Key Projects and Expertise

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PERIOD	EXTRACT OF SOME MAJOR INDEPENDENT CONSULTING PROJECTS
Jan. 2021 – Until now	Senior Quality Engineering & Project Lead Medical Devices: Global Corporate Integration Project (Germany and Switzerland plus 5 Sites in France, Ireland and U.S.A.) - Project Coordinator: o Integration of Corporate Quality System at 5 acquired Sites o Create and Maintain Site-Based Quality Integration Plans o Update the Legacy Quality System into EU-MDR- Ready Status o Aligned Remediation Approach with different Workstreams (Risk Management, Engineering, Manufacturing, R&D) o KPI reporting and communication with M&A-Team and other Stakeholder - Integration / Remediation Support: o Update of Risk Related Documents (RMF, RMR, FMEA´s) against Global Corporate- and EU-MDR - requirements o Update of the Inspection- and Control-Plans o Initiate Non-Conformance- / PMS- Activities: ▪ CAPA coordination (for internal and external findings) and ensure proper remediation ▪ Include NC/CAPA/Complaints/Scrap Rates/Trends into Remediations and Corrective Activities o Support Updates of SOP´s, WI´s, etc. o Provide guidance and training for implementation of robust structures on the integrated and remediated activities.
April 2020 – Dec. 2020	Senior Quality Engineering & Project Management Pharmaceuticals: Reconstruction and Remediation Project, (Southern Germany) - Project Coordinator: o Reconstruction of Manufacturing Area (incl. planning and monitoring of new equipment) o Establishing a new Hygienical concept o Establishing a ShopFloor Management for 2 Production Sites o KPI reporting and communication with stakeholder o Close communication with federal authorities (e.g. Regierungspräsidium Bayern) o CAPA coordination (for internal and external audit findings), own the CAPA plan and ensure proper remediation - Project Support: o Support Pharmacovigilance Topics: ▪ Complete Compliance tasks on time e.g. Review and Remediation of Complaints ▪ Input for root cause analysis in case of new deviation / Customer Complaints and other non-conformances o Guidance and training for implementation of robust structures on the shop floor o Establish state of art quality processes (SOPs, WIs, etc.) and support Change Control

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Mar. 2019 – Dec. 2020	Senior Quality Engineering & Project Management
	Medical Device (Coated / Resorbable): M&A Integration Project
	(Israel)
	
	- <u>Project Coordinator:</u>
	  - Confirm Due Diligence Results and asses the State of Compliance of the Quality System versus Internal (Corporate) and Regulatory Standards (ISO, FDA, etc.)
	  - Close reporting to local Core Team Leads and global M&A-Leader
	  - Prepare Manufacturing Transfer from Israel to European Sites of the acquiring Corporation
	- <u>Project Support:</u>
	  - Audit existing procedures and documents to the standards and report non-conformances and findings (both current state and retrospectively):
	  ▪ Analyzing of Audit- and Inspection reports (Internal / External), NC/CAPA-Files, Complaints and Complaint Handling, Maintenance Reports, Monitoring Data, Trainings, etc.
	  ▪ Perform CAPA verification of effectiveness and add activities as necessary.
	  ▪ Batch record review
	  - Update the Manufacturing- and Quality System to meet the Corporate Standards
	  - Update the Health and Safety System to meet local, international and Corporate Requirements
	  - Update the Complaint Handling System to reduce the runtime and ensure a compliant communication to the involved authorities
	  - Make recommendations to achieve compliance where shortfalls are found and identify improvement potentials, which increase the productivity and efficiency of manufacturing and facility and operational practices.
	
	  - Training – Support:
	  ▪ FDA Preparation (1st time FDA-Audit in the Company)
	  ▪ Support during the FDA inspection
	  ▪ Thorough understanding of GMP and GCP (Good Clinical Practices) guidelines.
	  ▪ Consultancy and guidance of all employees regarding Risk Assessment, Risk Analysis, Maintenance, NCR, CAPA, Complaint-Handling, etc
	  ▪ GCP, GVP, GMP, cGMP, GDP etc.
	  - Planning, implementing, follow up projects of
	  ▪ Pest Control
	  ▪ Fatigue Testing
	  ▪ Preventive Maintenance
	  ▪ Launching Product in the US

Mai 2018 – Mai 2019	Senior Quality Engineering
	Medical Device: Audit Readiness (FDA / TUEV)
	(Austria)
	
	- <u>Project Coordinator:</u>
	  - Leading 2 small project groups
	  - Tracking of Deadlines and Meeting with local and corporate Management
	
	- <u>Project Support:</u>
	  - Support ongoing Product- / Manufacturing Transfer

	○ Checking all the relevant internal and supplier related documents against former Audit-Findings ○ Assess NC/CAPA- and Complaint-Status ○ Coordination of ongoing activities incl. newly found corrective / preventive activities ○ Audit Preparation and Supporting Mock Audit
Aug. 2017 – April 2018	Senior Engineering Expert Life Sciences: Process and Cleaning (Re-)Validation and Document Review (NRW, Germany) - Project Support: ○ Support Validation activities: ▪ Performing Risk Assessment / Review the legacy Validations and Documentation ○ Analyzing all Supplier related documents (incl. Quality Agreements) ○ Analyzing relevant Engineering document as well as related SOP´s and WI´s ○ Ensure Traceability ○ Audit preparation
Mar. 2017- Aug. 2017	Senior FDA Audit Expert Pharmaceuticals: FDA Readiness for Solid-Drugs (Berlin, Germany) - Project Support: ○ FDA Preparation (1st time FDA-Audit of the Company) ▪ Gap Assessments ▪ Remediation Process ▪ Batch Record Review ○ Support Preparations and Documentation for: ▪ Launching Product in the US ▪ Setting up new documents for QMS, Production, QC for the US-Market ○ Support during the FDA inspection ▪ Front-Room / Back-Room
Oct. 2016 – Feb. 2019	Interim Deputy of Site Quality Lead (during Site Closure) Medical Devices: Complete Site Decommissioning (Austria) - Project Coordinator: ○ Coordinate the Manufacturing Transfer during Site Closure with local (Austria), European (Switzerland, Germany) and Global (U.S.A.) Sites and Leaders ○ Coordinate the structured Archiving of all Manufacturing- and Quality related Documents and Records into a Swiss Archive ○ Tracking of Deadlines and Meeting with local and corporate Management - Project Support: ○ Support ongoing Product- / Manufacturing Transfer activities to ensure the full compliance (internal and external requirements) until full closure ○ Taking over continuously more activities for continuously reducing internal employees: ▪ Quality Management, ▪ Complaint Handling, ▪ CAPA-Management, ▪ EHS-Management and

	▪ Doc. Control incl. Record Management and Archiving ○ Checking all the relevant internal and supplier related documents against former Audit-Findings to ensure full compliance during ongoing external audits until site-closure ○ Prepare and Lead Quality related Meetings: ▪ Monthly Management Reviews ▪ Ongoing NC/CAPA- and Complaint-Status Meeting ○ Coordination and Support of ongoing Activities incl. newly found Complaints, Manufacturing Investigations and Corrective / Preventive Activities ○ Audit Preparation and Supporting Mock Audit ○ Support the controlled and structured Hand-Over of the Site at its last day.
June 2016- Oct. 2016	Senior Quality Engineering & Project Support Pharmaceuticals: FDA-Readiness Check (Southern Germany) - <u>Project Coordinator:</u> ○ Assess the current status against previous FDA- and Notified Body-Findings ○ Identify urgently needed activities before the FDA-Audit is taking place ○ Plan and Support Remediations - <u>Project Support:</u> ○ Support the ongoing Updates of SOP´s / Engineering Documents / Risk Management Files ○ Review and optimize the Traceability of Products ○ Finish the open Complaint Handling activities ○ Preparation the Audit (incl. “Behavior-Training”)
April. 2016- Feb. 2017	Senior QA- and Complaint-Handling Expert Pharmaceuticals (Animals): (Aseptic Pharma) (Southern Germany) - <u>Project Coordinator:</u> ○ Assess the current status of general internal and external (Sales) Complaint Handling Activities for Vials, Ampules, Crèmes, Cartridges filled in a sterile/aseptic environment ○ Report Results, KPI´s and the deviations from the planned status to the local, European and Global Management ○ Identify urgently needed activities and potential for improvement ○ Plan and Support PQR´s - <u>Project Support:</u> ○ Perform Gap Assessments for Audit-relevant Documents and Workstation-Setups (also against GCP, GVP, GMP, cGMP, GDP etc.) ○ Support and Optimize Batch record Reviews ○ Support Change Control with creation of classification and review of cGMP-oriented processing ○ Support and Coaching of QA- and Production Employees in ▪ FDA Preparation and FDA Readiness ▪ Support during the FDA inspection ○ Planning, implementing, follow up projects after FDA-Audit ○ Initiate and Monitor Remediation Process

Jan. 2016-
Mai 2016
	Senior Quality Engineering & Audit Support
	Medical Devices: Prepare Re-Certification of Orthopedic / Trauma Implants and Combination Products
	(Austria)
	
	- <u>Project Support:</u>
	  ○ Review and Update related Quality Documents
	  ○ Review and Support ongoing activities for NC/CAPA´s and Customer Complaints
	  ○ Support needed Supplier Audit
	  ○ Perform internal "Worst Case"-Audit (Role as a "Worst-Case"-Auditor)
	  ○ Trainings local Management in Audit Topics

April 2015 -
April 2016
	Interim Lead Quality Engineer (Development & Innovation) for Combination Products
	Pharmaceuticals and Life Sciences: Vails, Ampules, Syringes (Glass and Plastic), Sterile/Aseptic Production
	(Austria)
	
	- <u>Project Coordinator:</u>
	  ○ Coordination of preparation of the submission documents for FDA
	  ○ Performing Gap Assessments, Review Risk-Management documents (e.g. FMEA, Risk Assessment, Risk Analysis)
	  ○ Projects Coordination of Sites in EU / US
	  ▪ Leading a small project group
	  ▪ Align Project Managements for Pharmaceutical Development
	  ○ Responsible for budget and planning of resources
	  ○ Review and Monitor Quality assurance within the project
	  ○ Tracking of Deadlines and Meetings
	- <u>Project Support:</u>
	  ○ Trainings Project Management for Pharmaceutical Development
	  ○ Quality assurance within the project
	  ○ Review legacy Recalls, Deviations, NC/CAPAs, Complaints, etc. to identify trends and ways of optimizations
	  ○ Support new / incoming Complaints and Recalls / Field Actions

Mar. 2015 –
Dec. 2015
	Senior Quality Engineering & Project Support
	Medical Devices: Orthopedic / Trauma / Sports Med Implants and Instruments
	(Southern Germany and Switzerland)
	
	- <u>Project Support:</u>
	  ○ Support the local Project Managers and Coordinate a structured Remediation between 3 Sites
	  ○ Support the Change of the complete Product Portfolio (sterile and non-sterile) to UDI (Unique device identification) Compliant Labels
	  ▪ Affected products: Sterile Implants, Single-Use, Injectable cements and artificial bone, antibiotic coatings, BMPs
	  ○ Update the internal SOP´s and WI´s to ensure a compliant creation and inspection of UDI-conforming Barcodes and Human readable Information on Labels
	  ○ Point of Contact for all external suppliers and internal worldwide divisions regarding UDI
	  ○ Review ongoing and newly created NCR´s/CAPA´s and Complaints against Labeling / Traceability Issues and implement appropriate Corrections and Remediations

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Jan. 2015 - Mar. 2015	FDA – Readiness Check-Up Medical Devices: Orthopedic / Trauma Implants (Switzerland) - Project Support: o Reviewing previous Regulatory- and Audit- findings and responses o Checking the implemented Actions / Corrections of the previous findings and responses (after the last audit) and initiation of a proper remediation o Checking the last NCR´s/CAPA´s/Complaints/Scrap-Rates against potential risks in the upcoming audit and initiation of additional activities o Audit preparation incl. Coaching in "how to act and react in Audits" o Ensuring that the facility is "Audit Ready" (clean and all are prepared and know how to behave)
Jan. 2015 - Feb. 2015	Senior Quality Engineering & Project Support Medical Devices: FDA-Readiness - Final Check (Austria) - Project Support: o Assess the current status against previous FDA- and Notified Body-Findings o Review closed activities before the FDA-Audit is taking place o Support the last ongoing Updates of SOP´s / Engineering Documents / Risk Management Files o Support finishing the open Complaint Handling activities o Preparation the Audit (incl. "Behavior-Training")
Aug. 2013 – Dec. 2014	**Global FDA Remediation Project** **Medical Devices, Switzerland, Germany and U.S.A.** **Project 2:** Improvement of Processes, Documentation and Sterility Assurance for Implants and Instruments of the newly created Loaner Department (Switzerland) - Project Support: o Support for new Loaner Department: ▪ Designing new SOPs ▪ Setting up a new Quality System acc. Corporate Standards on-site ▪ Quality Agreements against updates needed for the new site ▪ Establishing a new Training System for new employees o Review legacy documentation for improving the Loaner System ▪ Perform Complaint- and CAPA-Reviews ▪ Review Scrap- and Review-Rates o Support Certification: ▪ Preparing for final internal (Corporate-) Audit and ISO Certification ▪ Support closure of TÜV-Findings of "Sister-Sites" ▪ Preparation of FDA-Audit **Project 1:** Review of Documentation (DHRs), Archiving System and Sterility Assurance Remediations for Implants and Instruments against FDA- and TÜV-Findings and establish appropriate Remediation activities (Switzerland, Austria and Germany)

	- Project Support: o Determine and report on the state of compliance of the quality system versus regulatory standards (ISO, FDA, etc.) to Core Team - / Workstream- Leads o Audit site related procedures to the standards and report out on findings (both current state and retrospectively) in different sites in Switzerland, Austria and Germany. ▪ Provide Audit reports as directed to the local, European and US-Management. ▪ Make recommendations to achieve compliance where shortfalls are found. ▪ Review and Support of Dose Mappings and Dose Audits and Review documentation of Supplier ▪ Review the Validation of Gamma Irradiation - Sterilization ▪ Optimize the Pest Control System at 2 Manufacturing Sites ▪ Support the Cleaning Validation, Cleanroom Qualification, and "Water"-Validation o Analyzing and Supporting Activities: ▪ Perform root cause analysis and corrective / preventive actions for CAPAs as necessary. ▪ Perform CAPA verification of effectiveness as necessary. ▪ Analyzing NCR- and CAPA files. ▪ Analyzing inspection activities. ▪ Analyzing maintenance reports and monitoring data. o Bringing in of improvement proposals, which increase the productivity and efficiency of manufacturing and facility and operational practices. ▪ Consultancy and guidance of all employees regarding maintenance, NCR, CAPA etc. ▪ Support Internal Audit o Improve the local archiving activities to prevent similar failures in the future
May 2013 – Sept. 2014	Quality Engineering & Project Support R&D company for Pharmaceutical Coatings and Innovative Products, Germany - Project Support: o Support in upgrading the Quality Management (SOPs, Training) o Preparation for FDA Submission and Audit ▪ focus: Complaints, CAPA, Risk Analysis, Health and Safety Environment, Field Alerts and Actions, etc.) o Implementation of a Product Management o Implementation of a Supplier Management o Support in Technical documents / DMFs for Products: BMPs, vascular grafts o Affected products: BMPs, Vascular Grafts, Bone Grafts, Antibiotics, Aseptic productions
Jan. 2013 – Dec. 2013	Quality Engineering and Interim Management Manufacturer of Hyaluronic Acid, Germany and China - Project Support: o Interim support for the International Product- and Sales Manager o Support in the Quality Management (CAPA, Complaints, Risk Analysis, etc.) o Training of customers and distributors (worldwide)

	○ Initializing and support of studies for international market approvals (FDA, SFDA, CE) ○ Affected products: Hyaluronic Acid, Aseptic production, Injectable
Oct. 2012 – Jul. 2013	Quality Engineering & Project Support Manufacturer of Medical Devices, Germany and Poland - <u>Project Support:</u> ○ Installation of a complete Quality Management System for Trauma Implants and Instruments (according to ISO 13485) including SOPs, Development procedures, CAPA-System, Complaint Handling, etc. and monitoring of the market approvals, ○ Implementation of a Product Management ○ Training of external suppliers ○ Implementation of a HSE-System ○ Support in the market approval procedures (CE-Mark) ○ Affected products: Sterile Implants
Sep. 2012 – Aug. 2013	Quality Engineering & Project Support Manufacturer of Dental Implants, Germany and Canada - <u>Project Support:</u> ○ Upgrade of the Management System ○ CAPA, Pest Control, Risk Analysis, etc.) in preparation for FDA and CMDCAS for Ceramic semi-finished goods and products and Colors for Ceramics ○ Support in Product Management
Oct. 2010 – Oct. 2012	Quality Engineering & Project Support Manufacturer of Heart Support Devices (artificial lungs), Germany - <u>Project Support:</u> ○ Implementation of a complete Quality- and Health & Safety Management System (SOPs, Development procedures, CAPA-System, Complaint Handling, Field Action, Clean Room validation, etc.) ○ Support in the market approval procedures (CE-Mark) ○ Affected products: Sterile products
Jan- 2009 – Sep. 2010	Quality Engineering & Project Support Manufacturer of Medical Instruments, Germany - <u>Project Support:</u> ○ Installation of a complete Quality and Health & Safety Management System (SOPs, Development procedures, CAPA-System, Complaint Handling, etc.) for Ceramic Instruments ○ Support in the market approval procedures

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PERIOD	PROFESSIONAL EXPERIENCE
since 2018	Member of the DIN, Germany
since 2013	External Auditor (ISO 9001, 13485 and MDD active/non active) TUEV Nord Cert GmbH, Essen
since 2013	Founder Member of DIN EN 15224-Competence-Network
since 2011	Expert for Quality Management and Medical Devices mdc – medical device certification GmbH, Stuttgart
since 2011	Certified EHS Manager („SIFA“ or „FASI“) Verwaltungs-Berufsgenossenschaft, Germany and WiFi, Austria (since 2020)

EXPERIENCE IN THE FIELDS	PERIOD
Aviation	2010
Automotive	2009
Pharmaceutical Industry / Life Sciences Industry	2006
Medical Devices Industry (all Product Classes !)	2001
Emergency Medical Service / Hospital	1995

METHODICAL EXPERIENCE (EXTRACTS)	EXPERIENCE SINCE

<u>Pharmaceutical- and Medical Device Industry specific</u>
- GMP, cGMP, GDP
- Quality Systems- and Quality Assurance- Support
  ○ incl. “Daily Business”-Support
- Validation, Verification and Qualification Activities:
  ○ Plannings and Documentation (Master Plans, Reports, etc.)
  ○ Qualification/Validation according to ICH-Guidelines
  ○ Validation / Gamma Irradiation – Sterilization
- Doc. Control:
  ○ Creation / Implementation, Maintenance and Update of Quality Systems and Documents
  ○ DHR / Master Records and Batch Reviews
  ○ Training
  ○ Document Management
- Marketing, Business Development and Project Management
  ○ Assessments and Reporting
  ○ Workstream-Leads
  ○ Remediation
  ○ M&A
  ○ Integration
  ○ Site Decommissioning
- Contracts / Agreements / Supplier Management:
  ○ Quality Agreements
  ○ Supplier Quality
  ○ Design and implementation of APR/APQR
	2001

○ URS - Product Development and Product Management ○ incl. Sales Support - Communications with Authorities: ○ FDA, BSI, AGES, BfArM, Swiss Med, ANVISA, Notified Body, etc. - Labeling, UDI (EU/FDA) and TrackAndTrace (Pharma) - Health and Safety Management and Environment ○ incl. Pest Control Support	
<u>Standards, Regulations and Guidelines:</u> - ISO 9001; ISO 10993-1; ISO 13485; ISO 14155-1 and 14155-2; ISO 17025; ISO 19011; 21 CFR 820; CMDCAS; ICH Q9, Q10; TR 24971; IEC 62971 - 2017/745 (EU MDR) ; 93/42/EEC (MDD); 90/385/EEC (AIMD); 2017/746 (EU IVDR); 98/79/EC (IVDD)	2001
<u>Post Market Surveillance / Vigilance Systems:</u> - Establishment and execution of Field Alerts and Escalation process - Creation and Executions of CAPA´s, NCR´s and Deviations - Support Recalls and Field Actions incl. relevant communications with Authorities - Reporting (e.g. PMS-Reports; PSURs, etc.)	2001
<u>Risk Management:</u> - acc. ISO 14971, 5-Why, Root Cause, FMEAs, Risk Assessments, Risk Analysis, Risk Based Approaches, etc.	2003
<u>Auditing and Training:</u> - Internal Auditor - Performing and Support of Internal Audits, Supplier Audits, External Audits and Worst-Case Audits - Support in Remediation of Audit Findings - Trainings (incl. Code of Conduct of Audits)	1999

TECHNICAL EXPERIENCE EDV-SOFTWARE (Extracts)	**EXPERIENCE (SINCE)**	**LEVEL OF KNOWLEDGE (Basic, Intermediate, Advanced)**
Software- / ERP- / Doc. Control- Systems:		
- SAP	2006	Advanced
- VFlow	2008	Intermediate
- Filemaker	2009	Intermediate
- AGILE	2010	Advanced
- EtQ	2010	Advanced
- TrackWise	2011	Advanced
- LIMS	2011	Intermediate
- Pharm. Education	2011	Advanced
- SHAPE	2011	Advanced
- SDMS	2011	Advanced
	2011	Advanced
Conference Tools: - TEAMS, WebEx, ZOOM, FaceTime, CISCO, etc.	2006	Advanced
Windows and MS-Office Tools: - Word, Excel, PowerPoint, MS-Visio, MS-Projects, Office 365, Microsoft365, etc.	1995	Advanced

Apple OS and Tools: - IOS, iPadOS, WatchOS and MacOS - Apple Developer (since 2011)	2008	Advanced

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ADDITIONAL EDUCATION (EXTRACT)	EXPERIENCE (SINCE)
Zertifizierter Validierungsbeauftragter in der pharmazeutischen Industrie	2020
Certified Health and Safety Manager (Sicherheits-Fachkraft) for Austria, WiFi Linz	2020
Representatives for laser security (electromagnetic und optical radiation) Verwaltungs-Berufsgenossenschaft (professional associations), Bezirksverwaltung Duisburg	2013
Safety representatives for medical devices (according to §30 of the German law for medical devices and the european guidelines) mdc – medical device certification GmbH, Stuttgart	2012
GMP Certificate	2011
Pharmaceutical Contracts: GMP and Legal Compliance	2011
Health and Safety Manager (according to §7 ASiG), VBG und BG-W Verwaltungs-Berufsgenossenschaft (professional associations), Bezirksverwaltung Duisburg	2011
SCC for executive leaders Verwaltungs-Berufsgenossenschaft (professional associations), Tangermünde/Stendal	2010
Certified IRCA-Lead-Auditor TÜV NORD CERT GmbH, Essen / Nigel Bauers, London	2010
QEP-Multiplicator (German management systems for physicians) Kassenaerztliche Bundesvereinigung, Berlin	2010
Medical Device Advisor (Medizinprodukteberater, gem. §31 MPG)	2008
Quality Manager and Auditor (according to the ISO 19011) Institut für wirtschaftliche Fertigung + Qualitaetsmanagement IwF – REFA, Kempen	2007
EMERGENCY MEDICAL SERVICES: • Lecture for EMS/Paramedics (Train the Trainer) • Crisis Intervention Specialist • Instructor for Paramedics (Lehrrettungsassistent) • Paramedic for Air Ambulances (JAR-OPS 3.005) • First-Aid Instructor	1996