



QP • GxP-Consulting • Regulatory • Analytical

Our Services for the Life Sciences Industry



A&O Pharma GmbH



The Company



The Solutions



The Services

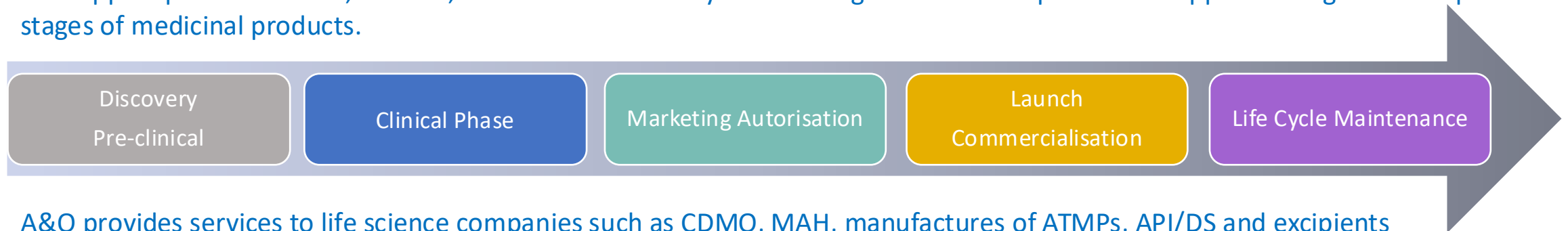


The Contacts

A&O Pharma GmbH – The Company

Where Quality matters.

We support pharmaceutical, biotech, and chemical industry with strategic advice and operational support during all development stages of medicinal products.



A&O provides services to life science companies such as CDMO, MAH, manufactures of ATMPs, API/DS and excipients of all phases of company maturity: established companies as well as start-Ups. This includes:

ATMPs / Biopharmaceuticals & Biotechnology, including:

- Radiopharmaceuticals
- Cell and gene therapies
- Immunotherapies
- Vaccines
- MABs
- Hormones

Pharmaceuticals – all dosage forms

A&O Pharma GmbH – The Company

Broad range of
expert know how

> 70 Clients

Approx. 100
successful projects

100 % satisfied
clients

Strong growth
since 2019

A&O Pharma GmbH



Present in the north and in the south of Germany

- Headquarter:
Am Sattel 17, 79588 Efringen-Kirchen, Germany
- Laboratory:
Fraunhoferstr. 3, 25524 Itzehoe, Germany
- Manufacturing:
Marie-Curie-Str. 8, 79539 Lörrach, Germany
(Packaging, Labelling and Distribution IMPs)

Website: www.aopharma.de

Your primary contact:

Dr. Olaf Mundszinger (Founder & CEO):
o.mundszinger@aopharma.de
mobile phone: +49 170 275 0459

Efringen-Kirchen &
Lörrach



A&O Pharma GmbH – The Company



Privately owned company,
founded in January 2019 by
Dr. Olaf Mundsinger, Chemist
and QP



April 2020 joining of Mr.
Alexander Trautmann,
Pharmacist, GMP&MDR
Consulting



January 2022: Dr. Klaus-Peter
Kreth, Pharmacist / QP joins the
company



January 2023: Ms. Leidy
Fajardo, QA Specialist Pharmacy
joins the company



September 2023: Dr. Emmanuel
Bey, Chemist / QP joins the
company



October 2024: Ms. Ute Hegener
and Dr. Barbara Siebertz,
Professionals in Regulatory
Affairs join the company



January 2025: Ms. Tatjana
Pazer, QPs joins the company
August/November 2025: Dr.
Lenka Taylor and Dr. Kai Huwig,
both QPs join the company



Q2 2025: Establishment of a
new and fully digitalized
Analytical Laboratory



June 2026: Mr. Thomas Lutz, QP
July 2026: Mr. Sascha Manthei
join the company

Externally supported by a qualified partner network.

A&O Pharma GmbH – The Team

QP Services	Special QP-Services	GxP Consultancy	Regulatory Affairs	Analytics
Dr. Olaf Mundszinger Dr. Emmanuel Bey Dr. Klaus-Peter Kreth Ms. Tatjana Pazer Dr. Thomas Lutz Dr. Lenka Taylor Dr. Kai Huwig Mr. Sacha Manthei • Qualified Persons in accordance with §14 AMG	Dr. Olaf Mundszinger • Batch Release of – sterile Products – Biotechnology products Ms. Tatjana Pazer • Batch Release of – sterile Products Dr. Lenka Taylor • Batch Release of – IMPs Mr. Sascha Manthei • Batch Release of – IMPs Release of ATMPs with external Partners	Mr. Alexander Trautmann • GMP Consulting & Audits • Education & Training Ms. Tatjana Pazer • GMP Consulting & Audits • Sterile manufacturing Ms. Leidy Fajardo • QA Specialist • GMP Consulting & Audits • Computer System Validation Ms. Ute Hegener • Strategic Consulting Dr. Barbara Siebertz • GDP Consulting & GMP/GDP Audits Dr. Thomas Lutz • GMP Consulting & Audits Dr. Lenka Taylor / Sascha Manthei • Clinical Trials Kai Huwig • GMP Consulting & Audits	Ms. Ute Hegener • Head of Regulatory Affairs • Marketing Authorisation Applications • Lifecycle maintenance • Information Officer in accordance with § 74a Dr. Barbara Siebertz • Master in Drug Regulatory Affairs • Marketing Authorisation Applications • Lifecycle maintenance • Information Officer in accordance with § 74a AMG Dr. Lenka Taylor / Sascha Manthei • Clinical Trial Application support • IMPD	Dr. Anne Katharina Schmidt • Head of Quality Control • Medicinal Products • Biotech Products Mr. Florian Götsche • Head of Analytical Laboratory Mr. Michel Tornow • Project Manager New Products Mr. Matthias Petersen • Laboratory technician Dr. Thomas Lutz • Qualified Person in accordance with § 14 AMG

A&O Pharma GmbH – The Solutions



Which are your plans and ideas to further increase your market success?

For A&O the individual needs of our clients are core. Our solutions are strictly tailored to our clients' needs and expectations.

As one-stop solution Service Provider, A&O supports you with our extensive experts' experience to save your time and costs and enables you to focus on your successful business through all stage gates of your products from early development to product withdrawal.

Whatever you need for the success of preclinical and clinical development, market access, and GxP as well as Regulatory compliance maintenance of your products – A&O is at your side.

A&O holds a German manufacturing and import authorisation (MIA) for investigational and market products for batch release and EU retesting. This makes us unique amongst most of the other service providers and significantly contributes to keep your organisation slim and efficient.



A&O Pharma GmbH – The Services

QP Services	Quality and Compliance Services	Regulatory Affairs Services	Analytics
• Qualified Person in accordance with §14 AMG • Batch Release of Drug Products and IMPs for chemical, sterile, Biotechnology products • Execution of a Batch Release certificate for release of the product(s) to the market or the clinical trial • Registration of released batches into Batch Register • EU Importation of (investigational) Medicinal Products • Surveillance of GMP compliant manufacturing and testing of the product(s) from starting material to finished Product • Review and release of manufacturing and testing instructions • QP declaration (API, IMPs) • Consultancy related to manufacturing and testing of the product(s) • Consultancy related to GMP-/GCP-compliant sourcing, manufacturing, blinding of IMPs	• GxP Consulting • GMP/GDP/GCP/GVP/GLP/GcLP Audits • Education & Training • GxP issue solving • Qualification • Validation • Tech Transfer • Risk Assessment • GxP Quality Systems • License Application • Inspection Readiness (EU, FDA) • Vendor Management incl. risk-based qualification, audits • QA Services incl. management of: – CAPA – Change Control – Deviations – Complaints – Self-Inspection – PQR • Interim Management, staff augmentation	• Strategic consultancy • Interim Marketing Authorisation Holder • REG Intelligence • Submission of MAA and CTA • Support for Scientific Advise procedures • Communication with Health Authorities • Lifecycle maintenance incl. variation applications and renewals • Product information and labelling texts • Information Officer in accordance with § 74a AMG • Support for product launches • Support for Merger & Acquisition activities • Preparation of IMPDs • Preparation of MAA Dossiers • Support for filing answers for procedural list of questions (LoQ)	• Modern, fully digitalized Analytical Laboratory (operational Q1/2025) located in northern Germany (Itzehoe) • Release-Testing / EU-Reanalysis of Finished Dosage Forms • Analytical Method Development • Trace analysis by LC-MS/MS (e.g. Nitrosamines in APIs and FDF) • Fast order processing thanks to efficient, fully digitalized processes
			Special Services
			• IMPs Secondary Packaging, Labelling and Distribution of IMPs • iMAH interim Marketing Authorisation Holder: Your fast track to the EU market • Sterile Manufacturing Annex 1 compliance Contamination Control Strategy Implementation of Hygiene Management

A&O Pharma GmbH – The Services

QP Services

QP Services:

- Batch Release (investigational and commercial medicinal products) under license of the client; notification as external QP by the client at the concerned competent authority
- Batch Release (investigational and commercial medicinal products) under the MIA license of A&O; notification as manufacturer in the Clinical Trial Application (CTA) or Marketing Authorisation Application (MAA)
- Compliance Monitoring of the manufacturing process from API to Finished Dosage Form (Drug Product)

QP Declaration for importation of APIs and (investigational) medicinal products from non EU countries

Product Importation

- Importation of investigational and market products under the MIA license of A&O; notification as EU QP certifying importation site in the Clinical Trial Application (CTA) or Marketing Authorisation Application (MAA)

GxP Issue Solving

- Compliance remediation activities, Consultancy related to manufacturing and testing of the product(s)

A&O Pharma GmbH – The Services

Quality and Compliance Services – Sterile Manufacturing

Support for GMP compliant Sterile Manufacturing

- Strategic consultancy
- New Annex 1 GAP analysis /implementation
- Support during construction and re-construction projects
- Contamination Risk Assessment
- Contamination Control Strategy
- Implementation of Hygiene Management
- Training on Hygiene Management
- Inspection Readiness
- Compounded Products (Cytostatics / parenteral nutrition) according to GMP or §35 ApoBetrO for pharmacies

A&O Pharma GmbH – The Services

Quality and Compliance Services

GxP Quality System

- Conceptual Design of QM-Systems
- Optimization/harmonisation of QM-Systems and Quality management processes
- Gap Analysis and writing of SOPs and other documents

GMP/GDP License Applications

- Preparation, compilation of application documents and package
- Communication with the concerned competent authority

Inspection Readiness

- Preparation for Authority Inspections and post-processing of inspections – assuring the Inspection Readiness of the client including gap analyses, compliance check tailored to the relevant regulatory requirements, strategic consultancy, operative support
- Mock inspection

Education and Training (In-house and external)

A&O Pharma GmbH – The Services

Quality and Compliance Services (cont.)

Qualification and Validation, Tech Transfer

- GMP facility concept, design, layout review
- Equipment Qualification
- Tech Transfer
 - Analytical methods and manufacturing process validation
- Cleaning validation
- Computer System Validation
- Validation risk assessment, protocols and reports
- Stability protocols and reports

Risk assessments / Risk Management

Interim Management

- Responsible Person (GDP)
- Responsible Person for Controlled Drugs
- Head of QA
- Information Officer

A&O Pharma GmbH – The Services

Quality and Compliance Services (cont.)

GxP Vendor Management/Audits

- Risk based Vendor Qualification and re-qualification
- Vendor audits
- Vendor Management Programm:
 - Consolidation of approved vendor lists across GxP functions
 - Vendor risk assessment
 - Development of a risk-based audit programme
 - Management and execution of the audit programme
 - Development of vendor metrics
 - Development of Quality / Technical Agreements (QTAs)
 - Oversight or management of audit follow-up, incl. CAPA close out
 - Technical support for issues management

QA Services incl. management of:

- CAPA, Change Control, Deviations, Complaints, Self-Inspection
- PQR
- Risk assessments (incl. Elemental Impurities)

A&O Pharma GmbH – The Services

Regulatory Affairs Services

Strategic Consultancy

Interim Marketing Authorisation Holder (iMAH)

- Acting as Applicant for Marketing Authorisations in EU
- Conducting and monitoring the Application Procedure
- Communication with Authorities
- Acting as Marketing Authorisation Holder after MA approval until launch
- Identification/establishing of a commercial distributor as MAH
- Transfer of MA to the distributing MAH

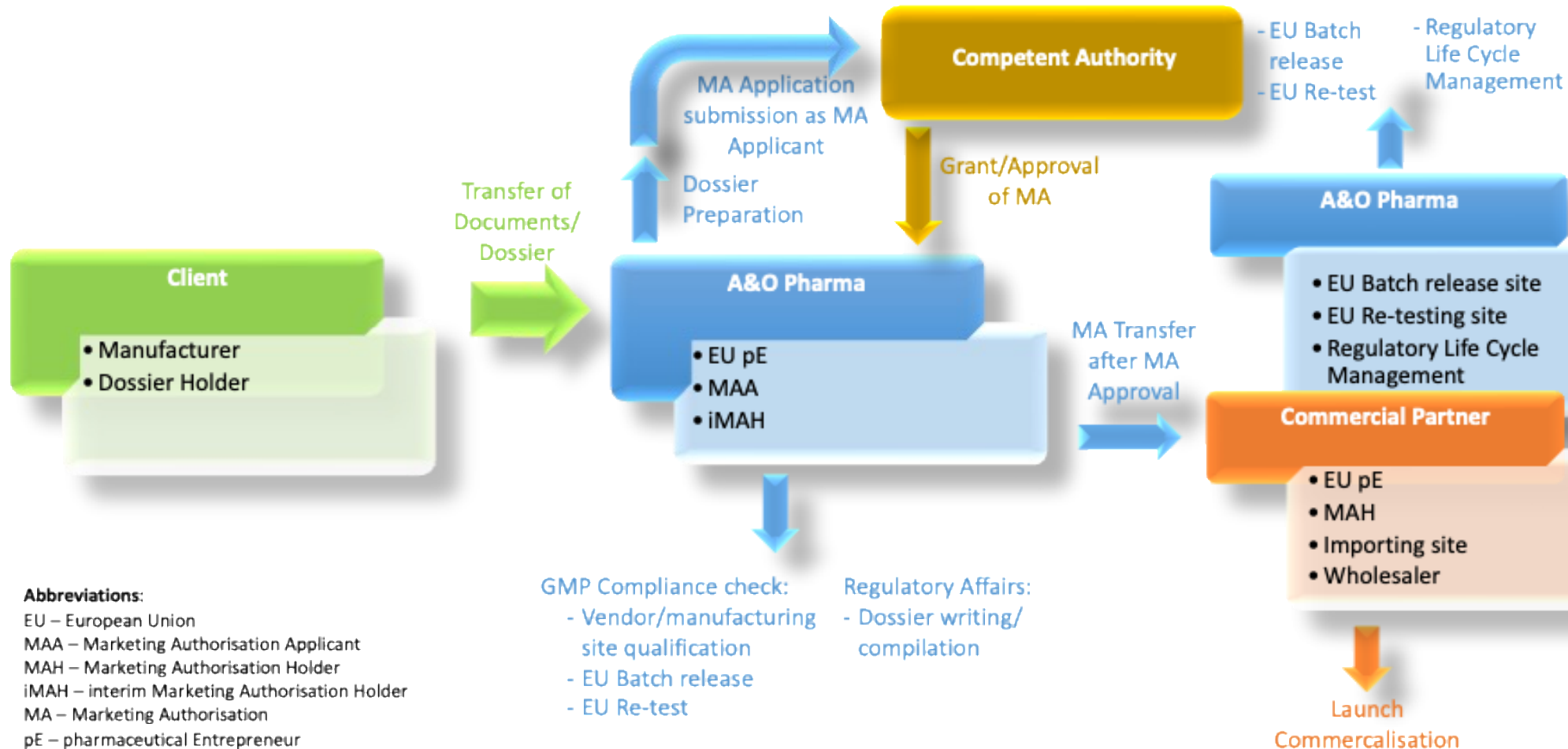


Marketing Authorisation and Clinical Trial Applications

- Preparation of MAA Dossiers (Dossier writing, filing, and eCTD publishing)
- Preparation of IMPDs (Dossier writing, filing, and eCTD publishing)
- Support for Scientific Advice procedures
- Communication with Health Authorities
- Submission of MAA and CTA
- Support for filing answers for procedural list of questions (LoQ)

Regulatory Affairs Services (cont.) – The iMAH Model

Your fast track to the EU market!



A&O Pharma GmbH – The Services

Regulatory Affairs Services (cont.)

Information Officer (IO) in accordance with § 74a AMG

- Assignment of the IO under the client's organisation
- Release of Product Information texts, mock ups, and packaging material
- Mandatory texts (Pflichttexte)

Product information and labelling texts

- Review of procedural texts
- Review of national texts
- Proof reading support for the Information Officer during text release

Lifecycle maintenance incl. variation applications and renewals

- Update of Dossier modules
- Variation classification
- Filing and submission of the variation package

A&O Pharma GmbH – The Services

Regulatory Affairs Services (cont.)

Support for product launches

- Part of the client's launch team for Quality and Regulatory aspects during the product launch
- Notifications to IFA and Lauer

Support for Merger & Acquisition activities

- Gap analyses, Due diligence (Quality compliance, CMC, Regulatory)
- Established and development products

A&O Pharma GmbH – The Services

Clinical Trial Services

QP and manufacturing services for clinical trials

- Batch release of IMP
- EU QP certification for IMPs manufactured outside of the EU
- EU QP declaration for IMPs manufactured outside of the EU

Coming soon (Q1/2027) at our new facility (Lörrach, Germany):

- Secondary packaging and Labelling (including blinding, as needed) of Investigational Medicinal Products (IMPs)
- GMP-/GCP-compliant storage of IMPs
- GDP-compliant shipment to the clinical trial sites



A&O Pharma GmbH – The Services

Clinical Trial Services (cont.)

Support for Clinical Trial preparation

- Consultancy related to GMP-/GCP-compliant manufacturing, sourcing, blinding of IMPs
- GCP-compliant labelling texts
- Consultancy related to trial set up in the clinical setting, limitations and possibilities at clinical sites
- Preparation of IMP/Pharmacy Manuals, Drug Account Logs and other documents for clinical sites

Clinical Trial Applications

- Preparation of IMPDs (Dossier writing, filing, and eCTD publishing)
- Support for Scientific Advice procedures
- Communication with Health Authorities
- Submission of CTA
- Support for responses to RFI (request for information) during CTA application

A&O Pharma GmbH – The Services

Analytical Services

Modern, fully digitalized Analytical Laboratory (operational Q2/2025) located in northern Germany (Itzehoe)

- Release-Testing / EU-Reanalysis of Finished Dosage Forms, including Batch Release
- Testing of starting materials: excipients and active ingredients in accordance with pharmacopoeia methods
- Testing of Cannabis flos and Cannabis extracts
- Analysis of biotechnologically produced medicines
- Development, validation and transfer of analytical methods
- Trace analysis using LC-MS/MS (e.g. nitrosamines in active ingredients and medicinal products, aflatoxins in plant products, Extractable & Leachables, swab test analysis)
- Testing of ICH stability samples
- Microbiological analysis of non-sterile and sterile medicinal products
- Fast order processing thanks to efficient, fully digitalized processes

Release-Testing / EU-Reanalysis of Finished Dosage Forms, including Batch Release

To ensure the quality and safety of a medicinal product, we carry out comprehensive testing in accordance with the product specification. Our range of services includes:

- IR spectroscopy for identity testing,
- UV-VIS spectroscopy,
- Thin-layer chromatography (TLC): identity and purity testing,
- Gas chromatography: content and purity determinations / determination of residual solvents, FID detector, headspace and direct injection,
- Liquid chromatography (HPLC, HPLC-MS/MS): content determinations, testing for related substances, identity testing, DAD and MS/MS detector,
- Clarity and opalescence of liquids,
- Colour of liquids,
- pH value,
- Relative density,
- Loss on drying,
- Water determination by the Karl Fischer method,
- Active ingredient release from solid dosage forms using a dissolution tester (on-/offline; paddle and basket),
- Disintegration time of tablets and capsules,
- Tablet hardness,
- Uniformity of content and mass of single-dose pharmaceutical forms,
- Determination of the withdrawable volume of parenteral preparations,
- Ethanol content,
- Methanol and 2-propanol,
- Microscopy

Can't find your method here? Get in touch! Many further tests can be carried out in collaboration with carefully selected and qualified partner laboratories.

A&O Pharma GmbH – Analytical Services

Testing of starting materials: excipients and active ingredients in accordance with pharmacopoeia methods

- Quality control of raw materials and starting materials,
- Testing for identity, content and purity in accordance with current national and international pharmacopoeias or the customer's own specifications (Ph. Eur., USP, etc.).

A&O Pharma GmbH – Analytical Services

Testing of Cannabis flos and Cannabis extracts

Medical cannabis flowers and extracts are tested in our GMP laboratory using validated methods, ensuring compliance with all quality requirements. This provides a reliable foundation for a successful entry into the German and European markets. The analytical tests cover the requirements set out in the German and European Pharmacopoeias (DAB/Ph.Eur.).

Analysis of cannabis flowers in accordance with Ph.Eur. 07/2024:3028 (Cannabis flos) and Ph.Eur. 07/2017:1433 (Herbal drugs):

- Identity testing: macroscopic, microscopic and by HPLC (Ph.Eur. 2.8.25),
- Assays for cannabinoids such as delta-9-tetrahydrocannabinol (THC), delta-9-tetrahydrocannabinolic acid (THC-A), cannabidiol (CBD) and cannabidiolic acid (CBD-A) by HPLC (Ph.Eur. 2.2.29),
- Purity tests: cannabinol (CBN, Ph.Eur. 2.2.29), foreign matter (Ph.Eur. 2.8.2), loss on drying (Ph.Eur. 2.2.32),
- Microbiological testing in accordance with Ph.Eur. 5.1.8 Cat. A, B and C as well as Ph.Eur. 5.1.4,
- Testing for aflatoxins B1, B2, G1, G2 (Ph.Eur. 2.8.18), ochratoxin A (Ph.Eur. 2.8.22), pesticides/dithiocarbamates (Ph.Eur. 2.8.13), heavy metals arsenic, lead, cadmium and mercury (Ph.Eur. 2.4.27),
- Determination of ash (2.4.16).

Analysis of cannabis extracts in accordance with the DAB definition of 'standardised cannabis extract' and Ph. Eur. 04/2019:0765 (Herbal drug extracts):

- Identity testing by HPLC (Ph. Eur. 2.2.27),
- Assay of cannabinoids such as delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) by HPLC (Ph. Eur. 2.2.29),
- Purity tests: cannabinol (CBN, Ph. Eur. 2.2.29), moisture content (Ph. Eur. 2.5.12),
- Solvent residues such as ethanol (Ph. Eur. 5.4),
- Microbiological testing in accordance with Ph.Eur. 5.1.8 and Ph.Eur. 5.1.4,
- Testing for aflatoxins B1, B2, G1, G2 (Ph.Eur. 2.8.18), ochratoxin A (Ph. Eur. 2.8.22), pesticides/dithiocarbamates (Ph. Eur. 2.8.13), heavy metals arsenic, lead, cadmium and mercury (Ph. Eur. 2.4.27),
- Determination of relative density (Ph. Eur. 2.2.5).

A&O Pharma GmbH – Analytical Services

Development, validation and transfer of analytical methods

Our experts develop and validate analytical methods on behalf of clients under GMP conditions. In doing so, we provide you with reliable support in meeting regulatory requirements, particularly in the context of the authorisation and registration of medicinal products.

We also offer tailored validation approaches for food and food supplements, based on pharmaceutical standards.

Our range of services includes:

- Development of new and optimisation of existing test methods,
- Validation in accordance with ICH Q2,
- Preparation of validation plans and validation reports,
- Method transfer: preparation of plans and reports,
- Preparation of testing procedures.

A&O Pharma GmbH – Analytical Services

Trace analysis using LC-MS/MS

(e.g. nitrosamines in active ingredients and medicinal products, aflatoxins in plant products)

Development and validation of analytical methods for the determination of impurities and (geno-)toxic contaminants at low concentrations under GMP or non-GMP conditions using high-performance, precise triple-quadrupole LC-MS/MS (Agilent Ultivo 6475).

LC-MS/MS provides all the necessary tools for the development of sensitive, robust and rapid targeted analytical methods for the quantification of substances at low concentrations in biological and non-biological matrices.

A&O Pharma GmbH – Analytical Services

Testing of ICH stability samples

We conduct stability testing of finished medicinal products, active pharmaceutical ingredients and medical devices containing medicinal products in accordance with current ICH and GMP guidelines. We cover long-term, short-term and in-use studies, analyzing all relevant parameters, including content, purity and dissolution profile.

Our range of services includes the preparation of test plans, clear evaluations and individual stability reports tailored to your needs – precise and in full regulatory compliance.

Stability storage is carried out in collaboration with carefully selected and qualified partner laboratories and covers all climatic conditions.

A&O Pharma GmbH – Analytical Services

Microbiological analysis of non-sterile and sterile medicinal products

- Microbial count determinations (bioburden) in accordance with Ph.Eur. 2.6.12 (TAMC/TYMC),
- Detection of specified microorganisms in accordance with Ph.Eur. 2.6.13,
- Tests on finished medicinal products in accordance with Ph.Eur. 5.1.4,
- Tests on herbal medicinal products for oral use in accordance with Ph.Eur. 5.1.8, categories A, B and C,
- Sterility testing in accordance with Ph.Eur. 2.6.1,
- Endotoxin testing in accordance with Ph.Eur. 2.6.14 and Ph.Eur. 2.6.32.

The tests are carried out in collaboration with carefully selected and qualified partner laboratories.

A&O Pharma GmbH – Analytical Services

Analytical Laboratory

Brandnew state of the art Equipment

- 2x Agilent 1260 Infinity III HPLC system, equipped with DAD; client/server architecture OpenLab
- Agilent 8890 GC / GC-MS-system, liquid & gas injection, FID; client/server architecture OpenLab
- Agilent 1290 Infinity III LC-MS/MS (Ultivo Triple Quadrupol)
- Sotax-Dissolution ATS Xtend system Online UV- / Offline HPLC-sampling mit Q-Doc-software
- Metrohm KF / KF-Headspace system with autosampler (Omnis-Software)
- FT-IR (Agilent), Hardness-Tester (Sotax ST50), Disintegration (Sotax DT50)
- Merck Milli-Q Watersystem
- GUS LABS/Q-LIMS for paperless, digitalized processes
- Narcotics BtM-licence

A&O Pharma GmbH – Case Studies

Project 1

To meet customer demand of an Excipient and API manufacturer seeking support for the upgrade of the quality system according to GMP requirements.

A&O delivered the following support:

- QA coaching to the client's leadership team
- QA SME support
- GMP facility design support
- Inspection readiness
- Training
- CSV support

A&O continuing support to this client as expert advisor, trainer and QP services

Project 2

During the final discussion of the new Annex 1 a CDMO specialized in the manufacturing of sterile (liquid & lyophilized) Drug Product wanted to ensure a smooth implementation of the coming requirements.

A&O delivered the following support:

- Initial gap-analysis
- Prioritized action list
- Concept for Contamination Control Strategy (CCS)

Project 3

A contract research institute planned to set up its own manufacturing site for biopharmaceuticals and to obtain a manufacturing license.

A&O provided the following support to the client:

- GMP due diligence
- URS review
- QMS upgrade
- 3rd party Audits
- Inspection readiness

A&O continuing support to the client as expert advisor and QP services.

Project 4

A Sponsor of a Clinical Trial is seeking to partner for the manufacturing, testing, packaging, blinding and release of an IMP.

A&O provided the following support to the client:

- GMP due diligence
- Provision of the IMPD and Technical Agreements
- Qualification of critical suppliers
- 3rd party Audits

A&O continuing support to the Sponsor as expert advisor and QP services.

A&O Pharma GmbH – Service Models

Our service models allow scalable partnerships.

Our experts are available when you need them – where you need them – from small scale tactical support to outsourcing of entire product portfolios

TACTICAL SUPPORT

(On-site) interim support of special functions/tasks for a defined timeframe:

- Special expertise and knowledge
- Reduction of overhead
- Flexible solution for peaks
- Cover for sick leave, maternity leave, hiring freeze, resource shortage

PREFERRED PROVIDER

Long-term tactical support, ongoing relationship:

- Extension of transactional project-by-project approach
- Relatively easy to implement
- Preferred providers according to their area of expertise
- Master Service Agreements
- Can be contracted ad hoc

STRATEGIC PARTNERSHIP

Mutual collaboration, shared objectives and milestones, outsourcing of:

- Functions
- Products
- Portfolios
- Regional responsibilities
- External service provider as strategic partner

A&O Pharma GmbH – Why partner with A&O?



A&O Pharma GmbH – Why partner with A&O?

Your benefits are:

- Time and cost savings by working with an experienced, reliable and service oriented team of Industry Experts
- We are solution oriented and we deliver high-quality output

Thank you very much !

A&O Pharma GmbH looks forward to working with you