Case Study
Pharmaceutical Development and Formulation

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A senior scientific team with deep industry knowledge and experience, leading six targeted domains, ensuring quality at every step and shaping our engagement to meet your exact needs.

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A flexible global network of expert, audited resource providers, available as needed to support your drug development objectives with precisely the right services at precisely the right time.

PHARMADIRECTIONS REPRESENTS A BREAK-THROUGH PARADIGM IN ACCESS TO THE BEST SCIENCE AND MOST FLEXIBLE RESOURCES IN THE INDUSTRY.

CONTACT US TODAY TO LEARN HOW WE CAN INTELLIGENTLY ACCELERATE YOUR DRUG DEVELOPMENT CMC PROGRAMS!

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Risk Mitigation and Formulation Development of a Once Daily Controlled Release Oral Product

Benefits of Case:
- Development of a high potency, low dose once daily controlled release dose form
- Create a medical and market advantage with new dose form
- Rapid solution of manufacturing issues during development

Background and Challenge:
The Client identified medical and market advantages to introducing a once-daily dose form (with improved tolerability) to compete with a commercially available immediate release product marketed by another pharmaceutical firm. The Client sought a partner to perform development of the product since development was particularly challenging due to the small dose (less than 1 mg daily) to be released in a controlled and sustained manner.

PharmaDirections Strategy:
- Tailored a multidisciplinary team of personnel to drive the formulation development and optimization based on the target drug release dissolution profiles recommended by in silico pharmacokinetic modeling
- Devoted and responsive oversight of development activities to insure on-time completion of development program

The Objectives:
- Develop three controlled release formulations with predicted *in vivo* behavior
- Assess pharmacokinetic performance and clinical safety/tolerability of proposed formulations
- Select one of three formulations with the targeted clinical pharmacokinetic profile for further development
- Manage development execution through network of service providers
- Execute GMP manufacture for clinical trial materials

Value for the Client:
- PharmaDirections managed all scientific development activities including formulation, analytical, *in silico* PK modeling to established IVIVC to generate product dissolution targets, and manufacturing to successfully complete development of the desired dose form
- PharmaDirections selected, managed and provided scientific oversight to multiple contractors for rapid execution of the analytical steps and development activities
- Risk mitigation of project activities by applying a multidisciplinary approach to solve development and manufacturing challenges
- Placed a person in the plant to investigate and rapidly solve a drug content uniformity problem to permit project to move forward on schedule

Results from PharmaDirections Combined Experience and Expertise:
Phase 1 clinical trial was performed with dose form and met requirements for once-daily sustained release target maintaining drug plasma levels with reduced peak plasma level.

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