PHARMACEUTICAL DEVELOPMENT

- Non-GMP and GMP pharmaceutical development
- Scalable development & manufacturing solutions
- Comprehensive analytical support
- High potent processing
OPERATING FROM STATE-OF-THE-ART, CUSTOM DESIGNED FACILITIES, OUR SCIENTISTS CAN DEVELOP YOUR CLINICAL CANDIDATE INTO AN OPTIMUM FORMULATION, AND MANUFACTURE ORAL DOSE PRODUCTS FOR ALL STAGES OF CLINICAL TRIALS (PH 0 – IV)

ALMAC’S INTEGRATED PHARMACEUTICAL DEVELOPMENT SERVICES INCLUDE:

PREFORMULATION
Our team of chemical and formulation development scientists work together to fully understand the physiochemical properties of your drug substance prior to formulating an optimum drug product for clinical supplies, using:

• Polymorph screening, crystal engineering & crystal form selection
• Physiochemical characterisation of API
• Excipient compatibility studies

NON-GMP DEVELOPMENT
Our non-GMP development services offer you greater flexibility and speed. With a state-of-the-art facility, we are able to focus on lab-scale experiments with batch sizes ranging from <1kg up to approximately 5kg scale for most technologies. With both our non-GMP and GMP facilities residing on the same campus, we can provide a seamless transition between the development and GMP phases of projects in early stage development.

By deliberately ensuring good integration of all technologies in both the non-GMP and GMP facilities, we can conduct non-GMP work efficiently then transfer rapidly to GMP manufacturing. Essentially, our seamless process reduces your overall project timeline to clinic and mitigates risk within clinical manufacturing activities.

EARLY STAGE DEVELOPMENT
Our flexible and efficient solutions are provided to develop a fit-for-purpose formulation for your early phase clinical trial. We offer a range of solutions for First-in-Human supplies, including:

• Drug in bottle
• Drug in capsule
• Conventional capsules & tablets
• Solubility enhancing formulations
• Drug product containing radio labelled API

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SCALABLE SOLUTIONS

SCALABLE & LATE STAGE DEVELOPMENT
Specialising in solid oral dosage forms, we have the technical experience and knowledge to develop robust formulations and manufacturing processes.

We have assisted many of our clients in the development of both immediate and modified release formulations, for their late stage clinical trials, registration batch manufacturing and commercial launches. Our expertise covers the development of the following dosage forms:

• Immediate & modified release drug products
• Fixed dose combinations
• Powder / granule filled sachets
• Multiparticulates

Our manufacturing technologies and processing scales range from hundreds of grams for small-scale process investigation studies to hundreds of kilograms for Phase III and registration batches.

HIGH POTENT PROCESSING
Meeting your potent processing needs, we have designed, manufactured and installed advanced containment technology to facilitate the processing of potent compounds in both our non-GMP and GMP facilities.

Key technologies such as Xcelohood™ for early phase development and bespoke engineering solutions that employ rigid and flexible film isolators around the processing zones of equipment ensure containment of airborne particulates, allowing us to process compounds with an OEL as low as 50ng/m³/8hr.
DATA DRIVEN DECISIONS

APPLYING A SENSIBLE, LOGICAL AND SCIENTIFIC APPROACH, WE MAKE DATA DRIVEN DECISIONS, PROVIDING COMPREHENSIVE DEVELOPMENT REPORTS, FOR INCORPORATION INTO YOUR REGULATORY FILING

QUALITY BY DESIGN
Our team has in-depth experience with Quality by Design applications and are experienced at interacting with regulatory authorities on this topic. We have incorporated the principles of ICHQ8, ICHQ9 and ICHQ10 into our quality system, and have developed internal guidelines on how to apply these to development projects. By understanding the parameters that are critical to the quality of the product and the safety of the patient, we build quality into the product from the start.

ANALYTICAL DEVELOPMENT
From our cutting-edge analytical laboratories, our highly skilled analysts deliver comprehensive solutions to support drug product development programs. Drawing upon our pool of scientific knowledge, we can greatly reduce the analytical challenges that typically arise during drug development.

Ensuring scientific continuity, our analytical scientists form an integral part of the development project team, sharing data, coordinating plans and schedules and delivering maximum efficiency.

GET IN TOUCH

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