

Stefan Schwarzbach

Technical Executive / Project Management / Software Engineering / Medical Devices

Stefan Schwarzbach

Experienced Research, Development and Quality Senior Engineer & Executive
Lilienweg 7, D-82234 Weßling, Germany

Tel. +49 8153 90998813

Fax +49 8105 9098814

Mobil +49 179 5162222

mail@stefan-schwarzbach.de

www.stefan-schwarzbach.de

http://www.xing.com/profile/Stefan_Schwarzbach

<https://www.linkedin.com/in/schwarzbach/>



Summary

Personal data	Married, 2 children, born 1980, German citizenship
Degree	Diploma in computer science, Technical University of Munich
Professional experience	Software development since 2001, Project management since 2007, Quality and Regulatory Affairs since 2007, R&D and Executive Management since 2010
Key aspects	<ul style="list-style-type: none">• Management<ul style="list-style-type: none">○ Development and implementation of corporate goals○ Networking and sales activities• Department management and team leadership<ul style="list-style-type: none">○ Building and disciplinary leadership of teams○ Communication, motivation and conflict resolution○ Mentoring with hands-on mentality• Project Management:<ul style="list-style-type: none">○ Definition of project goals, planning, control, project completion○ Development and introduction of project management processes○ Release, change and configuration management• Software development:<ul style="list-style-type: none">○ Conception, architecture and design, implementation and testing○ Embedded software development, system development○ Wireless data and power transmission systems○ Web 2.0 / RIA / Cloud development○ Game Development (3D Engine, Artificial Intelligence)• Quality management<ul style="list-style-type: none">○ Development of new and optimization of existing QM processes○ Carrying out internal audits and monitoring external audits• Risk management / FMEA<ul style="list-style-type: none">○ Identification, evaluation and minimization of risks• Regulatory Affairs<ul style="list-style-type: none">○ Development of approval strategies, Product approvals

Professional Background

Consulting: Medical Device Company in Sweden

March 2019 - today	Product development of external components and implanted components for an active cardiac support device
Key activities	Project management, software development, hardware development, risk management, documentation, testing
Tasks	<ul style="list-style-type: none">• Responsible for all activities for the product development of all external, patient-worn components.• Responsible for all power and communication related components of the implant• Responsible for upload of 24/7 data to a central data server• Development of firmware for ARM using C / TI-RTOS• Development of application and server software using C#/.Net• Development of hardware using Altium, Spice, Ansys, etc.• Development of mechanics using Solidworks

Consulting: Medical Device Company in Munich

Jan 2019 - today	Development of firmware for a medical diagnostic device
Key activities	Software development, documentation, testing
Tasks	<ul style="list-style-type: none">• Development of firmware for ARM using Eclipse• Development of application test software using C#/.Net• Definition and implementation of the integration and acceptance tests

Consulting: Automotive Company near Munich

Apr 2017 - today	Development of firmware and application test software for measurement devices located in cars. Development of electronics hardware for measurement devices
Key activities	Software development, documentation, testing Electronics development, documentation, testing
Tasks	<ul style="list-style-type: none">• Development of firmware using Atmel Studio• Development of application test software using C#/.Net• Development of electronics using Altium Designer• Definition and implementation of the integration and acceptance tests

Consulting: Medical Company in Switzerland

Jun 2014 - today	Development of firmware for an active implant
Key activities	Software development, documentation, testing
Tasks	<ul style="list-style-type: none">• Development of the implant firmware• Development of firmware for external devices (Inductive Implant Charger)• Development of application software• Development of toolchain applications• Documentation of the development results according to IEC 62304• Definition and implementation of module, integration and acceptance tests• Version and configuration management

DUALIS MedTech GmbH

Dec 2010 - Jan 2019	Chief Technical Officer (CTO) since March 2012, previously Head of Development in Software & Electrical Engineering
Key activities	Development and management of the development department, Monitoring of all development activities and project management, Technical Company representative towards customers, investors and suppliers

- Tasks
- Coordination of all development projects
 - Allocation of resources and budgets in collaboration with the project leaders
 - Assist project leaders in planning development tasks
 - Definition of staff goals, tracking the defined goals, staff training
 - Definition of internal development and quality standards in software-, electrical- and mechanical engineering
 - Planning and managing projects (> 3 million budget, > 15 employees)
 - Hands-on focus on software development, but also in electrical engineering
 - Internal audits and external audits
 - Support in risk management

Ingenio Solutions GmbH

Jul 2014 - Feb 2018 Development, production and sales of NeoCare baby monitor, the next generation baby monitor including vital sign tracking

Key activities Chief Executive Officer (CEO), Founder, Shareholder

- Tasks
- Building up company from scratch
 - Oversee all development activities
 - Software and algorithm development
 - Big data and cloud storage
 - Responsible for all sales and investor related activities

Consulting: Online Programmierung GmbH

Jul 2014 - Feb 2018 Porting and integrating existing applications into the Eclipse framework

Key activities Software development, documentation, testing

- Tasks
- Development of Eclipse plugins
 - Porting existing applications from C ++ / MFC to Java / SWT
 - Documentation of the development results
 - Definition and implementation of the integration and acceptance tests
 - Version and configuration management

DUALIS MedTech GmbH

Oct 2007 - Dec 2010 Project management, Quality Management consulting, Regulatory affairs, Software development, IT consulting

Key activities Project management, company strategy consulting, implementation and monitoring of a quality management system according to EN ISO 13485: 2003 / AC: 2009, development of approval strategies for active implants, software development, support of the IT infrastructure

- Tasks
- Definition of project goals from the requirements
 - Project planning and structuring
 - Risk assessments, cost planning, resource planning
 - Project implementation and follow-up, technical guidance of assigned employees
 - Project Reviews
 - Planning, design and partial implementation of an infrastructure for storing patient data in cloud storage, big data
 - Planning, design and development of a web-based frontend to view patient data (Rich Internet Application / RIA, based on the Google Web Toolkit / GWT and Java) and Windows clients (C ++ / C #)
 - Planning, conception and partial development of software for embedded systems (ARM, Windows / Linux, ASM / C / C ++), control of data buses (CAN / SPI / SSP / I2C / UART, USB) for the connection of peripherals (Bluetooth, MICS, Displays, buttons, ...)
 - Development, implementation and monitoring of quality management systems and training in accordance with EN ISO 13485
 - Implementation of risk management
 - Supervision of external audits and internal audits
 - Regulatory affairs, cooperation with notified bodies

Consulting: OPG – Online Programmierung GmbH

Dec 2007 – Feb 2011 Further development of a comprehensive network and file management software for the mainframe BS 2000 and Unix derivatives. Further development of a comprehensive text, hex and binary editor for Dos, Windows and Unix

Key activities Consultant in software development

- Tasks
- Conception and development of APIs.
 - Development of test environments
 - Implementation of customer requirements

Silent Dreams

Aug 2004 – Dec 2008 Development of complex computer games and other consumer entertainment products for PC and console.

Key activities Chief Executive Officer (CEO), Chief Technical Officer (CTO), Founder, Shareholder

- Tasks
- Lead game engine programmer
 - Development of a computer game based on a specially developed 3D engine and middleware (Windows, ASM / C / C ++ / C #, OpenGL / DirectX)
 - Negotiations with publishers and other investors
 - Public relation
 - Budget controlling, reporting, project management

German Aerospace Center (DLR)

Oct 2006 – Oct 2007 Project management, development of software for different mechatronic systems

Key activities Conception and development of hardware-related software.

- Tasks
- Control of various displays, input devices and radio modules for a control and monitoring handheld for an artificial sphincter implant (ARM7, ASM / C).
 - Development of monitoring and evaluation software for in vivo tests
 - Design and EMC simulation of an antenna for implants (402-406 MHz).
 - Development of a motor controller for brushless motors.
 - Control based on various sensors and physiological values.
 - Design of evaluation boards.

Trainings

Apr 2011 – Jun 2012 **NLP practitioner**
Comprehensive training for employee leadership, discussion techniques, conflict management and employee motivation

Nov 2011 **Process optimization in the medical technology industry**
Process Management, ERP Systems, Process Analysis and Validation in Software Development, Process Optimization with MITO, Kaizen and Six Sigma, Scrum Project Management, Lean Management, Product Approval

Feb 2011 **Product design and usability in medical technology**
Information, normative specifications for the implementation of the usability process according to EN ISO 62366. Explanations based on practical examples on the topics User Centered Design and Usability Vs. Corporate Identity

Jul 2010 **Clinical evaluation and testing of medical devices**
Regulatory requirements for assessment and testing (including EU-RL, MEDDEV, NB-MED, EK-MED, MPG), introduction to methods and elements of clinical evaluation, clinical evaluation based on clinical data, advantages and disadvantages, terms, sequence, essential content, documentation requirements

May 2010 **Process validation for medical device manufacturers**
Regulatory requirements for process validation, explanation of design qualification (DQ), installation qualification (IQ), operational qualification (OQ), process validation and risk management, process FMEA, documentation requirements
Regulations and standards for manufacturers of medical devices

Regulations in Europe and the USA, guidelines, guidelines, harmonized standards, recognized consensus standards, procedures for changes to regulations, work instructions for the control of standards and regulations

May 2010	Regulations and standards for manufacturers of medical devices Regulations in Europe and the USA, guidelines, guidelines, harmonized standards, recognized consensus standards, procedures for changes to regulations, work instructions for the control of standards and regulations
May 2010	CE marking of medically used software Software lifecycle processes (EN 62304), programmable electrical medical systems (EN 60601-1-4) and FDA guidelines, application of the risk management process, software documentation requirements
Feb 2010 – Apr 2010	Risk management according to DIN EN ISO 14971 for manufacturers of medical devices Regulatory requirements for risk management, structure and structure of the standard, risk management. Risk analysis, techniques for analyzing and assessing risks, impact on the QM system, definition of mitigation measures, creation of a risk management file, documentation and archiving
Feb 2010 – Apr 2010	Quality management according to ISO 13485: 2003 + AC2007 Structure of the standard, tasks and responsibilities of the QM representative, requirements for the QMS from ISO 13485 and the relevant EU directives (90/385 / EEC, 93/42 / EEC), implementation of the requirements (QM manual, procedures, Work instructions) and product documentation (DHF, DMR, DHR)
Mar 2010	Design and development of medical devices Regulatory overview, design process according to EN ISO 13485 and FDA 21CFR820, documentation structure and filing (Device Master Record, Design History File, Device History Record), support in creating an SOP "development".
Oct 2009	Project Management Intensive training according to PMI standard Project initiative, project planning, project risks, project controlling, project team management, claim management

School and University

Oct 2001 – Jun 2006	Study of Computer Science, Diploma, Technical University of Munich Main focus technical computer science and electrical engineering Graduation with very good result (1,5)
Sep 1991 – Jul 2001	Christoph-Probst-Gymnasium Gilching Mathematisch-Naturwissenschaftlich New Language Gymnasium Graduation with high school diploma
Sep 1987 – Jul 1991	Arnoldus Grundschule Gilching

Patents

EP3248650B1	Improvements in transcutaneous energy transfer systems
EP3131623B1	Improvements in transcutaneous energy transfer systems
DE102012201073B4	Tragevorrichtung zum Tragen einer Sendespule
US9265961B2	Carrying device for carrying a transmitting coil on a patient's body
EP2806944B1	Support device for supporting a transmission coil on the body of a patient

Publications and lectures

- 2011 **Transcutaneous Energy Transfer System (TET) for implantable cardiac assist devices and total artificial hearts**
B. Vodermayr, C. Riecke, N. Helms, S. Schwarzbach, N. Reiss, J. Gummert, A. Welz, G. Hirzinger, W. Schiller, T. Schmid (Wessling, Bad Oeynhausen, Bonn)
- 2010 **Transcutaneous Energy Transfer System (TET) with novel external carrier system**
B. Vodermayr, C. Riecke, N. Helms, S. Schwarzbach, N. Reiss, J. Gummert, A. Welz, G. Hirzinger, W. Schiller, T. Schmid
5th European Mechanical Circulatory Support Summit (EUMS) 2010
- A Transcutaneous Energy Transfer System**
B. Vodermayr, C. Riecke, N. Helms, S. Schwarzbach, N. Reiss, J. Gummert, A. Welz, G. Hirzinger, W. Schiller, T. Schmid
MEDTEC Europe 2010
- Transcutaneous Energy Transfer System (TET) with novel external carrier system**
B. Vodermayr, C. Riecke, N. Helms, S. Schwarzbach, N. Reiss, J. Gummert, A. Welz, G. Hirzinger, W. Schiller, T. Schmid
European society of artificial organs (ESAO) 2010, Journal of Artificial Organs
- 2009 **German Artificial Sphincter System (GASS) - Improvements and Innovations**
S.Schwarzbach, F. Goldschmidboeing, H.J. Schrag
TAR Conference 2009
- 2007 **Grotesque - Innovations and new technical features**
S. Schwarzbach, R. Kerstan, C. Edenfeld
Games Convention 2007
- Improvements and Innovations of the DLR-VAD and TET-System**
T. Schmid, B. Vodermayr, S. Schwarzbach, D. Liepsch, A. Welz, G. Hirzinger
ESAO Conference 2007, Journal of Artificial Organs
- 2006 **Grotesque - a new german roleplay game**
S. Schwarzbach, R. Kerstan
Games Convention 2006
- PID vs Fuzzy Logic Control for new Adaptive Transcutaneous Energy Transmission System (TET) for Implantable Devices**
Vodermayr, B.; Schwarzbach, S.; Gruber, R.; Schmid, T.; Schiller, W.; Hirzinger, Gerhard; Liepsch, D.; Welz, A., Journal of Biomechanics, 39 (1), S. 250
- 2005 **Adaptive Transcutaneous Energy Transfer System (TET) for implantable devices**
B. Vodermayr; S. Schwarzbach; R. Gruber; T. Schmid; W. Schiller; G. Hirzinger; D. Liepsch; A. Welz.
European society of artificial organs (ESAO) 2005, Journal of Artificial Organs

Programming languages and environments

Programming languages	C, C++, C#, Objective-C, J#, Java, PHP, SQL, X86-Assembler, ARM-Assembler, 8051-Assembler, LabVIEW, Perl, ...
Operating Systems	Windows, Linux, *BSD, HPUX, MacOS X TI RTOS, free RTOS, Keil RTOS, QF Framework, iOS 3.x/4.x/5.x, Android 2.x/3.x/4.x
Hardware Systems	ARM / Cortex, 8051, Intel X86/X64, iPhone, Android, ...

Bus Systems	I2C, CAN, CANFD, SPI, SSP, UART, 1-Wire, USB, SMBUS, Ethernet, FlexRay, ...
Wireless Systems	WLAN, Bluetooth, MICS, MedRadio, ZigBee, NFC
Development tools	Perforce Helix ALM, CVS, TRAC, Subversion, SAP Business One, MS Project, Enterprise Architect, ...
Software IDEs	Eclipse, Keil uVision, IAR Workbench, AVR Suite, Xcode, Labview, Visual Studio, ...
Hardware IDEs	Altium Designer, Spice, Ansys
Mechanical IDEs	Solidworks
Web languages and Web kits	.Net Core SDK, CSS, HTML, JavaScript, XML, XSLT, XPath, WSDL, GWT, Java Servlets, jQuery, Mootools, ExtJS, Flex, Gears, GwtExt, SmartGWT, SOAP

Languages

German	Native language
English	Fluent in speech and writing
French	Basic knowledge

Hobbies

Sports	Handball, Basketball, Beach volleyball, Hiking
Music	Choir, Singing, Musicals, Concerts
Traveling	