Quasaar

Quality by Efficiency and Innovation

Company

- Name: **Quasaar GmbH**
- Address: Lichtenkopfer Weg 1, D-66450 Bexbach
- Business Area: Contract Laboratory (GMP)
- Independent company, founded 02/2015 (HRB 102208)
- 1000 m² Lab/Administration, 860 m² Stability center
- 40 work places established
- DUNS number: 313388660
- FEI number: 3014297892

Certification

- 1st to 3rd GMP certification 2015, 2017, 2020 (Überherrn)
- FDA approval 05/2019 (Überherrn)
- 4th GMP certification February 2022 (Bexbach)
- 5th and last GMP certification February 2025 (Bexbach)

Management Quasaar

Dr. Markus Limberger

Dep. Head of Quality Assurance

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m.limberger@quasaar.de

- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 25 years GMP expertise in an industrial environment
- Focus on Quality Control, Quality Assurance & Project Management
- Experienced in installation & optimization of GMP and QM systems
- Many fold project experiences from collaborations with research driven pharma companies
- Head of QC and CTO of GMP service providers
- Regular expert speaker about QA and QC topics, member of the respective committee within APV
- Expert speaker and author of several related publications (GMP Berater Verlag)

Dr. Christoph Jacobs

Head of Quality Control

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- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 25 years GMP expertise in an industrial environment
- Focus on Quality Control, GMP requirements and Pharmaceutical Development
- Head of QC and Scientific Expert of GMP service providers
- Experienced with set-up and expansion of QC laboratories and Stability storage facilities.
- Highly experienced with audits by FDA, European or local authorities
- Expert for Dissolution studies and Analytical Method Development
- Regular expert speaker about analytical methods under GMP requirements

Quality by Efficiency and Innovation

- Many years of experience in quality control and pharmaceutical development
- Large storage capacities for stability and ageing studies
- GMP/GSP experienced, stable team
- Fast transfer from R&D to GMP enhances Speed-to-Market
- Relief in case of capacity bottlenecks
- Know-how input for technically demanding projects
- A certified and reliable partnership
- Flexible, on-time support & high reactivity in project management

➢ *High quality in compliance with regulatory requirements, coupled with experience, flexibility and target-oriented order processing leads to a high level of customer satisfaction.*

Portfolio Quasaar

Quality Control and Analytical Support

- Quality control of raw materials, excipients, packaging material, APIs and drug products
- Batch release (EU-retest), contract analysis GSP & GMP, analytical troubleshooting
- Biopharmaceutical characterization, comparative dissolution (SUPAC), solubility

Qualification, Validation and Transfer

- Development, optimization, verification and validation of methods, cleaning and transport validation
- Method transfer, execution and concepts – fast transfer from R&D to GMP
- Qualification of equipment, systems and processes

Stability and Ageing Studies

- Packaging studies, shelf life of reference standards, APIs, excipients and reagents in qualified climatic chambers
- Stability studies, ageing studies, compilation of stability protocols and reports
- Stress & compatibility studies, „Forced Degradation“ (ANVISA, FDA), formulation screening

Consulting und Training

- Audit preparation/Mock inspections
- Auditing/Qualification of suppliers
- Examination and compilation of GMP documents

Analytics - I

Liquid chromatography

- ***New*** LC-MS System by Waters Arc system with SQ Detector 2
- ***New*** 3 Waters H/UPLC
- UPLC (Agilent)
- H/UPLC (Merck-Hitachi)
  Detectors: UV-VIS, PDA, fluorescence, light scattering (CAD)
  - ➢ Generic method: Nitrite determination (Griess reagent) by HPLC (Range: 5-50 ppb)

Drug Release

- Paddle & Basket (USP 1 & 2) – half automated systems
- USP 3 & 4 equipment on demand
- Mini paddle-enhancer-cell
- Franz-cell system
- Flotalyzer
- Special techniques, special dosage form
- Biopharmaceutical characterization

Gas chromatography

- GC / GC-HS with FID detector
  - ➢ Generic method: Residual solvent, purity, automatic derivatization
  - ➢ Generic method: Ethylene glycol (EG) and/or diethylene glycol (DEG)

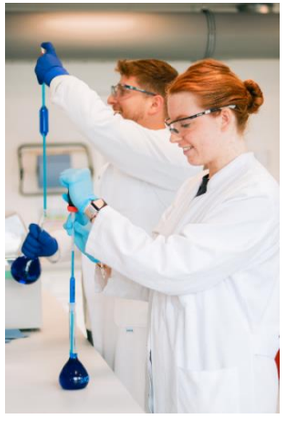
Special techniques

- Material-specific function tests
- Particle size distribution – Absence of nanoparticles
  - Laser Diffractometry LD (Helos-Sympatec)
  - Dynamic Light Scattering DLS (Malvern)
- Zeta potential (Malvern)
- Particle contamination
- Testing of inhalers
- Permeation measurements of packaging materials
- Small size CCIT (e.g. methylene blue bath test)
- Microbiological investigations (Outsourcing)
- XRPD, NMR, MS-MS (Outsourcing)

Analytics - II

Pharmacopoeial analysis (EP, USP, JP)

- Disintegration
- Breaking strength
- Friability
- Testing for visible / non-visible particles
- Microscopic characterization
- Identities (e.g. Thin Layer Chromatography, FTIR and UV)
- Limit value tests
- Appearance
- Ashing /digestion
- Drying, evaporation loss
- Clarity / Color / Opalescence of solutions
- Packaging material tests
- Average mass
- Drop size
- Acid, soap, hydroxyl, iodine number
- Melting point
- Filling volume
- Sieve analysis
- Viscosity (Netzsch/Brookfield)



Standard methods

- Determination of pH value
- Osmolarity
- Polarimetry
- Refractrometry
- Titration
  - Ion analysis, content (Methrohm or Xylem-SI-Analytik)
- Density measurement
- Solubility determination (pH-dependent)
- Distribution coefficient
- Melting point
- Water content by Karl-Fischer
  - Volumetric / coulometric
  - Oven-method (Metrohm)
- Water activity
- Moisture Analyzer

Outsourcing & Network

Expansion of expertise in the partner network:

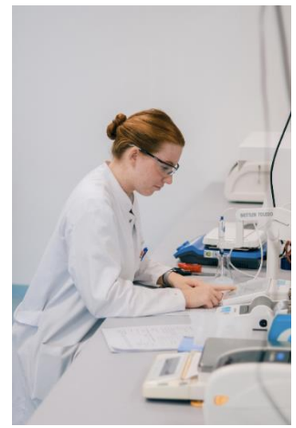
In addition to its in-house expertise, Quasaar has established qualified partners for:

- Microbiological testing procedures, verification & validation of methods
- Structural elucidation (XRPD, NMR, MS) and ion analysis (IC, ICP-MS, ICP-OES, AAS)
- Specific analysis of oils and fats
- Material testing and functional testing
- Biological testing procedures
- Production of micro-batches and CTM batches under GMP

We coordinate your outsourcing project as a central contact.
Our experience and qualified network also enable us to comprehensively handle large-scale projects.
The customer decides the extent

Running cooperations with:

- Erweka: Dissolution and biopharmaceutical characterization
- Fraunhofer IBMT St. Ingbert: Validation of innovative analytical methods



Stability center

ICH Climatic conditions (± 2 °C | ± 5 %)

25 °C | 60 % RH	280 m^3 + 80 m^3
30 °C | 65 % RH	30 m^3
40 °C | 75 % RH	180 m^3
30 °C | 75 % RH	2 x 80 m^3
5 °C ± 3 °C	80 m^3
-20 °C ± 5 °C	500 L (expandable)

Special conditions

25 °C | 40 % RH	1000 L -> 15m^3
40 °C | 25 % RH	1000 L -> 15m^3
25 °C | 75 % RH	1000 L
30 °C | 92 % RH	1000 L
55 °C | 50 % RH	15 m^3
50 °C | 50 % RH	15 m^3
30 °C | 35 % RH	on demand

Stress conditions: 25 → 80 °C and 0 → 95 % RH

Technical data

- Redundant regulation of temperature and humidity
- Storage of palettes, barrels und bulk possible
- Overheat and humidity control, monitoring system Yokogawa
- Alarm transmission by SMS, E-Mail

Additional service

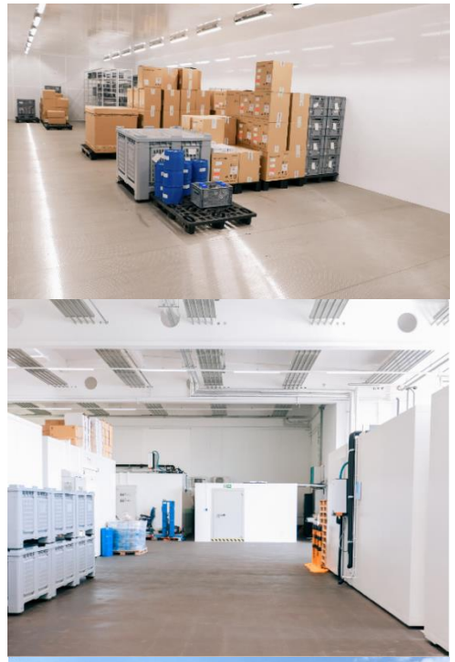
- New: Light stress according ICH (Atlas Sun tester CPS+)
- Cyclic conditions/transport validation -20 → 150 °C

***New*: Controlled substances (up to 10 m^3)**

Standard ICH conditions:

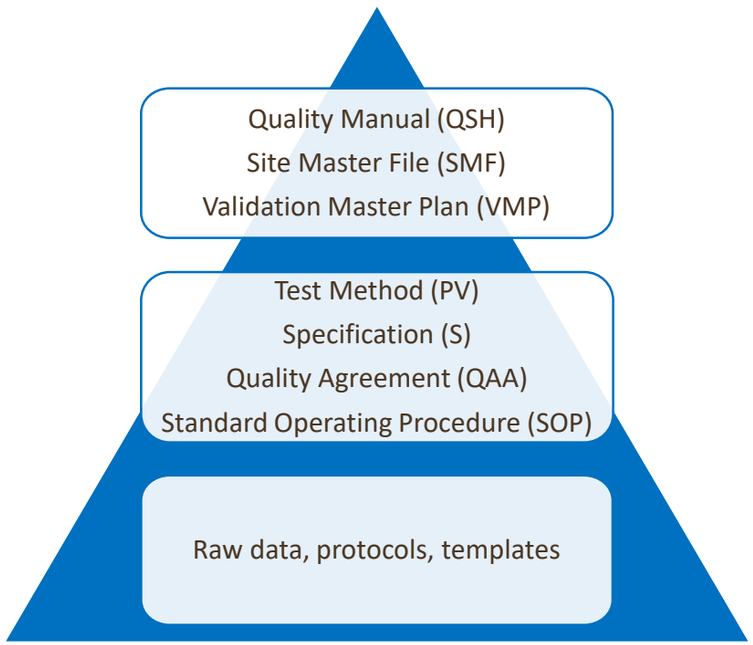
25 °C | 60 % RH, 30 °C | 75 % RH & 40 °C | 75 % RH

Warehousing: ambient room temperature

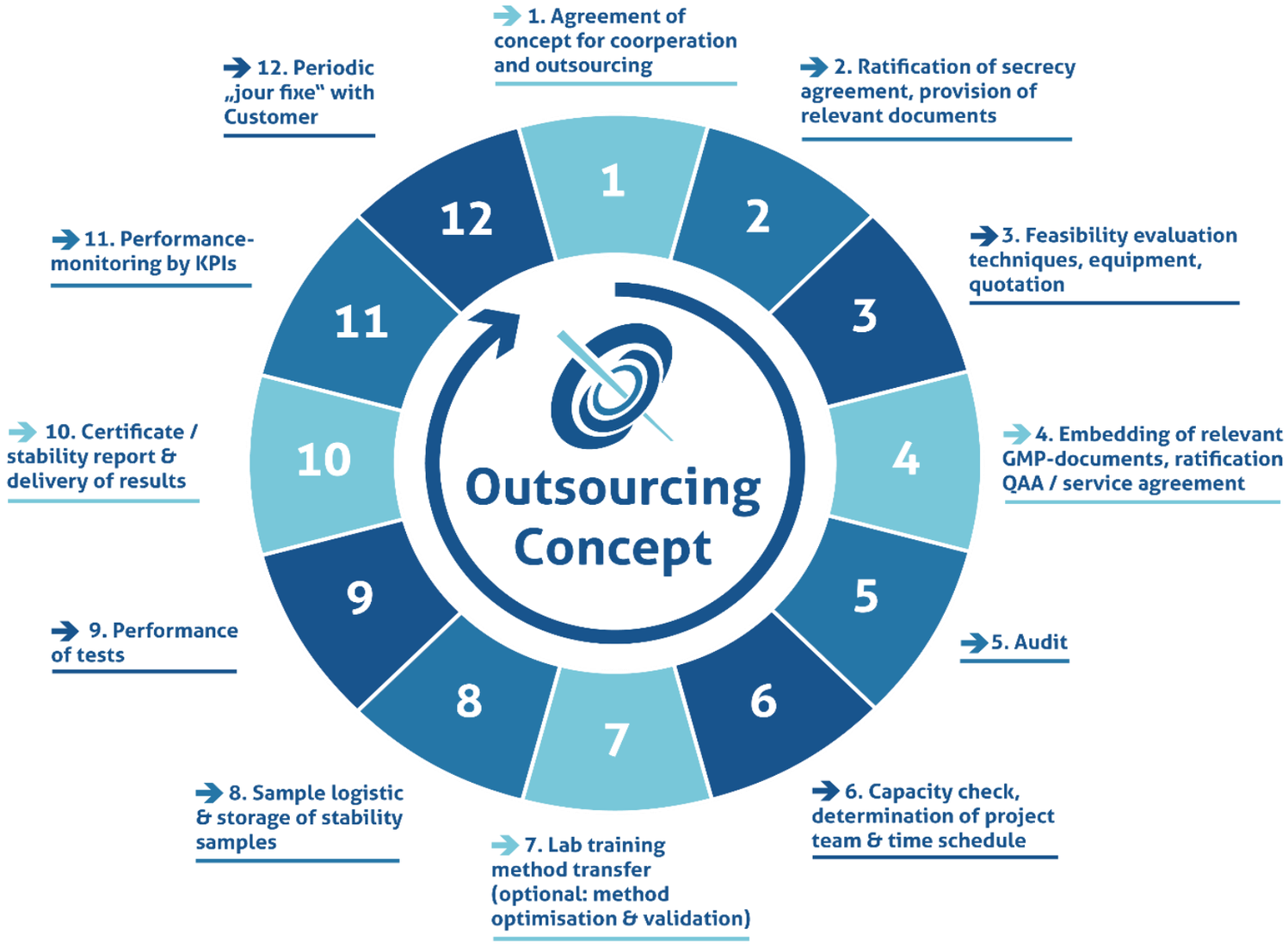


GMP-compliant quality management system

Efficient Quality System guarantees GMP-compliant workflows & proceedings



Concept Contract Services



Added Value Quasaar

- GMP-certified & independent company
- GMP experienced, stable team and experts (5 to > 25 years GMP experience)
- Competence in highly regulated Pharma and Life-Science (GMP, GSP)
- Excellent audit history with authorities / Big Pharma
- State of the art laboratories and technical equipment focused on QC / Analytics
- High flexibility in project implementation and accurate timeline management
- Specific know-how concerning special dosage forms, biopharmaceutical characterization, stress & compatibility testing, nanomedicine
- Overflow management & support for challenging projects
- Established networks for scientific and regulatory expertise
- Large-volume technical facilities for stability and ageing studies
- Room for expansion stability center, laboratories and GMP areas
- Combination of expertise and flexibility inside a highly regulated environment

Your Outsourcing Partner: Quasaar

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