



An introduction to Phetairos Pharmaceutical Science (PHARM SCI) Services

“Drug Supplies for clinical trials don’t arrive at study centres just because a clinician signed a prescription! The need to develop high quality API and Drug Product processes to ensure that supplies arrive when and where they are needed is of paramount importance in both the development and commercial setting. Phetairos consultants have unparalleled expertise and experience of making that happen.”

Phetairos – Overview

OUR ETHOS

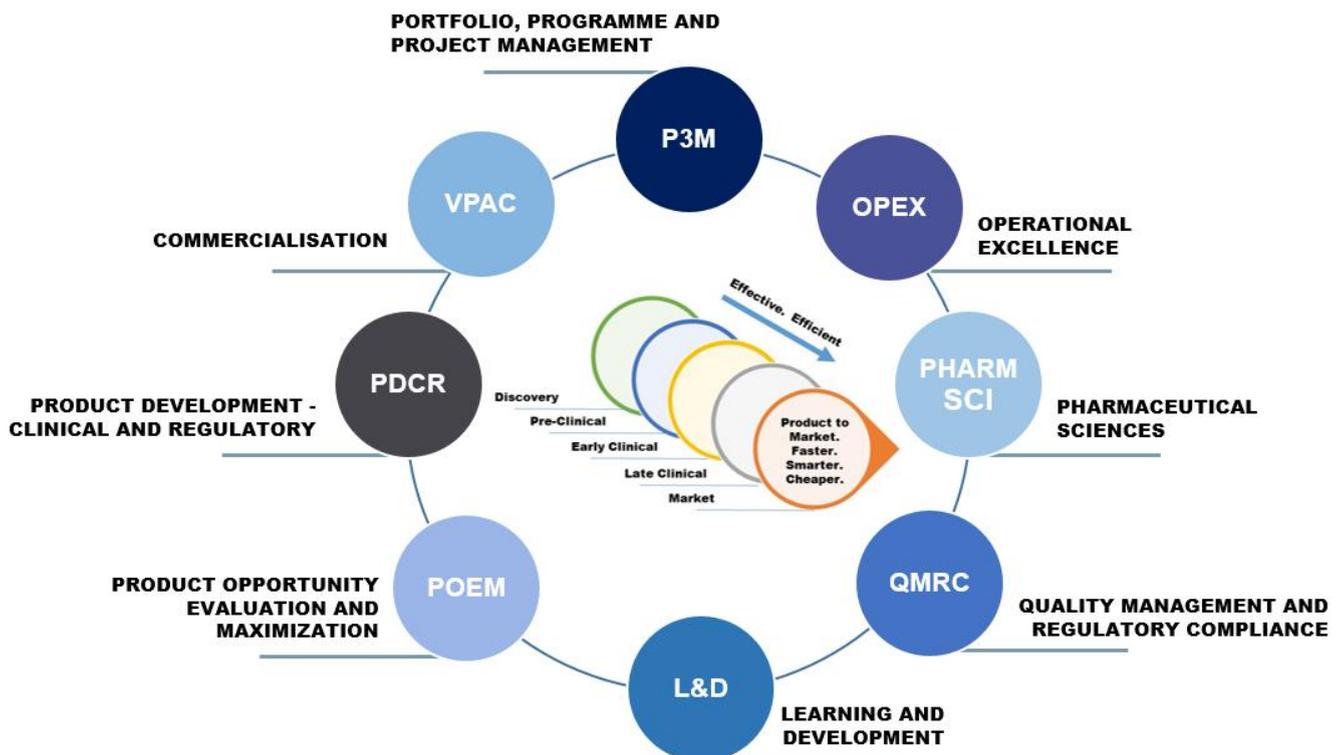
We are “committed to delivery through collaboration”: Phetairos is dedicated to consistent delivery of successful client outcomes through collaboration, quality assurance, flexibility, cultural alignment, transparency and knowledge sharing.

WHO WE ARE

We are a group of world-class BioPharmaceutical subject matter professionals, who put best practice to work for our clients, designing integrated innovative solutions - on both product and organizational levels - for the complexities of a constantly changing life sciences ecosystem & marketplace. The calibre of people we allocate to our clients’ projects, people with 20 and 30 years of hands-on experience in their subject matter, combined to a project team covering multiple subject matters depending on our client’s specific issues and situation complexity, is truly unique in the industry. Our unbiased approach enables our clients to realize their business goals by minimizing risk, raising product / portfolio value, saving cost and reducing time to patient.

WHAT WE DO – OUR SERVICES

With our unique fusion of expertise in the full range of disciplines across the product lifecycle, we help releasing the full potential of our client’s products, organisations and people.



We provide strategic decision making, planning, and management as well as optimised resourcing to execute strategic programmes and projects. We operate as a lean structure without organisational overhead and pass on the benefits created directly to our clients with payment linked to successful outcomes achieved against time, quality and cost based deliverables.

Pharmaceutical Science (PHARM SCI) Services

OVERVIEW

The area of pharmaceutical science in a pharmaceutical organisation is of particular importance because without it, there would be no medicines! In a highly regulated world where quality has never been more important, pharmaceutical science ensures that the right drug dosage in the highest quality products are delivered to every patient – every time!

SERVICES

- CMC Strategy and planning
 - Defining overall CMC strategy for individual projects, including Quality by Design as required.
 - Defining programme /portfolio pharm sci. strategy.
 - Defining outsource strategy & plan.
 - Defining synthetic development & bulk supply strategy.
 - Carrying out due diligence so that CMC regulatory and manufacturability issues of potential assets are uncovered and understood
 - Developing regulatory and technical CMC strategy for 505b2 assets
 - Defining formulation development and formulation strategy
 - Defining analytical method development and validation strategy including analytical QbD.
 - Develop project plans for pharmaceutical science elements to integrate into overall project plan.
 - Ensure that the Regulatory CMC strategy is optimised and harmonised with the wider development strategy
- Outsource management
 - Choosing CRO / CMO
 - Capability audits.
 - Quality audits.
 - Monitoring and controlling outsource contracts.
- Process Improvement
 - Review / analysis of current processes.
 - Possible use of Lean six sigma capability.
 - Define solutions.
 - Quality by design / Right first time
 - Change management / implementation
 - Learning and organisational development synergy.
 - Metrics for measuring improvements.
- Tech Transfer support
 - Process
 - Analytical

- Pharm Sci Portfolio Review
 - Support for internal review of projects.
 - Support for developing understanding and managing priorities.
 - Keeping projects on track to meet goals
- Supply chain logistics
 - Pharmacy strategy
 - Packing and distribution advice

CASE STUDIES

Case study 1:

- Situation: Understanding where a process produces degradation
- Service: The client had a novel drug delivery platform. However, the process introduced degradation and the client was unable to discover where. Using the twin Quality by Design tools of Risk Assessment and Knowledge Management, a facilitated process was used to completely map the process for all areas that may produce degradation
- Result: The client had a clear strategy for refining the process to reduce the risk of degradation as well as a much greater understanding of their process and technology platform

Case study 2:

- Situation: The client had developed a new manufacturing process for a biotech drug substance, which improved the yield, reduced the cost of goods and removed the raw materials of animal origin. However, a lengthy regulatory approval process was to be avoided.
- Service: Careful assessment of the whole manufacturing process and its regulatory implications, restricting the changes only on critical process steps, maintaining the control tests and specifications and eliminating the need for additional clinical studies the improved process was validated.
- Result: The client had a clear regulatory strategy of how to present and submit the manufacturing process improvement successfully as a minor regulatory process modification only so that it was approved in short assessment time by all major health authorities leading to the implementation of improved process significantly earlier than anticipated.

Case study 3:

- Situation: The Client had a completely outsourced model for all its CMC activities and managed this without specialist CMC in-house personnel. The company were facing many cases where CMC issues occurring at CMO's was jeopardising development timelines.
- Service: All relevant staff were interviewed to get an in-depth understanding of where the problems were occurring. A number of the most pressing problems were taken in hand directly and CMC operations were either moved from under-performing CRO's or the CRO's advised on what actions to take to correct issues.
- Result: Whilst the immediate issues were being dealt with, a report was prepared for the client which highlighted the need for on-house specialist resources, in particular that a Head of Pharmaceutical Sciences with extensive industry experience be recruited. This was accepted and a short list of suitable candidates quickly assembled from the consultant's network. An excellent candidate was rapidly recruited and CMC is now in firm control within the company.

HOW DO PHETAIROS ADD VALUE?

Solutions tailored to your needs:

- Best-in-class knowledge, skills and experience to guide projects, programmes and portfolios to deliver their full value.
- Hands-on strategic consultancy services, loaned executives, or complete project teams.
- When you need it, for as long as you need it.
- Accountability: Payment linked to successful outcomes achieved against time, quality and cost based deliverables.
- Flexible commercial options including fixed price contracts

You benefit from expert business interventions that support at multiple levels:

- Strategic planning & decision making
- Management and execution of key business activities including drug development programmes, outsourcing, technology choices and investments.
- Cost optimisation programmes and strategic workforce optimisation.
- Optimised resourcing of demand including strategic demand management and planning at portfolio level through to tactical resource optimisation.

Sharing “lessons learned” from across life sciences and other industries to drive innovation that delivers competitive advantage.

- New development models drawing elements from open/collaborative innovation enterprises.
- Enhancing risk management practices by learning from mature industries.

HOW DO WE WORK WITH YOU?

We work as your trusted colleagues, accountable, aligned, committing quality and performance excellence, from advice on specific issues to full outsourcing:

Advice:

- Consulting advice on issues requiring rapid response
- Guidance on difficult to solve problems

Partial Outsourcing

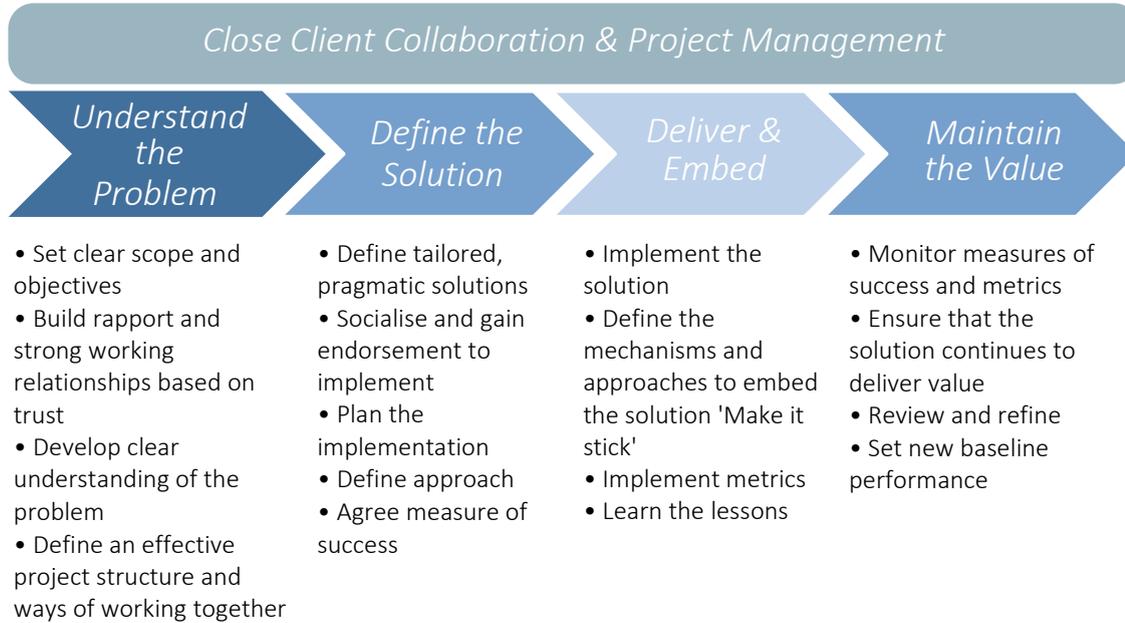
- Lead components of major projects
- Individual experts dedicated for extended periods

Full Outsourcing

- Fully loaned executives
- Turn-key projects with dedicated teams

HOW WILL WE OPERATE ON YOUR PROJECT?

We create tailored solutions and seamless integration to fit your product, your organisations' needs and your goals. These are not quick fixes but any changes are aimed to be embedded – it's a solution that lasts and not a quick sticking plaster.



CONTACT FOR FURTHER INFORMATION



Contact: Mr. Claude Houet
Title: Director
Telephone: +49 (0) 172 6340202
Email: projects@phetairos.com
Website: www.phetairos.com