

THE SHORTEST WAY FROM ENGINEERING TO QUALIFICATION.

Think. Work. Integrate.

PITZEK 
GMP CONSULTING

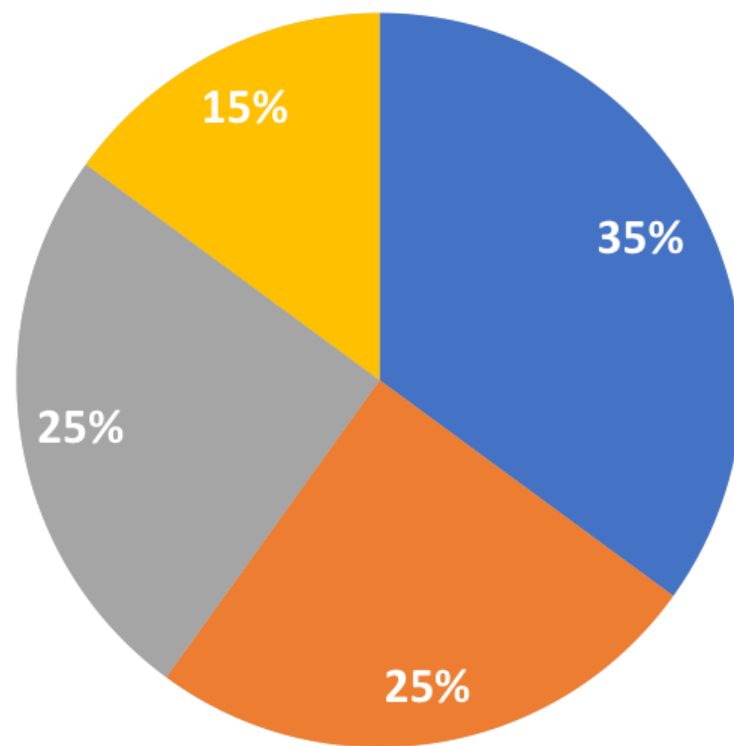


The Company

- **Founded 2012 by Thomas Pitzek**
- **Company headquarters in Weisenheim am Sand (near Mannheim),
Branch in Neustadt an der Weinstrasse
Subsidiary (Pitzek GMP Consulting Pte Ltd) in Singapore**
- **30 employees**
- **Around 30 years of experience in the GMP field**
- **Team of engineers from the life science sector**
- **Revenue 2017 approx. 4 million EUR**
- **ISO 9001:2015 certified**



Portfolio



- Qualifizierung/Validierung
- GMP-Engineering
- Projektmanagement
- GMP-Consulting

A woman with her hair in a ponytail, wearing a white lab coat, is looking towards a piece of laboratory equipment. The equipment is a metal frame holding several test tubes. The text '0,5 -1ml long' is visible on the equipment. The word 'Competencies' is written in large blue letters over the image.

Competencies

- **Isolator Technology**
- **Sterile and aseptic production**
- **Containment**
- **Homeopathy**
- **Medical Technology (in Singapore)**



Memberships

- **Chairman of the ISPE Steering Committee of the Working Group Regional CoP Aseptic Processing**
- **Part of the ISPE Steering Committee of the Working Group Regional CoP Containment**
- **Co-author of VDI 2083, Cleanroom Technology, page 18:2012-01.**



Basic & Detail Engineering & Qualification Aseptic Filling Line

Period: 06/2014 - ongoing

Task:

Basic & detail engineering & qualification of an aseptic filling line

Project content:

- Creation of the process description
- Creation of specification / requirements specification
- Preparation of tender documents
- Participation in the creation of the line layout
- Supervision of the award processes
- Technical support of the project until completion OQ
- Trades responsibility for the filling line and the isolator
- Project management of the filling line (incl. tracking of the project plan)



Section

- Vial washer
- Hot air sterile tunnel
- Isolator
- Filling line
- Capper

Procurement / Implementation Coater

Period: 09/2014 – 05/2016

Task:

Project management for the procurement of a coater and reconstruction of the required clean rooms

Project content:

- Creation of user requirements up to allocation of the process plant
- Project management of all trades (EMSR/TGA/HVAC/high-purity media/construction)
- Coordination of the output of an old plant
- Coordination of clean room upgrading
- Incorporation of the coater incl. all secondary structure/ ancillary systems
- Commissioning of the entire plant and the clean rooms



Medicine Technology

We offer interim solutions, are problem solvers, project managers, internal independent auditors and also hands-on consultants in the areas of GMP: **Quality management, development and production and supplier management** of medical device manufacturers and their suppliers. Relevant standards/ regulations/ laws ISO 9001, ISO 13485, 21 CFR part 820 (FDA) are always taken into account.

Our main areas of responsibility include:

- Facility qualification, process validation, cleaning validation, CSV and product validation,
- Deviation management, complaint management,
- Document management incl. document reviews,
- Change management,
- Risk management,
- Organisation & people management,
- CAPA management,
- Audit management (audit preparation and follow-up as well as execution of internal audits),
- Supplier management in tool making, injection moulding, packaging production/service, battery production, electronic components and production of surgical instruments and implants (i.e. supplier selection, supplier qualification, supplier audit, supplier monitoring, project support and management, product acceptance on site)



A woman with her hair in a ponytail, wearing a white lab coat, is looking towards the right. In the background, there is a piece of laboratory equipment, possibly a pipette or a similar instrument, with various components and labels. The overall scene is in a laboratory setting.

Project as a Service

- **Owner-managed**
- **Short distances/fast reaction times**
- **Long-term partnerships**
- **Experienced and highly qualified experts**
- **Customer friendliness / personal project briefing (relevant information, no false promises, no catchphrases, personal support)**
- **After sales competencies (dealing with problems and complaints)**



Vision

- **Customized:**
"Project design around you"
- **We want to be the chameleon that is well networked with customers, partners and competitors**



Thank you very much

Pitzek GMP Consulting

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