotrypser and Shock Wave Devices.

2001 – 06/2006 **Freelance Journalist (DE)**

Customers: Stuttgarter Zeitung, Süddeutsche Zeitung, CHIP, PC Professional, Soundcheck, Spectrum of Science and several small magazines, including business magazines and online magazines. Main topics:

- HiFi, music, computer and peripherals. Music electronics,

musical instruments, software, music software, scientific topics, electronics, economic topics, courses.

Professional experience - permanent position:

2000 - 2001	**Lehrinstitut Onken** (CH) Editor in the sector "Teaching aids" - Creating textbooks for correspondence courses in the field of PC applications - Creating copy writing
1998 - 2000	**Vogel Verlag, München** (DE) Editor for the magazine CHIP. "Magazine industry" - Editing articles - Writing own articles (also title topics) - Product Overviews - product presentations - Online Article
1997 – 1998	**Bruchmann Verlag, München** (DE) Editor for the Magazine ELRAD. "Magazine industry" - Editing and writing articles - Product Overviews - Product presentations - Preview - Gloss - Editorial - Structure of the ELRAD homepage
1996– 1997	**B.L.E., Radolfzell** (DE) Technical Editor in the sector "Mechanical Engineering" - Creating manuals
1992 - 1996	**Technical Writer, Perkin-Elmer, Überlingen** (DE) Technical Editor in the "Analyzers" sector - Creation of technical manuals, operating instructions, software descriptions, short instructions, etc. - design of documents - Manage the documents - Archiving - Create change messages - Public relation - Creation of advertising material
1991- 1992	**Eletronic Technician, Perkin-Elmer, Überlingen** (DE) Information electronics in development - Construction of experimental circuits - Tests of circuits and devices - material investigations - Modifications to circuits - Create change messages - Creating test instructions - Create development logs
1990 - 1991	**Service technician, Perkin-Elmer, Überlingen** (DE) Service technician in the service department - Worldwide service for analysers of environmental and process

analytics.
- Conducting seminars for customers, with a focus on service to analysis devices of environmental and process analytics.
- Telephone help and advice
- Create service messages

1986 - 1990 **Bodenseewerk Perkin-Elmer, Überlingen** (DE)
- Information electronics in production with different tasks.

Education:

1984-1986 Bfw, Schömberg, apprenticeship for information electronics with successful completion.

1996 In-house training in the Bodenseewerk Perkin- Elmer as technical editor.

2008
- Specialist management systems with exam and certificate.
- Dudentraing
- Canadian Medical Devices Conformity Assessment System
- Basic in ERP
- SAP

Languages:

German: Native Language

English: Fluent

Key skills:

- Specialist Management systems (TÜV Certificate)
- Dudentraing (Certificate)
- Canadian Medical Devices Conformity Assessment System (Certificate)
- Much experienced in medical directives and formalities. For example, in DIN ISO 13485 Medical Device Directive (MDD), MDR, ISO 13485, EN 60601-x-x and FDA (820 (21 CFR part 820) regulations. Knowledge of the Robert-Koch-Institute guidelines, ISO 15883, ISO 17665, and ISO 17664, Risk Management, CAPA, Supply Management, Change Management, ISO 14971, ISO 10993-.
- Outstanding knowledge of Q-Systems and regulations in Europe and USA, Japan, China South America (Brazil etc.) and more
- Much experienced in pharma rules. For example, GMP
- Strong communication skills
- Excellent writing in German and English
- Readiness of mind
- Analytical thinking
- flexible

Holger Landau