ab initio pharma

With you from the beginning.

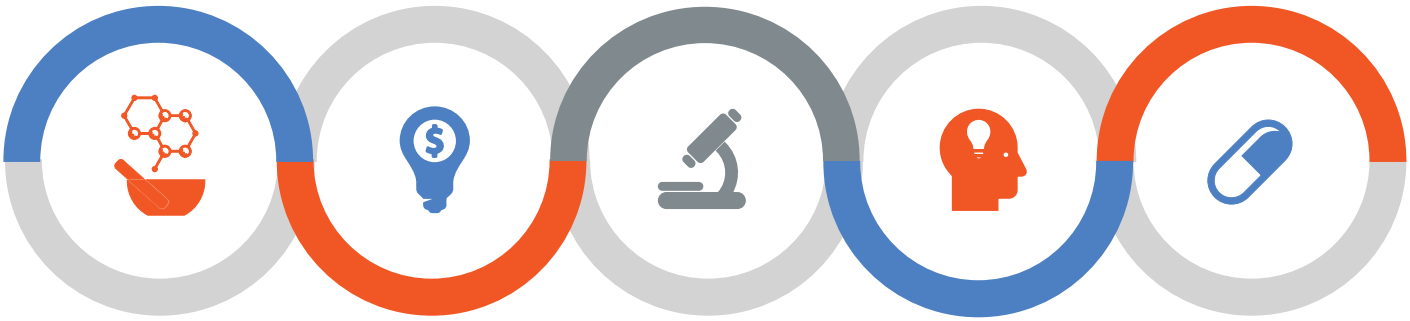
Founded in 2019, Ab Initio is the Latin term 'from the beginning'

Ab Initio Pharma is an independent Australian owned company, based in Sydney Australia.

At Ab Initio Pharma, we go by this philosophy -supporting our clients from the very beginning of the drug development process all the way to final product ready for clinical trials.

We are an end-to-end service provider specializing in inhalation, oral and topical dosage forms with pharmaceutical drug delivery R&D, analytical testing and manufacturing solutions.

Ab Initio Pathway



R&D
Formulation development of NCE for therapeutic administration.

IP
Enhancing IP position via development of innovative delivery solutions.

TESTING
Commercial product characterisation & testing services .

SUPPORT
Expert support team & consultancy service.

MANUFACTURE
GMP manufacture for 1st in human and small scale commercial release of final product.

All enquiries please contact.
enquiries@ab-initio-pharma.com

Transforming Ideas into Therapeutics innovations.

RESEARCH & DEVELOPMENT:

- Complete formulation development : Repurposed drug or NCEs
- Enhancing IP positions
- Physico-Chemical & Product Testing
- Basic drug & excipient characterization
- Extensive in vitro characterization
- Pharmacopeia aerosol-based technologies
- Preclinical physiologically relevant cell-based models
- Analytical Development
- Technical Documentations
- Product characterization
- Testing services: Aerosol testing and sizing

QC TESTING AND ANALYTICAL SERVICES:

- Analytical method development and validation according to ICH guidelines
- QC release testing on raw materials, intermediates and finished products
- Aerosol performance testing for inhalation and nasal products
- Reference standard management (including guidance on NCE's)
- Experienced in pharmacopeial testing (USP, EP/BP)
- Environmental monitoring including viable /non-viable air sampling and contact plates
- In-house stability chambers, stability testing and shelf-life determination

GMP MANUFACTURING SERVICES INCLUDE:

- Full GMP license to manufacture of non-sterile dosage forms for clinical trials (MI-2021-LI-13035-1), including release for supply
- Inhalation products
- DPI, pMDI, soft mist and nebulisers
- Liquids & Suspensions
- Capsules for oral administration
- Semi solids, Creams & Ointments
- Nasal products
- Suspensions & Solutions
- Powders & Granules
- Lyophilised products
- Capability to handle NCE's and high potency drug substances (ie hormones, steroids, antibiotics)
- Placebo manufacturing
- Utilisation of dedicated equipment and single use technologies
- Experienced in technology transfer (bench to production scale)
- Temperature and humidity-controlled cleanroom
- Labelling, packaging, blinding and randomization services
- Quality management system compliant to PICs 09-15

WAREHOUSING & LOGISTICS:

- Secure facility with controlled access and surveillance monitoring
- Clinical material storage and distribution to trial sites
- Temperature controlled shipping solutions
- Ambient and cold chain storage areas
- S8 license, experience handling S9
- Import & export permit applications
- Permit applications
- NSW Wholesale license

RSP No: RSP000017
APVMA License No: 2277
S8 License No: S8M2390

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