AgRay

MINIMIZING THE EXPENSES

AgRay Portfolio

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A brief about us

AgRay represents a culmination of quality, delivery time efficiency, cost saving pricing and reliability to our clients and partners.

We strive to be your reliable partner empowering your experts with much-needed knowledge and technology transfer of processes, followed by a well-designed roadmap to ensure that quality requirements are met.

At the end of the business portfolio, we go further to facilitate seamless regulatory strategy and support in order to bring your product to your strategic market. Our submission procedure advisory support could save you cost and time to market. We focus on solutions to your needs.

In a competitive market, you can trust us for a golden solution with a competitive pricing structure that is tailor made for individual long term and short term projects.

Our Experts have over 15 years experience in both large companies and independent projects. Therefore we are confident to deliver clients project on time and on a budget.

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Our Services

- Technology Transfer
- Marketing Authorisation Application Management & Medical Device Registration
- Clinical & Quality Management
- Life Cycle Management
- In & Out licensing of finished dosage and API’s
- Product pipeline development strategic advisory
- Formulation and CMC support services

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Steps Of Technology Transfer

- Dossier Due-diligence
- API Sourcing/Procurement/Registration
- Intellectual Property (“IP”)/Patent clearance (API and Formulation)
- Technology transfer to Client site
- Manufacture of cGMP pre-exhibit scale-up batches and release testing
- Technical support for pre-exhibit scale-up batches manufacturing at the site chosen by Client
- cGMP exhibit or registration batches manufacture and release testing
- Technical support for exhibit batches manufacturing at the site chosen by Client
- Formal stability testing of exhibit batches for regulatory filing

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Steps of Marketing Authorization Application Management in Technology Transfer Process

- Dossier compilation, localization, updating and translation
- Application preparation and MAA management
- Design and management of local pre-clinical studies as required by local MoH
- Design and management of local Bioequivalence (“BE”) studies
- Support for development and registration questions raised by local MoH

**AgRay will provide an explanation of the current IP/patent circumstance for product. Client will finalize IP investigation in local market.*

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Steps of Marketing Authorization Application Management

- ➢ Dossier GAP analysis
- ➢ Dossier compilation, localization, updating and translation
- ➢ eCTD data dossier conversion
- ➢ Full dossier writing from Modules II to V
- ➢ MAA management:

i. Design and management of local pre-clinical studies as required by local MoH
ii. Design and management of local Bioequivalence (“BE”) studies
iii. Readability testing for PILs and labelling
iv. Support for development and registration questions raised by local MoH

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Clinical & Quality Management

- On site and off site GMP mock audit based on EU and FDA standards
- Clinical trial designs & project management
- Scientific advice and health authority meetings
- Medical writing and literature search
- Bio-equivalent studies
- Pharmacokinetics
- Due diligences

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Formulation and CMC support services

- Drug substance preformulation studies
- Preclinical formulation development
- Drug-excipient compatibility studies
- Solid oral dose prototype development
- Injectable prototype development
- Bioavailability enhancement
- Clinical formulation development
- Quality by design (QbD)
- Pharmaceutical process development
- Technology transfer and process scale-up
- Safety assessment
- Drug product life-cycle management

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Life Cycle Management (part 1)

- Post Authorisation Measures
- PASS – Post Authorisation Safety Studies is any study relating to an authorized medicinal product conducted with the aim of identifying, characterizing or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk-management measures.
- PSURs – Periodic Safety Update Reports are pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product.
- Renewals - MA are valid for five years and needs to be renewed thereafter. An application for renewal needs to be submitted at least 9 months before the date of expiry. In cases where the MAH does not submit a renewal application, the MA will lapse.
- Withdrawals - MA are valid for five years and needs to be renewed thereafter.

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Life Cycle Management (part 2)

- We support follow up measures - Where the Committee is prepared to grant an opinion (initial or a post- authorisation opinion) but where some issues remain to be addressed by the applicant, Follow-Up Measures (FUMs) or Specific Obligations (SOs) may be imposed.
- Our experts are experienced in providing much needed ad-hoc support for urgent Safety Restrictions is an interim change to the product information due to new information having a bearing on the safe use of the medicinal product.
- We could file variations in EU- Any post-marketing changes in marketing authorization & dossier
- AgRay MoH support includes Marketing Authorisation Transfers - may be transferred from the existing authorisation/licence/registration holder to another holder using a transfer procedure. An MA transfer may occur before a product is authorised or, for MAs, after authorisation, to a company related to the existing holder or to an unrelated company.

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In & Out licensing of finished dosage and API's Cycle

AgRay is currently partnering with CMOs in order to secure mandates that allows us to exclusively recommend and introduce trusted clients for licensing transactions.

- ➢We liaise with our CMO partners to find licensee client who would like to inlicense their products
- ➢Negotiation of licensing deals
- ➢In & Out licensing of Dossier + supply of products
- ➢Introduction of both licensee and licensors for direct negotiation
- ➢market research and provision of database for available products targeting different therapeutic areas
- ➢Evaluation and recommendation of licensable product based on market analysis

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Product pipeline development strategy advisory

AgRay combines research abilities, technical and regulatory knowledge with an insight of market dynamics and clinical needs to assist our clients and partners in prioritizing and developing viable product pipelines.

Health agencies gather information about disease outbreaks, prevalent illnesses and adverse effects of existing therapies and medicines, then upload this information to a central online location for spread control evaluation and response strategy. This information also informs new drug research, new product formulations and licensing of existing drugs.

We harness available tools and publications as an effective and powerful target discovery engines that identify the high cancer rate in a local population.

AgRay has built a robust database of products in order to give our clients an unmatched advantage in their local markets

We could rapidly grow a strong pipeline of oncology drug candidates based on the most efficient target discovery engines, presently available to the pharmaceutical industry.

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End to End Road Map

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THANK YOU! ☺

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