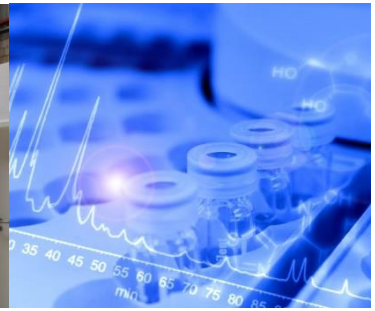
Quasaar

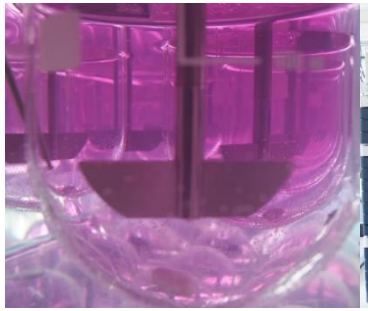
Quality by Efficiency and Innovation

Ministerium für Soziales, Gesundheit, Frauen und Familie

BESTÄTIGUNG DER ÜBEREINSTIMMUNG MIT GMP

CERTIFICATE OF GMP-COMPLIANCE




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)
- DUNS number: 313388660
- FEI number: 3014297892

Certification

- 1st GMP certification October 2015 (Überherrn)
- 2nd GMP certification November 2017 (Überherrn)
- 3rd GMP certification November 2020 (Überherrn)
- 4th and last GMP certification February 2022 (Bexbach)
- FDA approval 05/2019 (Überherrn)
- ANVISA certification 2022 (ongoing)

Quality by Efficiency and Innovation

- 1st GMP certification October 2015 (4th GMP certification March 2022 in Bexbach)
- FDA approval 09/2019, ANVISA certification ongoing (audit in 2021)
- Independent company (founded 02/2015 HRB102208)
- Many years of experience in quality control and pharmaceutical development
- Relief in case of capacity bottlenecks
- Know-how input for technically demanding projects
- Flexible, on-time support & high reactivity in project management
- Large capacities for stability studies and storage
- A certified and reliable partnership & GMP/GSP experienced, stable team
- Fast transfer from R&D to GMP enhances Speed-to-Market
- Large-volume climatic chambers for stability and ageing studies
- High quality, innovation and efficient work environment guarantee high customer satisfaction and regulatory compliance

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

Stability and Ageing Studies

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

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, processes and climatic chambers

Consulting und Training

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

Management Quasaar, years of collective expertise

Dr. Markus Limberger

- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 20 years GMP expertise in an industrial environment
- Focus on Quality control and Quality assurance
- Many fold project experiences from collaborations with almost all renown research driven pharma companies
- > 10 years Head of Technical Management of a GMP service provider (PHAST GmbH), installation of GMP and QM systems
- Regular expert speaker about QA and pharma analytics, member of the respective committee within APV
- Expert speaker and author of several related publications (GMP Berater Verlag)

Dr. Christoph Jacobs

- Study of chemistry, PhD in pharmaceutical and medical chemistry
- > 20 years GMP expertise in an industrial environment
- Head of the API expert team with a provider of analytical services (Across Barriers GmbH)
- Head of QC with set-up and expansion of the QC lab (PHAST GmbH)
- Highly experienced with audits by FDA, European or local authorities
- Expert in dissolution studies and many other QC - methods
- Regular expert speaker about analytical methods under GMP requirements

Relocation to Bexbach

New adress: Lichtenkopfer Weg 1
66450 Bexbach
Start date: 03-2022

New Premises in Bexbach

Industriegebiet Am Kraftwerk
Lichtenkopfer Weg 1
66450 Bexbach

1000 m² Lab / Administration
760 m² Stability center

Status 2022
- Start 07.03.2022
- Investment equipment/premises 2,5 Mio €
- 35 work places establisher (Expansion 50)

Goal 2022/2023
- 5 more work places per year

Technical Equipment – Methods 1

Liquid chromatography:

- HPLC / UPLC (Agilent, Merck-Hitachi)
  2 additional systems purchased
- Detectors: UV-VIS, PDA, fluorescence, light scattering (CAD 2nd detector)

Drug Release:

- Paddle & Basket (USP 1 & 2) automated systems (USP 4 planned)
- Mini paddle -enhancer-cell, "Franz"-cell
- special techniques, special dosage forms
- Biopharmaceutical characterization

Gas chromatography:

- GC / GC-HS (residual solvent, purity, automatic derivatization)

Spektroscopy:

- FTIR (Bruker), UV (Agilent)
- Detector: FID

Titrators:

- Ion analysis, content determination (Methrohm, Xylem-SI-Analytik)

Water determination / Karl-Fischer titration:

- volumetric / coulometric, oven-methode (Metrohm)

New: Atlas Sun-tester, Melting point, Malvern Zetasizer, Viscosimetry (Netzsch), Water activity

Technical Equipment – Methods 2

Pharmaceutical-technical methods:

- Disintegration
- Breaking strength
- Friability
- Testing for visible / non-visible particles
- Microscopic characterisation
- Pharmacopoeia analysis
- Identities
- Limit value tests
- Appearance
- Content - Purity
- Ashing/digestion (2)
- Drying, evaporation loss
- Clarity-colour-opalescence of solutions
- Leak test, Packaging material tests
- Uniformity of content
- Average mass
- Drop size
- Acid, soap, hydroxyl, iodine number
- Wet chemical methods
- Filling volume
- Thin Layer Chromatography
- Sieve analysis
- Viscosimetry

Standard methods:

- Determination of pH value
- Osmolarity
- Polarimetry
- Refractrometry
- Density measurement
- Solubility determination (pH-dependent)
- Distribution coefficient
- Melting point
- Water activity

Special techniques:

- XRPD (Outsourcing)
- Material-specific function tests
- Particle size distribution (also toxic substances)
- Zeta potential (Malvern)
- Laser diffractrometry LD (Sympatec)
- Dynamic Light Scattering DLS (Malvern)
- Particle contamination
- Testing of inhalers
- Permeation measurements of packaging materials
- Microbiological investigations (Outsourcing)

Stability Center Quasaar

Climatic conditions (standard ICH)

25 °C / 60 % r. h.	280 m³
30 °C / 65 % r. h.	30 m³
30 °C / 75 % r. h.	180 m³
40 °C / 75% r. h.	80 m³
5 °C ± 3 °C	80 m³
-20 °C ± 5 °C	

2 new high volume chambers > 80 m³ established in 2022!

Special conditions

50 °C - 80 °C, 0 % to 95% r.h.

50 - 55 °C / 20 - 30 % r. h.	(according ASTM)
25 °C / 40 % r. h.	(1000 L established)
40 °C / 25 % r. h.	(1000 L established)

Light stress according ICH established in 2022

Cyclic conditions/transport validation -20 °C to 150 °C

Storage area for controlled substances available

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

Outsourcing Concept

Ministerium für Soziales, Gesundheit, Frauen und Familie

Zertifikat-Nr./Certificate no:
DE_SL_01_GMP_2015_0041
Aktenzeichen/Reference Number:
G:\GMP\Quasaar

BESTÄTIGUNG DER ÜBEREINSTIMMUNG MIT GMP	CERTIFICATE OF GMP COMPLIANCE
Teil 1	**Part 1**
Ausgestellt nach einer Inspektion gemäß	Issued following an inspection in accordance with
☒ Art. 111 (5) der Richtlinie 2001/83/EG	☒ Art. 111 (5) of Directive 2001/83/EC
☒ Art. 80 (5) der Richtlinie 2001/82/EG	☒ Art. 80 (5) of Directive 2001/82/EC
☒ Art. 15 der Richtlinie 2001/20/EG	☒ Art. 15 of Directive 20O1/20/EC
☒ § 64 Abs. 3f Arzneimittelgesetz	☒ Sect 64 para 3f Arzneimittelgesetz (German Drug Law)
Die zuständige deutsche Überwachungsbehörde bestätigt:	The competent authority of GERMANY confirms the following:
Die Firma **Quasaar GmbH** **Comotorstrasse 2** **66802 Überherrm**	The company (see left)
Anschrift der Betriebsstätte **Quasaar GmbH** **Comotorstrasse 2** **66802 Überherrm** **Deutschland**	Site address (see left)
wurde im Rahmen der nationalen Arzneimittelüberwachung inspiziert in Verbindung mit der Tätigkeit gemäß § 14 Abs. 4 Nr. 3.	has been inspected under the national inspection programme in connection with its activity according to Sect 14 para 4 no 3.

DE_SL_01_GMP_2015_0041 Unterschrift: Ute Knott Seite 1/4

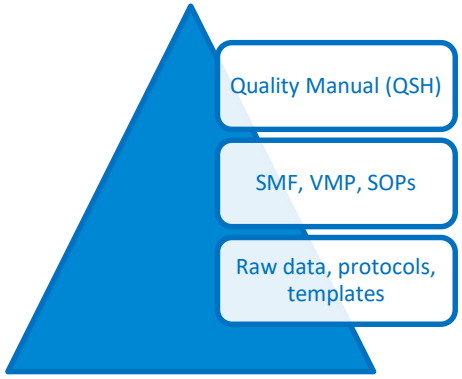
Build-up of collaboration

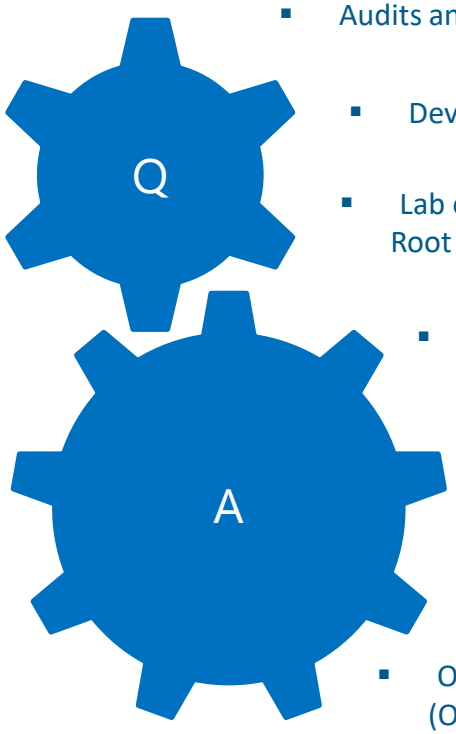
1. Agreed definition of basic concept for outsourcing cooperation
2. Ratification of secrecy agreement, exchange of relevant documents
3. Quotation built on feasibility evaluation and compilation of techniques and equipment to be used
4. Integration of all relevant GMP documents, ratification QAA / service agreement
5. Definition of project team & time schedule plus capacity check
6. Audit

Living collaboration

1. Installation of methods (if needed optimization & validation)
2. Lab training on site & method transfer
3. Sample logistic & storage of samples for stability tests
4. On-going work on tests and analysis
5. Certificates and stability reports, reporting of results to the customers (connectivity to customer–LIMS)
6. Performance monitoring by KPI
7. Regular Jour Fixe with the customer team

Efficient Quality System guarantees GMP-compliant workflows & proceedings





- Audits and inspections
- Deviation
- Lab evaluation, Root cause analysis
- Self inspection
- Complaints
- CAPA-Management
- OOX (OOS, OOE, OOT, OOC)

Added Value Quasaar

- GMP-certified & independent company
- Competence in highly regulated Pharma and Life-Science (GMP, GSP)
- State of the art laboratories and technical equipment focused on QC / Analytics
- Large-volume technical facilities for stability and ageing studies
- GMP experienced, stable team and experts (5 to > 20 years GMP experience)
- Established project management for outsourcing activities
- Overflow management & support for challenging projects
- High flexibility in project implementation and accurate timeline management
- Excellent audit history with authorities / Big Pharma
- Specific know-how concerning special dosage forms, biopharmaceutical characterization, stress & compatibility testing, nanomedicine
- Established networks for scientific and regulatory expertise
- Combination of expertise and flexibility inside a highly regulated environment
- Room for expansion stability center, laboratories and GMP areas

Quality by Efficiency and Innovation

Perspective / Goals 2022

- New location Bexbach
- ANVISA Certification – Center for Equivalence Testing
- Establishment LIMS System Maqsima Lab+
- Upgrade Stability Center – additional climatic chambers
- Increase employees (35)
- Increase of business (20%)

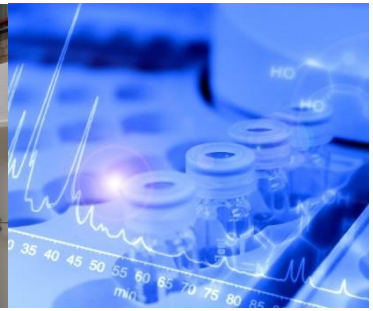
Your Outsourcing Partner

Quasaar Team

Quasaar GmbH

Dr. Markus Limberger
T +49 (6826) 818962 12
m.limberger@quasaar.de
M +49 (162) 9677500
Lichtenkopfer Weg 1
66450 Bexbach
www.quasaar.de

Dr. Christoph Jacobs
T +49 (6836) 818962 11
c.jacobs@quasaar.de



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