

## PERSONELL INFORMATION

Date of birth:	December 23 <sup>rd</sup> , 1975
Place of birth:	Eberswalde (Brandenburg/Germany)
Family status:	married
Children:	2 full-aged
Hobbies:	- hiking / travelling - Cooking / Baking - 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 <ul style="list-style-type: none"><li>- German (Mother language)</li><li>- English</li></ul> Advanced skills in speech and writing <ul style="list-style-type: none"><li>- French</li></ul>
-----------	--

## 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 Chemgineering 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
2019 – 2021 ongoing	Ivers-Lee	<p>Qualification of</p> <ul style="list-style-type: none"> <li>- print camera inspection unit</li> <li>- two leak detection systems for stickpacks and blisters</li> <li>- checkweigher</li> <li>- several solid form dosing units (micro tablets)</li> <li>- New Active Blister filling and packaging line</li> <li>- New carousel stickpack packaging line</li> <li>- Two new serialization units</li> </ul> <p>Requalification of</p> <ul style="list-style-type: none"> <li>- Solid form packaging machine for new products</li> <li>- Serialization unit after moving</li> </ul> <p>Validation of</p> <ul style="list-style-type: none"> <li>- Stickpack packaging processes</li> <li>- Blister packaging processes</li> <li>- AutoInjector assembling and packaging process</li> </ul> <p>Project Management and Launch Support</p> <ul style="list-style-type: none"> <li>- Launching and registration of new Autoinjector product in US, EU and non-EU Markets</li> </ul> <p>Engineering Support</p> <ul style="list-style-type: none"> <li>- Specification (URS) of a new active blister line</li> <li>- Specification (URS) of a new carousel blister leak detection machine</li> <li>- Specification (URS) of a new AI assembling machine / line</li> <li>- Specification (URS) of a new AI housing cover machine</li> </ul>
2020	Merz System	<p><i>CSV support</i></p> <p>Development and Creation of HDS and SDS for a new carousel stickpack machine</p>
2020	Früh	<p><i>CSV support</i></p> <p>Validation of new SW for tactile 3D measuring machine for blisters and foil</p>

Year	Customer	Project scope
Since 2019 permanently	Allpack Group	Qualification of <ul style="list-style-type: none"> <li>- Cartoning machine for blisters</li> <li>- Flexo printing machine for blister foil</li> <li>- Blister packaging machine</li> </ul> Process validation <ul style="list-style-type: none"> <li>- Cartoning machine for blisters incl. flexo print unit incl. process FMEA creation</li> </ul>
2019	Biognosys	<i>CSV support</i> Temperature Monitoring gap analysis, support and consulting
2019	Früh	<ul style="list-style-type: none"> <li>- Implementation of new product (PFS) at existing machines with requalification of these 3 machines (secondary and tertiary packaging)</li> <li>- Qualification 2 new print camera inspection units</li> <li>- Validation of new process</li> </ul>

PROFESSIONAL ACTIVITIES (employed)

Year	Employer	Activity
10/2016 →02/2019	Früh Verpackungstechnik AG	Department Head Qualification, Validation & Services <ul style="list-style-type: none"> <li>- Department leadership</li> <li>- qualification responsibility of production plants, infrastructural facilities and lab equipment</li> <li>- Responsibility of validation of GxP relevant software solutions, rinsing &amp; sterilization processes of medical devices</li> <li>- ISO &amp; authority inspections (Swiss Medic, FDA)</li> <li>- Project management implementation Serialization (Track &amp; Trace)</li> <li>- interface function for customer and supplier</li> <li>- project management, specification development, purchase process, commissioning of systems incl. FAT/ SAT</li> </ul>
11/2010 →09/2016	Chemengineering Technology AG	Group leader qualification, validation & compliance II <ul style="list-style-type: none"> <li>- Group and project leadership</li> <li>- Responsibility of GMP and qualification trainings</li> <li>- qualification coordination and project management</li> <li>- GMP Trainer</li> <li>- 50+ customer projects</li> </ul>

Year	Employer	Activity
10/2007 →10/2010	Legacy Pharmaceuticals Switzerland AG	<p>Dep. Head of QA and Head of qualification and validation</p> <ul style="list-style-type: none"> <li>- Depute of Head QA</li> <li>- CAPA Manager</li> <li>- GMP Trainer</li> <li>- Large project manager (&gt;300 systems)</li> <li>- authority inspections responsible (Swiss Medic, FDA)</li> </ul>
01/2002 →05/2007	Steinbeis Transferzentrum Pharmatechnik	<ul style="list-style-type: none"> <li>- new aseptic filling processes</li> <li>- Steam Sterilizer</li> <li>- VHP decontamination airlock</li> <li>- vial filling lines (liquid and lyophilized powder)</li> <li>- freezer dryer (Bulk freeze drying)</li> <li>- QA Project manager</li> <li>- Project and qualification manager</li> <li>- HVAC systems</li> <li>- Water, gas and steam systems</li> <li>- new containment area (OEB5) with all manufacturing systems and air locks</li> <li>- authority inspection</li> </ul>

#### CONTINUING EDUCATION

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 Hospital Schweiz)

See more details on

[www.spenocon.net](http://www.spenocon.net)