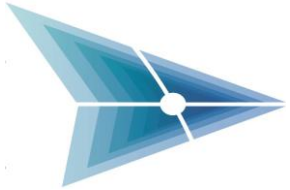


THE EASIEST WAY
FROM COMPLEX QUESTIONS
TO ENLIGHTENING SOLUTIONS.



The company



- Founded in 2012 by Thomas Pitzek
- Head office Neustadt a.d.W.
- Branch office North-East, Berlin
- Subsidiary Vienna
- About 40 employees



- Areas of Competence:
 - Engineering
 - Qualification/Validation
 - QMS/Hygienic Concepts
 - Technology Transfer
 - Automation/CSV



- Team of engineers LifeScience
- Many years of experience in gmp environment
- DIN ISO 9001:2015 certified



Industries

Mechanical Engineering



Pharma



API-Manufacturer



Biotechnology



Medical Technology



References



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössische Armeepotheker



Haupt Pharma Wolftratshausen GmbH
Unternehmen der aenova-Gruppe



Medi-Globe Urotec GmbH



spirit of excellence

Richard Wolf GmbH



Wasserburger Arzneimittelwerk GmbH –
Recipharm



Bayer Pharmaceuticals



Bavarian Nordic



BWT Wassertechnik GmbH



F. Hoffmann – La Roche AG



Merck KGaA



AstraZeneca



Pritidenta



Minascient



Becton Dickinson



CordenPharma GmbH



Optima



Packaging · Fulfillment · Logistics

IDEAL PHARMA PACKAGING GmbH



Portfolio

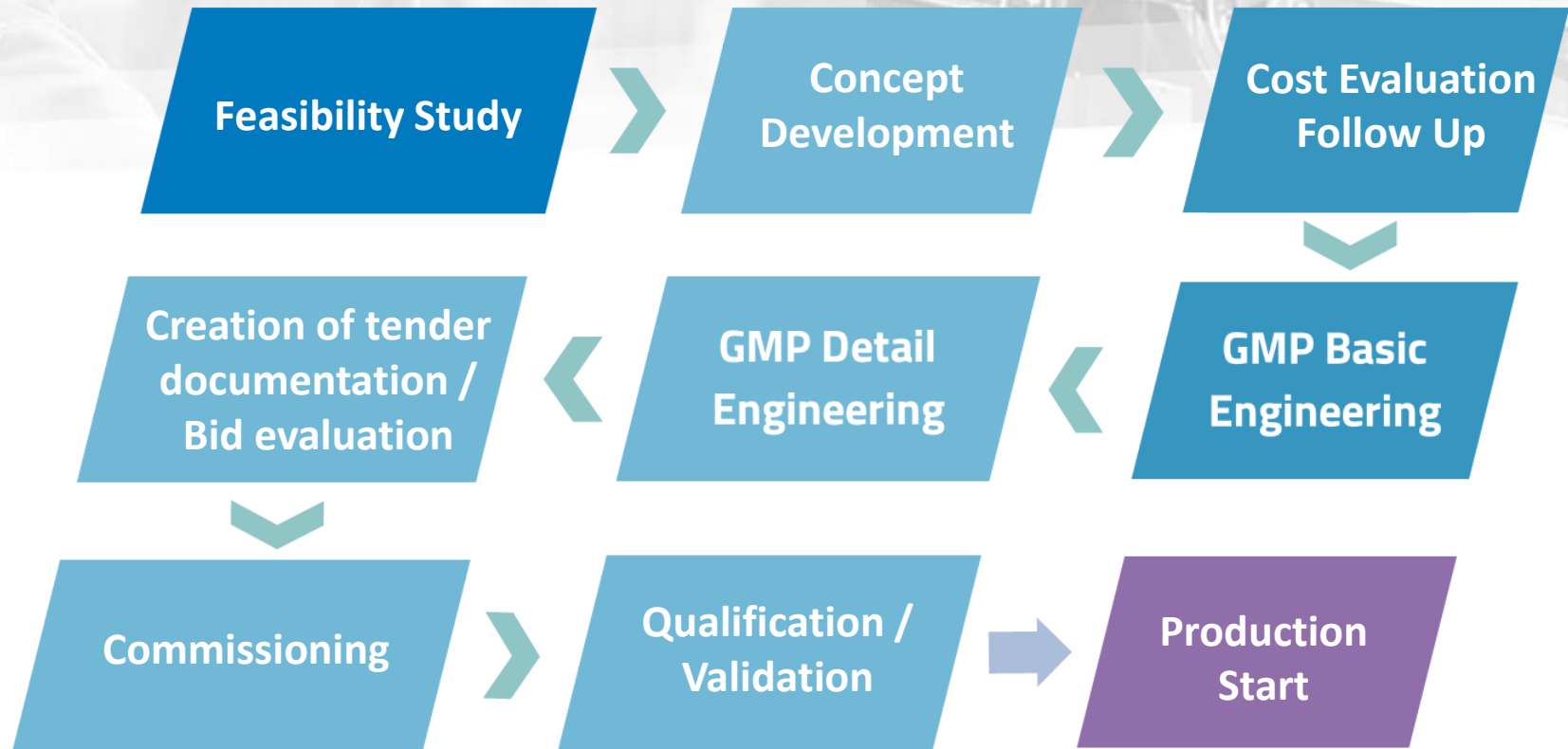
**GMP-Engineering
Qualification / Validation**

**Automation
Computer System Validation (CSV)**

**Quality Management Systems
(QMS)**

Our Engineering Solutions

From feasibility to the start of production – we offer solutions in all phases of a project



Special Know-how Engineering / Qualification / Validation

Isolator Technology/Containment

Solids (WSG, tablet press, coater, etc.)

Clean media (pharma/biotech)

Biotech (Upstream/Downstream)

Liquida / Fill & Finish (Filling Lines,
Lyophilization, Packaging etc.)

Clean rooms (e.g. material/personnel logistics)

Optical control (Visual inspection)

Technology Transfer

Automation



EXCERPT PERFORMANCE HARDWARE

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

EXCERPT SOFTWARE PERFORMANCE

- Integration concepts for superimposed systems such as MES, LIMS, ERP, eQMS etc.
- Gap analyses according to valid regulations (e.g. Data Integrity, GAMP5)
- Coordinate and accompany system migrations
- Workshops/training (e.g. GAMP5 / CSV etc.)

Computer System Validation (CSV)

EXCERPT SERVICES COMPUTER SYSTEM VALIDATION

- Preparation of the complete GMP documentation:
 - Risk analysis according to GAMP 5 / VP / URS / FS, SDS, HDS / DQ, IQ, OQ, PQ etc.
- Execution of the FAT and SAT tests and documentation
- Execution of qualification/validation incl. test plans and test protocols
- Site coordination/project management



Quality Management System (QMS)/ Hygienic Concept

EXCERPT SERVICES QMS-CONSULTING

- Elaboration of quality management systems (e.g. DIN ISO 9001, 13485, GMP etc.)
- FDA/ANVISA/Annex1 readiness (Audit preparation)
- Workshops/Training QMS/GMP

EXCERPT OF SERVICES HYGIENE-CONSULTING

- Elaboration of clean room cleaning concepts / hygiene concept
- Cross-site process harmonization
- Preparation and implementation of cleanroom training (behavior in the cleanroom, etc.)

We are what we live

Quality

We focus on quality always and everywhere

Customer orientation

The customer at eye level

Teamwork

We enjoy working in a team

Knowledge

We are always up to date

Reliability

Customers and partners can count on us

Personal responsibility

Our employees quickly take on responsibility





VISION
Each project,
one step ahead

MISSION
Passion on Point

LEITBILD



Engagement

- **Lectures HS Albstadt-Sigmaringen + HS Mannheim + HTW Berlin in the field of Qualification/Validation and Engineering**
- **Support of the HS Mannheim in the mentoring program**
- **Examiner at CAMPUS Birkenfeld + HS Albstadt-Sigmaringen**
- **Membership and support of the sponsoring associations of various universities**
- **Financial and personnel support for the day-care center LICHTBLICK in Neustadt a. d. Wstr.**



Thank you

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