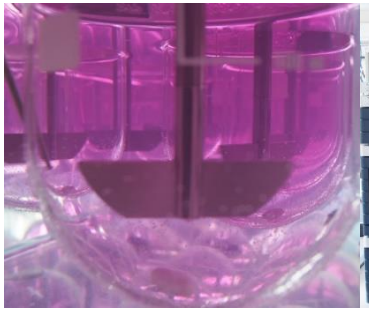
Quasaar

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)
- 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 2023 (ongoing)

Quality by Efficiency and Innovation

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

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

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

New Premises in Bexbach

Industriegebiet Am Kraftwerk
Lichtenkopfer Weg 1
66450 Bexbach

1000 m² Lab / Administration
760 m² Stability center

Status 2023
- Start 07.03.2022
- 35 work places established (Expansion to 60)

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) autom. systems (USP 4 planned)
- Mini paddle -enhancer-cell
- Franz-cell system
- Flotalyzer
- special techniques, special dosage forms
- Biopharmaceutical characterization

Gas chromatography:

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

Technical Equipment – Methods 1

Spektroscopy:

- FTIR (Bruker),
- UV (Agilent)

Titrators:

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

Water determination / Karl-Fischer:

- Volumetric / coulometric
- Oven-methode (Metrohm)

Particle size

- DLS: Malvern Zetasizer
- LD: Helos Sympatec

New equipment

- Melting point
- Viscosimetry (Netzsch)
- Water activity

Technical Equipment – Methods 2

Pharmaceutical-technical methods:

- **Pharmacopoeial analysis (EP, USP, JP)**
- Disintegration
- Breaking strength
- Friability
- Testing for visible / non-visible particles
- Microscopic characterisation
- 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:

- 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)
- XRPD, NMR, MS-MS (Outsourcing)

Stability Center

Climatic conditions (standard ICH)

25 °C / 60 % rh	280 m^3
30 °C / 65 % rh	30 m^3
30 °C / 75 % rh	180 m^3
40 °C / 75% rh	80 m^3
5 °C ± 3 °C	80 m^3
-20 °C ± 5 °C	500 L

2 new high volume chambers > 80 m^3
25 °C / 60 % rh and 30 °C / 75 % rh

Special conditions

50 °C - 80 °C, 0 % to 95% rh
25 - 60 °C / 25 - 75 % rh

25 °C / 40 % rh	(1000 L)
40 °C / 25 % rh	(1000 L)
30 °C / 35 % rh	on demand
25 °C / 75 % rh	(1000 L)
60 °C / 65 % rh	(15 m^3 established)

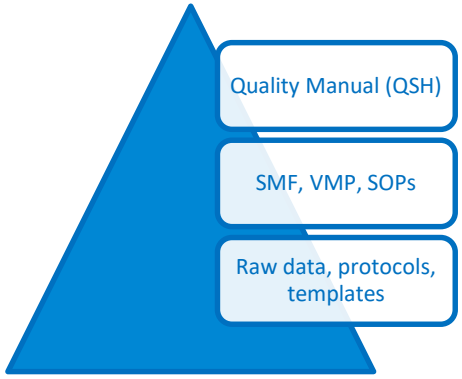
Technical data

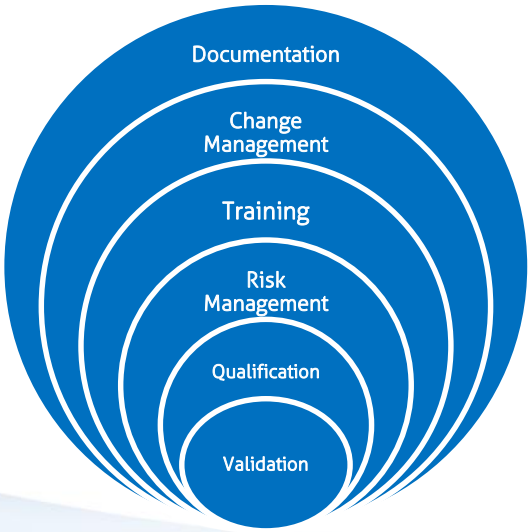
- Redundant regulation of temperature and humidity
- Storage of palettes, barrels und bulk possible
- Overheat and humidity control, monitoring system Yokogawa
- Alarm transmission by SMS, E-Mail

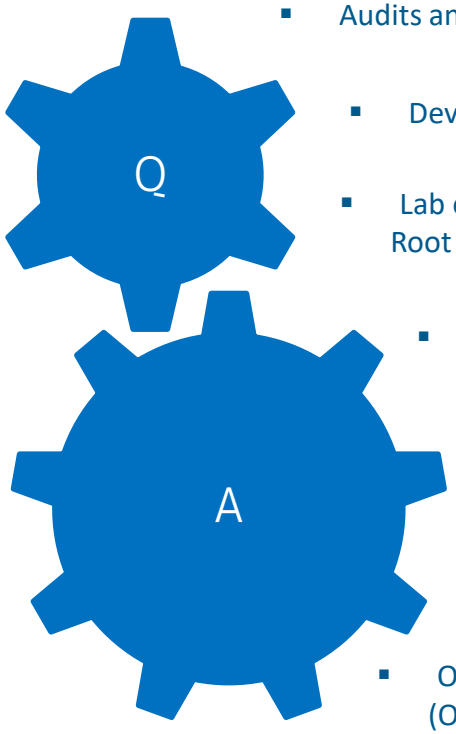
Additional service

- Light stress according ICH
- Cyclic conditions/transport validation -20 °C to 150 °C
- Storage area for controlled substances established

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)

Concept Contract Services

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

Your Outsourcing Partner

Quasaar Team

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