

Dr. Bernd Rieger-Leschus

Linth- Escher-Weg 1 a
CH-8856 Tuggen SZ
Tel.: +41 76 340 04 48
riegerbernd1@googlemail.com



Date of Birth

1st of June 1959

Nationality

Swiss

Civil Status

living in a long-term relationship

Curriculum vitae

CAREER HISTORY

since 11.2023

vali.sys ag, Bubikon, Switzerland

Position Quality Manager (Qualification Specialist)

Responsibilities Creation of documentation in the area of validation and qualification of cleanroom monitoring systems, software validation (GAMP5), development of an ISO 9001 and ISO 17025 quality management system, establishment of a new Q-laboratory for calibration and verification, management of test and measurement equipment. Process optimization according to Six Sigma guidelines, Change-, Complaint-, CAPA- and NC-Management, creation of a competence matrix and in-house training (via video podcasts/webinars also for customers).

01.2023-11.2023

Logotech c/o Capaul Group AG, Jona, Switzerland

Position Technical Consultant Quality (freelance)

Mandates (e.g.) ALPLA Germany, Process Insights Swiss, HeiQ, Hermanos Lopez

Responsibilities Consulting of companies and organizations regarding the creation and assessment of the maturity of the respective Quality System, support during external (customer, technical services, etc.) and internal audits, assistance with CAPA measures, qualification and validation of machines, processes and products, transfer of clean room / sterile / hygiene and microbiology know-how, preparation of organizations for ISO 9001, 15378, 13485, 22000, 14001, 14646, 17025, 16949 and regulatory requirements from MDR and GMP. Lean Six Sigma project support as well as tailor-made Q-systems adapted to the individual case

02.2022-01.2023

Ganahl AG, Mönchaltorf, Switzerland

Position Head of Quality Management

Responsibilities Management and development of the Quality organization, Management of a QA team, participation in the HACCP risk team (FSSC; ISO 22000) and Black Belt in the Lean Six Sigma team, elaboration of strategies to improve the injection-blow molding process, in particular validation of all necessary parameters to comply with GMP guidelines, microbiological/hygienic aspects and particle testing for clean rooms, implementation of the transformation of the company towards ISO 14001, 50001, 45001, 15378 and interface preparations of ISO 9001 for all the aforementioned standards (complete re-design)

09.2018-01.2022

CombiFuel Swiss AG, Wangen, Switzerland

Position Director Corporate Excellence, Associate SCM

Responsibilities Member of the Executive Board, Head of QM

Management and development of the Quality Organization and development of a corporate strategy for the parent company CleanTech Swiss AG, establishment of a previously non-existent ISO 9001 system with electronic QMS, ensuring compliance with UN ECE standards and IATF 16949, interaction with development (R&D) to obtain component certification in accordance with ECE R 115, process development, ensuring supplier evaluation (SCM) and qualification (audits), development of KPIs, regulatory requirements, EMC tests, project coordination, corporate safety officer, Regulatory requirements, plastic injection moulding of electronic housings (design and monitoring) and homologation tests

05.2017-08.2018

MEDISIZE SCHWEIZ AG, Nürens Dorf, Switzerland

Position Head of Quality Management

Responsibilities Member of the management, management and development of the quality organization (15 FTE), ensuring compliance, interaction with production to develop long-term goals, process development in the area of injection blow moulding and injection moulding, ensuring customer needs, development of KPIs, QMS documents, leader of the Site Quality Council, standards ISO 13485, ISO 15378, 21 CFR 820, BRC and ISO 9001 as well as implementation and monitoring of regulatory requirements, budget responsibility, audit management, development of measurement methods, management of the GEMBA board

08.2012-04.2017

SCHOTT AG, St. Gallen, Switzerland

since 01.2015

Position Associate Quality Manager (QM Project Leader)

Aufgaben Deputy Leader of the Quality Department

Monitoring and review of all quality projects from the Balanced Score Card and the Q departments, GMP training, training of the quality department, IMSU (occupational safety and accident prevention) officer for the Q unit, Lean Six Sigma training, management of the Q board with reporting tools (dashboards, BSC reports), technical management of the Q unit (35 FTE) as deputy quality manager, process development injection moulding for syringe production from COP/COC in clean room class ISO 5

07.2013-01.2015

SCHOTT AG, St. Gallen, Schweiz

Position Head of Quality Engineering

Aufgaben Team leadership and ensuring the cGMP and ISO 13485 quality level

Planning, control and expansion of all technical quality aspects in direct interaction with product development, production and engineering (coaching), technical and personnel management of a competent team (13 FTE) with the functions Validation & Verification, Environmental Monitoring, Calibration & Metrology, Quality Engineering and Customer Quality, expansion of technical and professional competences in the team through training and interdisciplinary exchange with other specialist departments, systematic recording and analysis of KPIs, support with customer complaints, internal audits and statistical evaluations (root cause analysis)

08.2012-06.2013	Position	Project Manager Automated Inspection Systems
	Responsibilities	Management of projects for measurement- and inspection-systems, developed for unique and highly sophisticated image processing, tailor made solutions to examine cosmetic aspects and particle contamination from the top to the bottom of medicinal glass products (parenteral pharmaceutical packaging), initiation of corrective actions in case of deviations, creation of GMP-compliant documentation, technical responsibility for the planning, budget, and supply chain, imaging software, measurement references, calibration, glass manufacturing, optics, reproduction, validation (DQ, IQ, OQ, PQ), manufacturing- measurement technique, quality assurance, DIN EN ISO 45000 standards, data analysis, SPC, attribute/variable checking, tolerances, quality loop
1.2012-07.2012		Degradable Solutions AG, Schlieren, Switzerland
	Position	Project Manager Industrialization of Bioresorbable Products
	Responsibilities	Development of implants that eliminate unresolved surgical and dental problems and break down in the body once they have served their purpose; Production according to the strictest GMP requirements (FDA class 3, ISO 13485) in a class-7 clean room; Process validation, production documentation, prototype construction, quality and supply chain management
06.2008-12.2011		Qiagen Instruments AG, Hombrechtikon, Switzerland
05.2009-12.2011	Position	Platform Manager Medical Technology
	Responsibilities	Lifecycle management of several platforms (so-called bio-robots) from development to phase-out, ISO 13485 and cGMP compliance; Six Sigma, project and change management; quality management; TQM; verification & validation; budget responsibility: CHF 1 million; management responsibility for 20 employees in the project
06.2008-04.2009	Position	Manager Final Testing/IPC/CAQ in the Operations division
	Responsibilities	Ensuring testing and qualification of lab equipment; guaranteeing the exacting quality standards (statistics, Six Sigma); compliance with regulatory requirements (cGMP/IVD); management responsibility for 14 employees
05.2005-05.2008		Auto Innovacion S.L., Malaga, Spain
	Position	Commercial/technical manager for the newly created strategic "Automotive" business unit (automotive supply, metal processing in automotive engineering); reported directly to the managing partner; sales and profit responsibility for among others the Export and Logistics business unit
	Responsibilities	Responsible for sales, order execution, logistics, incl. procurement and production; support of the branches in South America; linguistic support during negotiations (Spanish-English); management responsibility for 12 employees; Introduction of the ISO 16949 standard (standardizes existing general quality management system requirements in the automotive segment)

09.1996–04.2005

Gruelvan Industrias S.L., Malaga, Spain
Business unit turnover approx. EUR 75 million

Position Technical (Plant) Manager with powers of attorney

Responsibilities Coordination of domestic and overseas customer business; commercial support services for commercial vehicle projects; development of my own patent ideas and their registration; initiation and implementation of change processes: introduction of ISO 9001, structural and operational organization and CAQ; management responsibility for 35 employees

05.1996–08.1996

Relocation to Malaga, Spain, for personal reasons

09.1994–04.1996

Deutscher Herold (Deutsche Bank Group), Wuppertal, Germany

Position Financial Specialist

Responsibilities Management of construction loans and leasing transactions in the automotive segment; sales of products in the financial services sector

09.1988–08.1994

Leschuplast Kunststofftechnik, Remscheid Lüttringhausen, Germany
(parents' business)
Business unit turnover approx. EUR 10 million

Position Assistant in the commercial/technical department; deputy manager
(from 6.1992)

Responsibilities Assistance in the management of construction projects; acquisition of new customers, introduction of IT in the company; process optimization for the production of injection- and extrusion-moulded parts

STUDIES

2025		Honorary Doctorate for CareHPV, Dunster Business School (Zug)
2013		Hamburg Academy for Distance Studies (Germany) QMB (Quality Management Commissioner), Degree with Diploma Knowledge and skills for the establishment and operation of a modern Quality Management System (QMS), preparation for the TÜV examination
2012		Firebrand Training Academy Course Six Sigma Black Belt certification Content EC Council training in the form of a part-time postgraduate degree, imparting in-depth knowledge on describing, measuring, analyzing, improving and monitoring business processes using statistical means and imparting methods, the use of which students can address the goals and key financial ratios and phenomena as well as subjects relating to customer needs (including internationalization and globalization, customized offers and services). The course of studies ended with a TÜV-certified diploma in May 2012.
2008–2010		Master of Business Administration (MBA) Würzburg University, Germany (Course language: English) Focus: Business integration Master's thesis: Life Cycle Assessment (ISO 14001)
1980–1988		BSc Mechanical engineering , Bergische Universität, Wuppertal, Germany Focus: Plastics engineering Thesis: Rubber elasticity and non-Newtonian flow of molten plastic
	Internships	11.1983–12.1983 Maschinenfabrik Thielenhaus GmbH, Germany Quality assurance 07.1980–09.1980 Battenfeld AG, St. Augustin, Germany Technical maintenance of injection- and extrusion-moulding machines
	Activities	Student representative Management of a student rock band

SCHOOLEDUCATION

04.1965–06.1969	Primary school in Wuppertal, Germany
07.1969–05.1979	Grammar school in Wuppertal, Germany; Qualification: Abitur (school-leaving certificate)

MILITARYSERVICE

06.1979–08.1980	Air force in Nienburg, Germany
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VOCATIONAL TRAINING

09.1988–06.1990	Training as a commercial/technical assistant in my parents' business Remscheid Lüttringhausen, Germany
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TRAINING/FURTHERTRAINING

2024	Cleanroom qualification, Swiss Cleanroom Concept (Magden, Switzerland)
2024	Qualification expert ISO/IEC 17025, VOREST AG (Pforzheim, Germany)
2019/2024	Safety officer SUVA (SiBe), LPG/CNG expert according to SVS examination
2019	Expert for liquid gas powered vehicles (SVS, Switzerland)
2018	GMP Auditor (Concept Heidelberg, Germany)
2017	Scientific Writing (FORUM Institute, Heidelberg, Germany)
2016	QMS according to ISO 9001:2015 (SNV, Winterthur, Switzerland)
2015	Fractography Training (SCHOTT Mainz, Germany)
2014	Mathematical Simulation and Lean Transformation (SCHOTT Mainz, Germany)
2014	GAMP 5 Software- and Computer Validation Specialist (Concept Heidelberg)
2013	Quality Management Commissary (University Hamburg, Germany)
2012	Optical Control Systems (Concept Heidelberg, Germany)
2012	Six Sigma Black Belt, Firebrand Academy (Rotenburg an der Fulda, Germany)
2011	Six Sigma Yellow and Green Belt, SGO (Zurich, Switzerland)
	MS Project 2010 training, Digicomp Academy (Zurich, Switzerland)
	QIAGEN cGMP training (Hilden, Germany)
2009	QIAGEN project management training (Hilden, Germany)
2005	Goals, instruments, commercial and fleet sales procedures, Opel Academy (Rüsselsheim, Germany)
2004	Training as an automobile expert, Modal Academy/DESAG (Mainz, Germany)
1997/1998	Seminar on vehicle reform projects, I.T.V. Academy of the University of Seville (Spain)

LANGUAGE SKILLS

German	Native language
English	Business fluent oral and written
Spanish	Business fluent oral and written
French	Improvable basic knowledge

ELECTRONIC DATAPROCESSING

MS Office, SAP, Majesty ERP, Pivotal CRM, Cobra CRM, CAQ, Fast Track, Test Track, AQTIO, SCIO, BaaN, Epicor, common internet applications i:Solution CAQ, BLP ERP, Odoo, Adobe Premiere CC, DaVinci Resolve, Cyberlink Power Director Video Editor, Cubase Pro 15, Easy DMS, Turbo-Optic, MiniTab, JMP 10 (SAS), SINIC (CAQ)

SPECIALSKILLS

Patents	www.freepatentsonline.com/EP1288066.html
Homesites	www.logotech.biz , www.cr-music-club.ch
Driving Licences	Passenger Car, Truck, Motorboat, Drones
Lecturer	GMP, Lean Six Sigma, Validation and Qualification, GAMP 5, Sterilization, Cleanroom Technology
Hobbies	Playing and recording studio music, skiing, biking, fitness, travelling