Quality by Efficiency and Innovation

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)
- 1250 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

CEO/ Dep. Head of Quality Assurance

+49 (6826) 818962-12
m.limberger@quasaar.de

- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 25 years GMP expertise on an industrial quality level
- 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

CEO / Head of Quality Control

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c.jacobs@quasaar.de

- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 25 years GMP expertise on an industrial quality level
- 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

Expansion Analytical Methods

Liquid chromatography

- ***New***: LC-MS System by Waters Arc system with SQ Detector 2
- **New:** 3 Waters H/UPLC
- ULC (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
- **New:** USP 3 & 4 & 7 equipment on demand (ERWEKA)
- USP 5 & 6
- 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

- SFC-System (planned)
- Phys-chem Descriptors LogD, PBA, TSOL, KSOL
- 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)

Expansion Analytical Methods

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
- Refractometry
- Titration
  - Ion analysis, content determination (Methrohm, 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
- **New:** Tamped & bulk density

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 (Lab site at Bexbach!)
- Material testing and functional testing (Medicinal products)
- Biological testing procedures

Quasaar acts as single point of contact!

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: Development & Validation of innovative analytical methods

Cooperation ERWEKA - 1

Quasaar is application laboratory for ERWEKA

Comparative Measurements and Method Transfer

- Performance comparison of release devices from different manufacturers and types
- Preliminary studies or official method transfer under GMP conditions
- Experienced laboratory team provides on-site support and training if required
- Preparation of all relevant GMP documents and SOPs

Development and Validation

- Complete method development of the release method, from solubility tests, determination of device type and method parameters to verification of discriminatory properties
- Development & validation of analytical methods for release evaluation (U-HPLC, photometer, etc.)
- Revalidation of methods when changing method parameters (filter, sinker, media, concentration range, formulation, etc.)
- Feasibility review of converting manual methods to automation (including validation)Troubleshooting & optimization of release methods (duration, media, robustness, etc.)
- Preparation of test specifications and SOP

Drug release studies

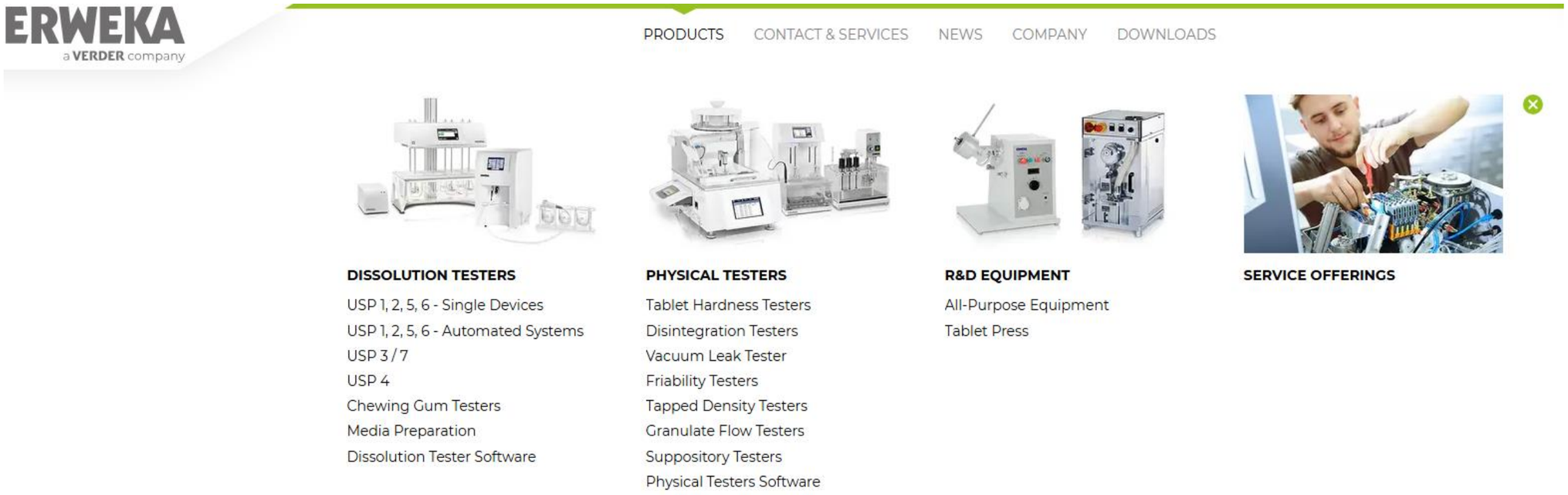
- Quality control and stability studies under GMP / Biopharmaceutical characterization of formulations
- Performance of dissolution profile in different media / pH values - Bioequivalence testing for originator / comparator
- Special release tests: Enteric acid resistance, buffer transfer, enzyme addition, infinity test, intrinsic dissolution, simulation media, influence of food, alcohol, stress conditions etc.

Cooperation ERWEKA - 2

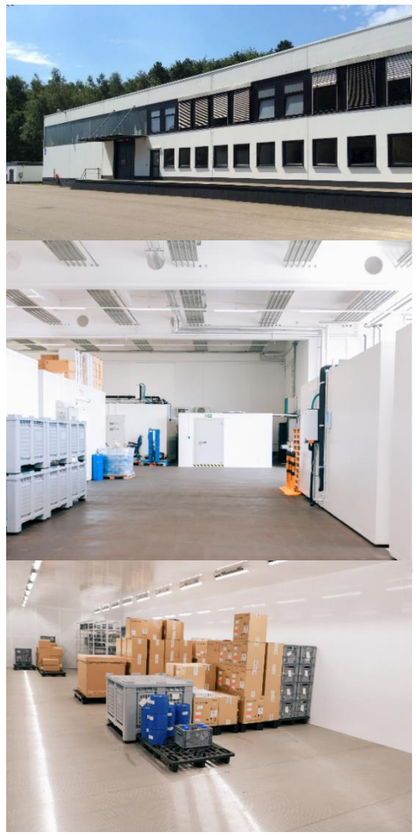
Quasaar is application laboratory for ERWEKA

Support Equipment

- Design of customized drug release tester for the release of special dosage forms
- Design of specific adapters or expansion of relevant device parameters (temperature, volume, rotation speed, etc.)
- Provision of qualification concepts and implementation of qualification activities
- On-site support from an experienced technical team



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	1 x 120 m^3 + 1 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

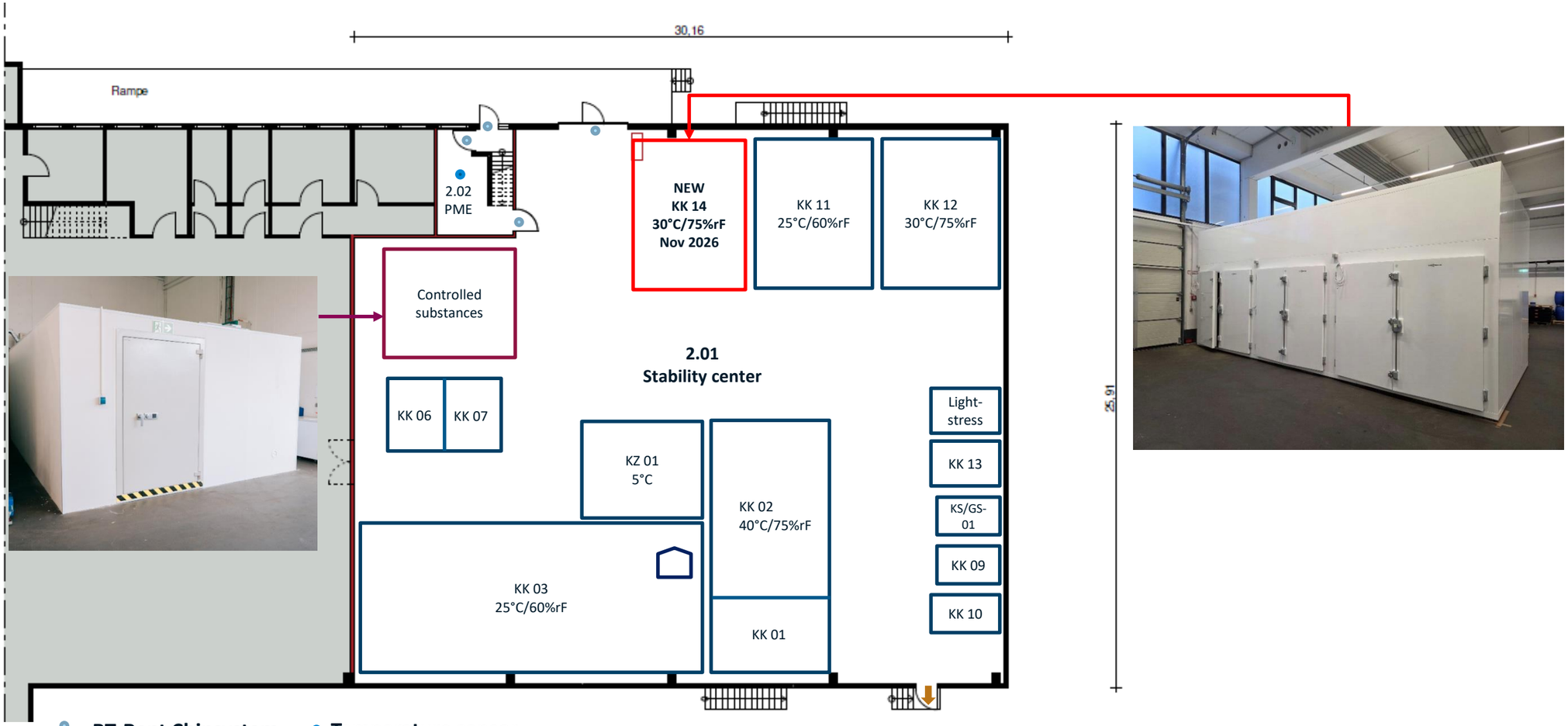
Additional service

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

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

Stability center & Sample registration - Halle 4



BT-Rent Chipsystem Temperature sensor

Door, escape way Quarantine area incoming goods (high volume)

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

Meet Quasaar in 2026

05.03.2026 Mainz

Pharma Forum

Pharma trifft Medizintechnik

IPEC Europe Excipient Conference

2026

– An update on regulatory developments and excipient applications in Drug Delivery –

Your Outsourcing Partner: Quasaar

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