

PERSONAL INFORMATION

Date of birth: December 23rd, 1975
Place of birth: Eberswalde (Brandenburg/Germany)
Family status: married
Children: 2 full-aged
Hobbies:
- hiking / travelling
- Motor cycling
- Private gardening

EDUCATION

1998 – 2001 UNIVERSITY FOR APPLIED SCIENCES ALBSTADT-SIGMARINGEN (DE)

Pharmaceutical Technology with core theme
«Quality, production and plant management» with
degree «Dipl.-Ingenieur Pharmatechnik» in 2002

LANGUAGES

Business fluent in speech and writing

- German (Mother language)
- English

Advanced skills in speech and writing

- French



PROFESSIONAL CAREER

Since 03 / 2019 MANAGING DIRECTOR and company owner
10 / 2016 – 02 / 2019 DEPARTMENT HEAD at Früh Verpackungstechnik AG
11 / 2010 – 09 / 2016 GROUP HEAD at Chemengineering Technology AG
10 / 2007 – 10 / 2010 DEPUTE HEAD QA AND LEAD VALIDATION MANAGER at Legacy Pharmaceuticals Switzerland AG
01 / 2002 – 09 / 2007 PROJECT LEADER at Steinbeis TZ Pharmatechnik

REFERENCES (Customer)



REFERENCES (Projects)

Year	Customer	Project scope
04/2022 - 04/2023	Allpack Group (Reinach)	<p>Procurement, Commissioning and Qualification of</p> <ul style="list-style-type: none"> ○ Cartoning and serialization machine for tablets, ○ Incl. creation of all documents ○ Q&V of new and updated devices of the cartoning and display packaging line for implementation of product serialization / aggregation for China incl. documents ○ CQV of a new Wipotec OCS system (printing and TE labelling) into an existing line incl. documents ○ CQV of a new HAPA late stage customization blister printing machine incl. automated packaging identification devices incl. documents ○ C&Q of a new & retrofit packaging line for solid dosage forms with primary packaging incl. flexo-printing system and secondary packaging machines incl. documents ○ Q&V of new format parts for blisters and bottle filling machines incl. documents
10/2021 - 01/2022	SIS Medical (Frauenfeld)	<p>Creation and revision of basic documents as preparation for a successful NB audit, such as</p> <ul style="list-style-type: none"> ○ Masterplans (Qual/Val, TMV, CC, ..) ○ Validation master plan matrix ○ Qualification master plan
09/2021 - 12/2022	Früh (Fehraltorf)	<ul style="list-style-type: none"> ○ Creation + revision of SOP's for an Audit Trail review process ○ Project management support for a new configuration of a current PFS product and qualification for several systems, such as <ul style="list-style-type: none"> - cold and clean rooms (up to ISO 7) - labelling machines - manual PFS assembling devices - further internal Qualification support ○ Requalification of a Track & trace unit after Software update ○ Creation and revision of SOP's for Audit Trail review process ○ (successful) FDA inspection support, such as <ul style="list-style-type: none"> - SOP creation and updates - validation of a new ERP module incl. URS and RA - Updates of several Master Plan documents

Year	Customer	Project scope
02/2021 - 12/2022	NES Fircroft at AKORN AG (Hettlingen)	<p>Freelance employed as Senior Administrator Qualification & Validation with responsibilities for:</p> <p>All commissioning and qualification activities of</p> <ul style="list-style-type: none"> ○ A Pharmaceutical Ball Mill ○ An VHP Isolator incl. weighing system ○ Suspension equipment with three mixing vessels Incl. CIP system and SIP functionality ○ Clean media supply and clean room (class C) <p>Furthermore, this position in an integrated Quality position, responsible for</p> <ul style="list-style-type: none"> ○ Project changes ○ Project and qualification deviations ○ Technical evaluations and trouble shootings ○ Communications with suppliers ○ Quality and qualification project management
05/2019 - 05/2022	Ivers-Lee (Burgdorf)	<p>Qualification of</p> <ul style="list-style-type: none"> - new carousel blister leak detection machine - print camera inspection unit - two leak detection systems for stickpacks and blisters - checkweigher - several solid form dosing units (micro tablets) - New Active Blister filling and packaging line - New carousel stickpack packaging line - Two new serialization units <p>Requalification of</p> <ul style="list-style-type: none"> - Solid form packaging machine for new products - Serialization unit after moving <p>Validation of</p> <ul style="list-style-type: none"> - Stickpack packaging processes - Blister packaging processes - AutoInjector assembling and packaging process <p>Transport validation to test lab (Ireland) incl. mapping</p> <p>Project Management and Launch Support</p> <ul style="list-style-type: none"> - Launching and registration of new Autoinjector product in US, EU and non-EU Markets <p>Engineering Support</p> <ul style="list-style-type: none"> - Specification (URS) of a new active blister line - Specification (URS) of a new carousel blister leak detection machine - Specification (URS) of a new AI assembling machine / line - Specification (URS) of a new AI housing cover machine

Year	Customer	Project scope
2020	Merz System (Lich DE)	<i>CSV support</i> Development and Creation of HDS and SDS for a new carousel stickpack machine
2020	Früh (Fehraltorf)	<i>CSV support</i> Validation of new SW for tactile 3D measuring machine for blisters and foil
2019 - 2021	Allpack Group (Reinach)	Qualification of <ul style="list-style-type: none"> - Cartoning machine for blisters - Flexo printing machine for blister foil - Blister packaging machine Process validation <ul style="list-style-type: none"> - Cartoning machine for blisters incl. flexo print unit incl. process FMEA creation
2019	Biognosys (Schlieren)	<i>CSV support</i> Temperature Monitoring gap analysis, support and consulting
2019	Früh (Fehraltorf)	<ul style="list-style-type: none"> - Implementation of new product (PFS) at existing machines with requalification of these 3 machines (secondary and tertiary packaging) - Qualification 2 new print camera inspection units - Validation of new process

PROFESSIONAL ACTIVITIES (employed)

Year	Employer	Activity
10/2016 →02/2019	Früh Verpackungstechnik AG (Fehraltorf)	Department Head Qualification, Validation & Services <ul style="list-style-type: none"> - Department leadership - qualification responsibility of production plants, infrastructural facilities and lab equipment - Responsibility of validation of GxP relevant software solutions, rinsing & sterilization processes of medical devices - ISO & authority inspections (Swiss Medic, FDA) - Project management implementation Serialization (Track & Trace) - interface function for customer and supplier - project management, specification development, purchase process, commissioning of systems incl. FAT/ SAT

Year	Employer	Activity
11/2010 →09/2016	Chemengineering Technology AG (Münchenstein)	Group leader qualification, validation & compliance II <ul style="list-style-type: none"> - Group and project leadership - Responsibility of GMP and qualification trainings - qualification coordination and project management - GMP Trainer - 50+ customer projects
10/2007 →10/2010	Legacy Phar- maceuticals Switzerland AG (Birsfelden)	Dep. Head of QA and Head of qualification and validation <ul style="list-style-type: none"> - Depute of Head QA - CAPA Manager - GMP Trainer - Large project manager (>300 systems) - authority inspections responsible (Swiss Medic, FDA)
01/2002 →09/2007	Steinbeis Transferzent- rum Pharmatechnik (Leonberg DE) At Pfizer (Illertissen DE) and Boehringer- Ingelheim (Biberach DE) and Valeant (Birsfelden)	<ul style="list-style-type: none"> - new aseptic filling processes - Steam Sterilizer - VHP decontamination airlock - vial filling lines (liquid and lyophilized powder) - freezer dryer (Bulk freeze drying) - QA Project manager - Project and qualification manager - HVAC systems - Water, gas and steam systems - new containment area (OEB5) with all manufacturing systems and air locks - authority inspections

CONTINUING EDUCATION

Since 2015	several presentations/courses at SCC events and Pharma Lounges
2007-2015	Cleaning validation (several courses)
2006	Expert for hygiene
2006	Pharma – IT – Expert
2005	Pharmaceutical Water Systems
	Cleanrooms
2004	Expert for Auditing – GMP-Auditor
2003	Expert for validation

PUBLIC RELATIONS ACTIVITIES

- 2013 – 2015 Presentation at a show area at Pharma-Lounges at Karlsruhe and Stuttgart with the topic «Qualification of a clean room»
- 2011 Technical lecture «GMP at hospitals» at IHS (Ingenieur Hôpital Schweiz)

See more details on

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