



THE SHORTEST WAY FROM ENGINEERING TO QUALIFICATION.

Think. Work. Integrate.



The Company

- **Founded 2012 by Thomas Pitzek**
- **Company headquarters in Neustadt an der Weinstraße**
Subsidiary (Pitzek GMP Consulting Pte Ltd) **in Singapore**
- **40 employees**
- **Around 35 years of experience in the GMP field**
- **Team of engineers from the life science sector**
- **Revenue 2019 approx. 4,5 million EUR**
- **ISO 9001:2015 certified**

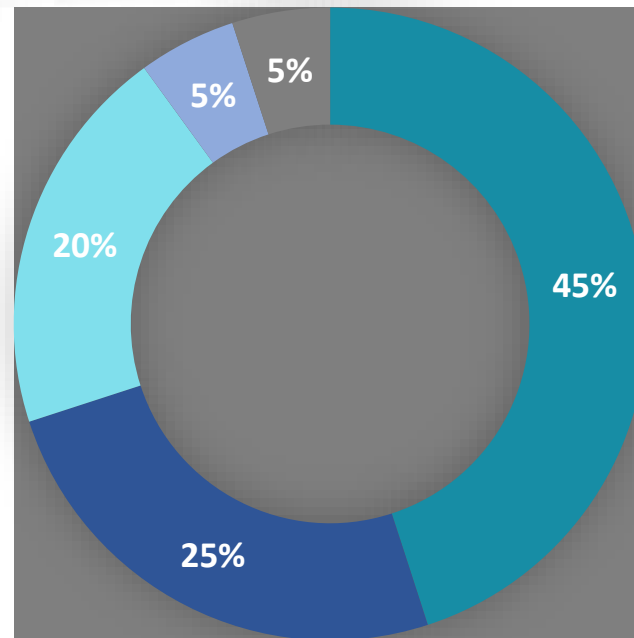




Competences

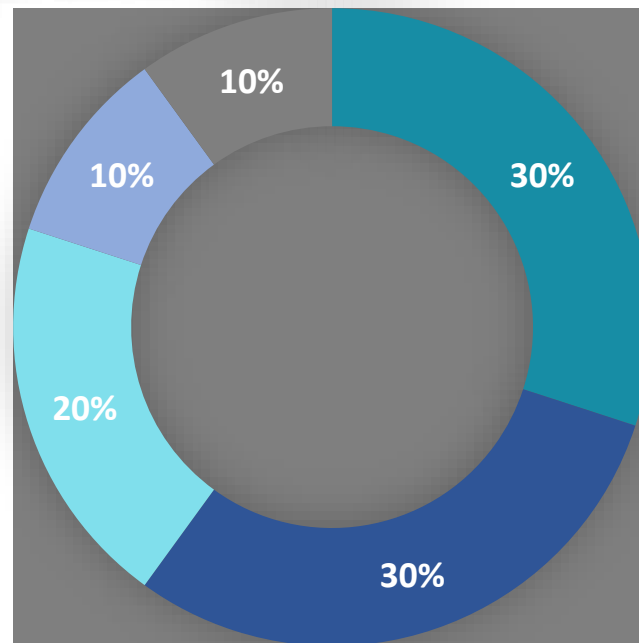
- **Isolator Technology**
- **Sterile and aseptic production**
- **Containment**
- **Solids**
- **Fill & Finish**
- **Clean Media**

Industries



- Pharma
- Medical
- Mechanical Engineering
- Biotechnology
- API Manufacturers

Portfolio



- Qualification/Validation
- GMP Engineering
- Project management
- GMP Consulting
- Planning / Construction
- Technology transfer (New)

Medical technology

Period: Feb 2015; Nov 2015; June 2016; August 2017; May, June 2018
continuously ongoing

Tasks:

Supplier (quality) management (supplier qualification, supplier monitoring)

Project content:

- Supplier selection (Who is the right supplier for that special thing?)
- Supplier qualification for tool making, injection moulding, packaging production/service, battery production, electronic components and production of surgical instruments and implants
- Performing of supplier audits
- Supplier monitoring
- Performing of product and components transfer



Medical technology

Period: continuously

Tasks:

Process development/creation

Project content:

- Development of new manufacturing processes (handling from welding machines, assembly devices, cleaning of medical devices)
- Creation or rework of deviation processes, validation processes, documentation processes, change processes, supplier management





Medical technology

Period: continuously

Tasks:

Audit remediations (TUEV, FDA, Anvisa)

Project content:

- Preparation of remediation plans
- Monitoring of all activities (deviations, capa)
- Supervising of all measures related to the deviations and capas

Medical technology

Period: continuously

Tasks:

Internal audits as independent person

Project content:

- Preparation of internal audits (ISO 9001, ISO 13485, FDA CFR 820 development, manufacturing, purchasing and quality management)
- Preparation of audit reports and action plans
- monitoring of implementing the measures
- Effectiveness review related to the deviation or capa





Medical technology

Period: continuously

Tasks:

Conduction of gap-analyses and related measures

Project content:

- Creation of gap analyses in the production area, the quality management and supplier quality management
- Correction of all these detected gaps as well the monitoring
- Preparation of internal audits as effectiveness check

Medical technology

Period: continuously

Tasks:

Equipment qualification and process validation

Project content:

- Creation of Validation mater plans
- Qualification of injection moulding machines, automatic assembly machines, assembly devices, laser marking machines
- Validation of injection moulding processes, cleaning processes, laser marking processes, welding processes
- Conduction of reviews (requalification/revalidation)





Medical technology

Period: Nov 2015 – Jan 2018

Tasks:

Organisation management in the Quality Management

Project content:

- Reorganisation of the whole Quality Management (QM)
- Establishment of new and structured QM departments with different teams (Design Quality Assurance, Quality Assurance, Quality Management Systems)
- Hiring of qualified trained persons (incl. interviews) in collaboration with HR and QM department



Project as a Service

- **family managed**
 - Short distances / fast response time
- **Long-standing partnerships**
- **Experienced Experts**
- **Customer friendliness/personal project briefing**
 - relevant information, no false promises, no phrases, personal care
- **After Sales Competences**
 - Positive handling of problems and complaints

A woman in a white lab coat is shown in profile, looking towards the right. She is holding a small object in her hand. In the background, there is a piece of medical equipment, possibly a patient warming unit, with a white cloth draped over it. The word "Vision" is written in a large, blue, sans-serif font over the image.

Vision

- **Customized:
„Projectdesign around you“**

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.**





Thank you

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