

AUTOMATION CSV VALIDATION
HYGIENE
QUALITY MANAGEMENT
AUDIT
PROJECT MANAGEMENT
WE MAY NOT BE SUPERHEROES
QUALIFICATION ENGINEERING



... but we still move mountains for you.



COMPANY



PITZEK GMP CONSULTING

- Founded in 2012 by Thomas Pitzeck
- Head Office Neustadt a. d. Weinstraße
- North-East branch, Berlin
- Around 40 employees
- Team of engineers from the life sciences sector
- Many years of experience in the GMP environment
- DIN ISO 9001:2015 certified

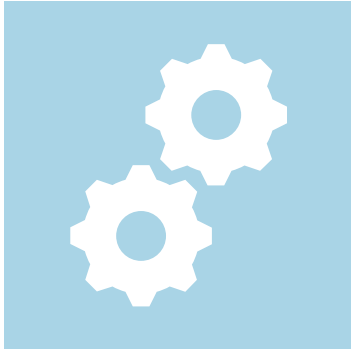
AREAS OF EXPERTISE

- GMP Engineering
- GMP Qualification/Validation
- QM/QA/Compliance
- Automation/CSV
- Hygiene Concepts
- Technology Transfer

BRANCHES



Biotechnology



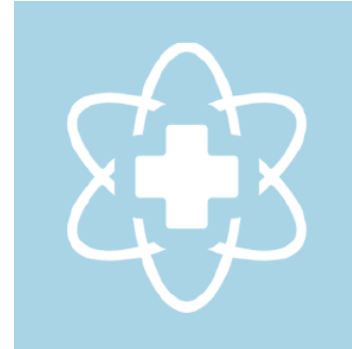
Engineering



Pharma



API-Producer



Medical Technology

OUR CUSTOMERS



Biotest AG



PSM GmbH



Krones AG



techniconsult



Wasserburger Arzneimittelwerk GmbH
Recipharm



Bayer Pharmaceuticals



Bavarian Nordic



BWT Wassertechnik GmbH



Roche Deutschland GmbH



Merck KGaA



AstraZeneca



MIP Pharma GmbH



Takeda GmbH



SW Pharma Schiffweiler (Esteve)



CordenPharma GmbH



Optima



Boehringer Ingelheim Pharma
GmbH & Co. KG



WAGO GmbH & Co. KG



Fette Compacting GmbH



Sanofi

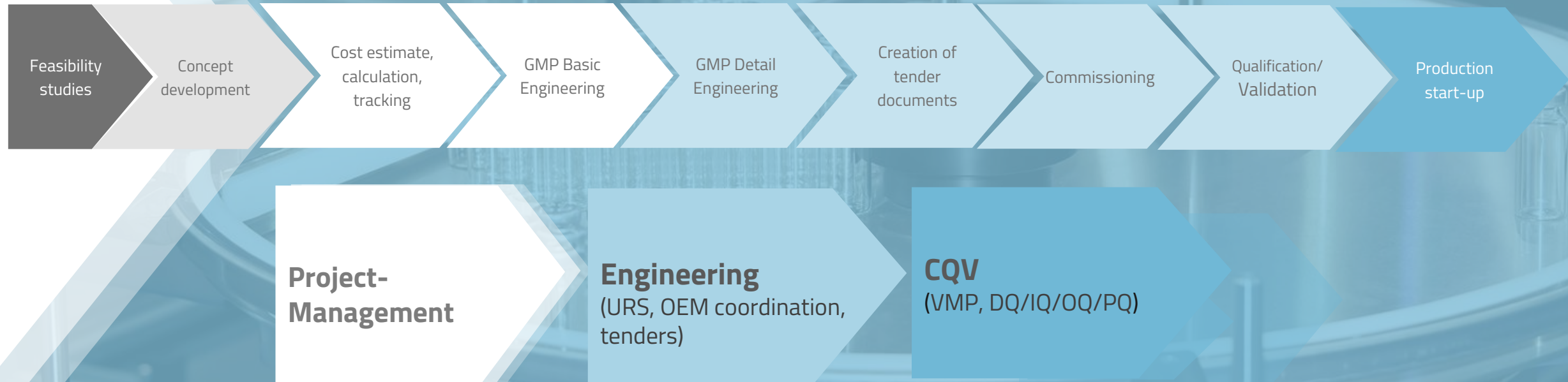
OUR ENGINEERING SOLUTIONS

FROM FEASIBILITY TO THE START OF PRODUCTION - WE OFFER SOLUTIONS FOR ALL PHASES OF A PROJECT



Specialized in GMP production processes/equipment:

ENGINEERING / QUALIFICATION/ VALIDATION



SPECIAL KNOW-HOW

ENGINEERING / QUALIFICATION / VALIDATION



Containment

Solida

Cleanroom

Liquida/Fill & Finish

ENGINEERING / QUALIFICATION / VALIDATION

Clean Media

Visual Inspection

Biotech

Technology Transfer

AUTOMATION



HARDWARE SERVICES

- **Infrastructure Concepts**
- **IT/OT**
 - Cyber Security
 - Consulting Workshops
- **Planning of electrical distributions, I/O signals and interface communications**

SOFTWARE SERVICES

- **Integration Concepts for software systems** (MES, LIMS, ERP, eQMS etc.)
- **GAP Analyses in accordance with applicable regulations** (e.g. Data Integrity, GAMP5)
- **Coordination and support of system migrations**
- **Workshops/Training** (e.g. GAMP5/CSV etc.)

COMPUTER SYSTEM VALIDATION (CSV)



- **Preparation of complete GMP Documentation**
(according to EU-GMP Annex 11/FDA 21 CFR Part 11):
 - VP / URS / FS, SDS, HDS/DQ, IQ, OQ, PQ etc.
 - Risk Analysis according to GAMP 5
 - Carrying out the FAT and SAT tests and documentation
- **Implementation of GMP Qualification/Validation**
incl. test plans and test protocols
- **CSV-Projectmanagement**



QUALITY MANAGEMENT SYSTEM (QMS) QA-COMPLIANCE



SERVICES QMS-CONSULTING

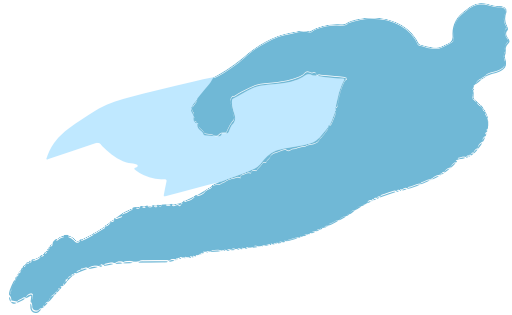
- Development of quality management systems (z.B. DIN ISO 9001, 13485, GMP etc.)
- FDA/ANVISA/Annex1 Readiness (Audit preparation)
- Workshops/Training QMS/GMP

SERVICES QA-COMPLIANCE/HYGIENICS

- CAPA Management/Change Control/Deviation Management
- SOP-Creation/Review/GAP Analyses
- Development of Cleanroom Cleaning Concepts/Hygiene Concepts
- Creation and implementation of Cleanroom Training (behavior in the Cleanroom, etc.)



WE ARE WHAT WE LIVE



- **KNOWLEDGE**
We are always up-to-date
- **QUALITY**
We focus on quality always and everywhere
- **CUSTOMER FOCUS**
The customer at eye level
- **RELIABILITY**
Customers and partners can rely on us
- **TEAMWORK**
We enjoy working as a team
- **PERSONAL RESPONSIBILITY**
Our employees quickly take on responsibility

STATEMENT OF GMP HEROES



VALUES

- Knowledge
- Quality
- Customer Orientation
- Reliability
- Teamwork
- Personal Responsibility

MISSION



Passion on point.

VISION



Each project, one step ahead.

ENGAGEMENT



- Lectures HS Albstadt-Sigmaringen + HS Mannheim + HTW Berlin in the field of Qualification/Validation and Engineering
- Promotion of the HS Mannheim in the mentoring program
- Cooperation agreements dual study + Lectures CAMPUS Birkenfeld + HS Albstadt-Sigmaringen
- Membership and support of the support associations of various universities
- Partnership for GMP standards with MIC (Medical Device Innovation Center), Mainz
- Financial and personnel support for the LICHTBLICK day care center Neustadt a. d. Weinstraße





AUTOMATISIERUNG CSV VALIDIERUNG
HYGIENE
QUALITÄTS-MANAGEMENT
AUDIT
PROJEKTMANAGEMENT
WIR SIND ZWAR KEINE SUPERHELDEN
QUALIFIZIERUNG ENGINEERING



Many thanks!

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GMP CONSULTING

