Why choose A&O Pharma?

Whether your product is already marketed globally, in clinical phases, or under development, **a well-defined strategy is crucial.**

Our team of experienced professionals brings extensive GxP, analytical, and regulatory expertise to **guide you every step of the way.**

A&O Pharma GmbH also offers unique solutions for importing products into the **EEA, EU re-analysis, and batch release**, being one of the few service providers with its **own Manufacturing and Import Authorisation (MIA) for these services.**

Partner with A&O Pharma GmbH
Let us support your journey towards **successful product commercialisation with smart, cost-effective solutions** tailored to your needs fast and efficient.

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A&O PHARMA

Where Quality matters.

Are you planning the next steps towards **commercialisation of your products?**

Are you looking for an **experienced partner** with **extensive GMP, GDP, analytical, and regulatory experience to guide you?**

Are you looking for **a smart and cost saving solution for the import of your products into the EEA, the EU re-analysis and batch release?**

If your answer to one or more of the questions is "yes", then A&O Pharma GmbH is your partner of choice.

We provide **Quality and Compliance, Regulatory Affairs and Analytical Services** fast and efficient.

Our Quality and Compliance Services

- QP services incl. assignment of QP function, batch release FDF/IMP
- Product import FDF/IMP
- GxP issue solving incl. Qualification and Validation, Tech Transfer, and comprehensive risk assessments (incl. Elemental Impurities & Nitrosamines)
- GxP Quality System and license applications
- Inspection Readiness (EU/FDA)
- Vendor Management incl. risk-based qualification and audits
- QA services: management of CAPA, change control, deviations, complaints, self-inspection, preparation of PQR
- Interim Management, staff augmentation
- Education and Training

Our Analytical Services

- A state of the art, fully digitalised analytical laboratory
- Release-testing / EU-Retest of Finished Dosage Forms (FDF)
- Analytical method transfers and validation
- Trace analysis by LC-MS/MS (e.g., Nitrosamines in APIs and FDF)
- Fast, efficient order processing

Our Regulatory Affairs Services

- Submission of MAA and CTA
- Scientific Advise Procedures, communication with Health Authorities
- Lifecycle maintenance incl. variations and renewals, product information and labelling texts
- Information Officer in accordance with §74a AMG
- Support for product launches and Merger & Acquisition projects
- Preparation of IMPDs, MAA Dossiers