



# An introduction to Phetairos Operational Excellence (OPEX) Services

*“Some managers believe the lean principles not to be feasible within their industry. But this is to miss the point, which is vision: you may not get there within your lifetime, but try - others certainly will.”*

# Phetairos – Overview

## OUR ETHOS

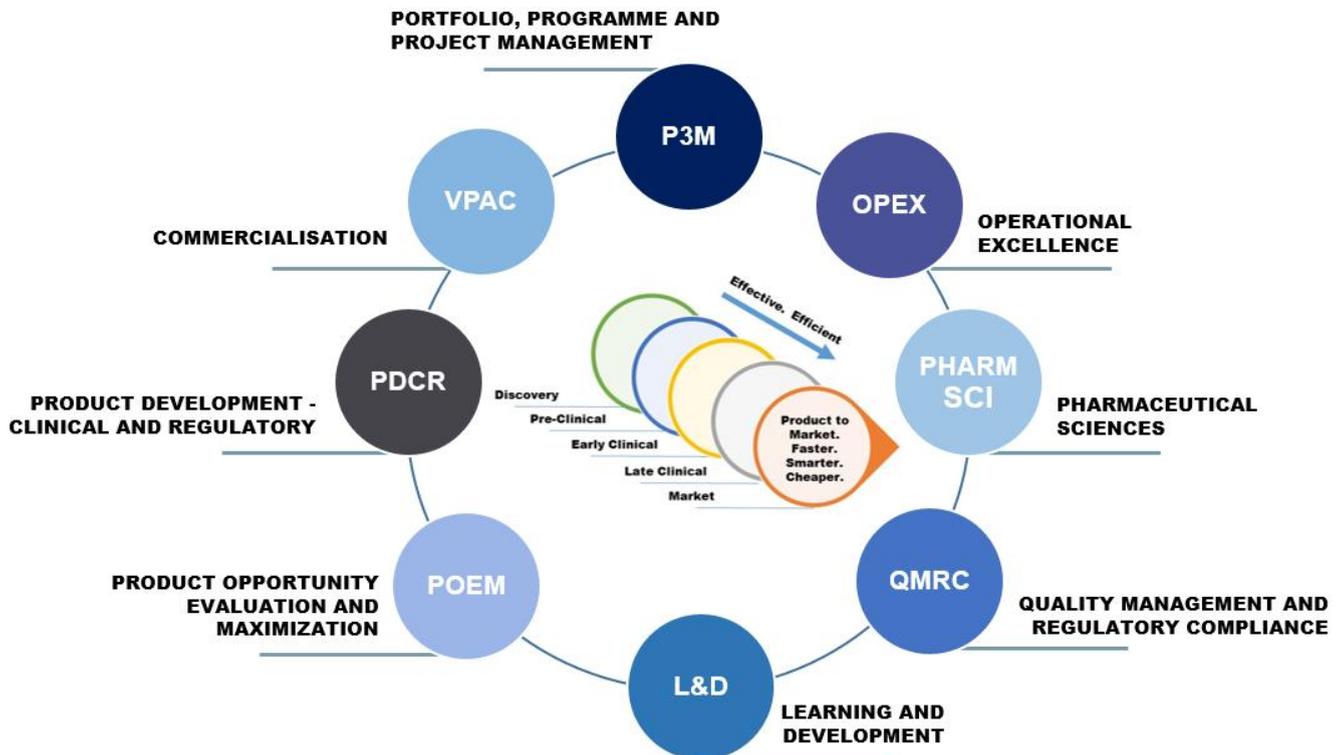
We are “committed to delivery through collaboration”: Phetairos is dedicated to consistent delivery of successful client outcomes through collaboration, quality assurance, flexibility, cultural alignment, transparency and knowledge sharing.

## 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.

## Operational Excellence (OPEX) Services

With rising R&D costs, expiring patents, challenges from generics and the inherent difficulty and time to discover and develop new medicines, the R&D in pharmaceutical industry is forced to take a renewed approach to how it operates. PHETAİROS supports clients in this endeavour, basing itself on the Lean Six Sigma methodology which is about delivering exactly what the customer wants, exactly when (with no delay), at a fair price and with minimum waste. This provides a clear and consistent line of sight for all functions; enabling a step change and a sustained continuous improvement.

Lean is based around the development of systems that focus on the customer, eliminating waste by directing efforts to deliver value to the customer and increasing speed through systems by improving flow. Six Sigma is based on the understanding and elimination of variation in processes to increase process capacity. OPEX combines the principles of Lean and Six Sigma to deliver sustained improvements in processes, customer satisfaction and staff motivation.

We at Phetairos have associates with hands on experience in leading OPEX programmes as either line or change managers to deliver significant sustained improvements in the systems supporting R&D delivery. These sustained improvements have been achieved across life sciences R&D, operations, supply chain and commercial from shop floor to board room. Ultimately OPEX is about people and our approach builds confidence and capability within the people using OPEX processes to direct and sustain the improvements. Our experience has taught us that OPEX has the ability to build a motivated, engaged business based on efficient and constantly improving processes that deliver customer delight.

Some examples of how clients benefited from our services (more information in the case studies below):

- Over 25% reduction in timelines by analysing the problems and developing solutions
- Delivery of their product, on time and in full, while reducing lead times by over 50%, significant reduction in working capital and sustained further continual reductions
- Keeping products on the market by increase compliance from 20 % to 90 % in just six months
- Successful implementation of high-value business improvement projects, including reducing supply chain delivery costs by over 30%
- Building an efficient process, for cross functional teams, to register products ahead of competitors
- Experienced and motivated staff collaborating across boundaries, creating innovative, tailored solutions for the customer

### SERVICES

Our approach is based on delivering rapid and sustainable improvements to your business. Our associates will work hands-on with you and your team applying their personal and varied experience to help build rapport, trust and respect. We coach your staff in OPEX approaches and principles to build capacity within your organisation. Our open and structured approach helps to bring out the underlying issues and develop creative solutions that address the root causes of problems.

Our services are built around the core DMAIC (Define, Measure, Analyse, Improve, Control) framework that underpins the application of OPEX.

**Define:** Work closely with stakeholders to develop a project charter that defines the problem, outlines the business case, agrees success criteria (what is important to the customer) and achieves a common understanding of the

process to be improved.

**Measure:** Understand the extent of the problem being studied and focus efforts in the correct areas; gather data on the baseline performance and create a current state value stream map.

**Analyse:** Delve into the problems being studied to identify root causes using data to support conclusions.

**Improve:** Based on an understanding of the root causes of problems, define improvements to the process that will mitigate these. Test the improvement plan ahead of full-scale implementation using active learning cycles to adapt the process as required.

**Control:** Design a control management system to ensure that the improvements realised are sustained and built upon.

OPEX has been traditionally based in manufacturing environments but have equally successfully been applied in other environments including Research, Development, service sectors and Healthcare. Our associates have experience of the application of OPEX across a variety of environments (including manufacturing and Pharmaceutical R&D from idea to regulatory approval) combined with hands-on experience working within the systems we are striving to improve. This powerful combination gives our associates a significant advantage over other providers of OPEX services when working with Pharmaceutical R&D.

Our services are scalable to your needs from 1:1 coaching, team or business unit performance improvement through to organisational turn around.

- Process optimisation – built around Operational Excellence and sustained improvement
  - ✓ Waste elimination
  - ✓ Efficiency / Yield step changes
  - ✓ Increase staff satisfaction through greater motivation and engagement in owning and sustaining improvements
  - ✓ Increase market share through higher customer satisfaction
  - ✓ Increase share price through higher investor satisfaction
- Lean management – built around collaborative problem solving coaching
  - ✓ Identify current issues, wastes and work with you to build future state from the perspective of the customers and investors
  - ✓ Set up measures for critical tasks, business units and base line current performance
  - ✓ Agree, plan and implement changes and track changes
  - ✓ Agree and build reviews –A3 learning-into current meetings and roles to sustain changes
- Critical Review of project plans –Lean and risk to deliver, turn around project delivery
  - ✓ Review current project performance, objectives, plans, risks, processes and climate and performance
  - ✓ Recommend options for improvements
  - ✓ Local, hands on coaching and support to deliver and sustain deliver

## CASE STUDIES

Case study 1: Delivery of product, on time and in full, while reducing lead times were by over 50% and significant (\$m's) working capital reduction. Further reduction sustained over following years.

- ❖ Situation: The client, manufacturer of a \$multi-million drug, was losing customers and contribution to the business due to poor supply chain and operational performance. All existing assets were fully utilised. Stock projections would not hit policy levels within target time. High variability of manufacturing performance. Low confidence that longer term plan would be delivered (6months +). Uncertainties in both demand and manufacturing output due to introduction of new product device.
- ❖ Our Approach: We worked with the client to understand the business needs and developed a new Lean strategy. This approach was to move from highly variable push of material through supply chain to pulling supply with high confidence and low variability. Simple metrics and data gathering were put in place using existing information systems. Quick hits were identified from initial analysis and feedback. Facilitated teams from shop floor alongside support functions and management solved major operational issues. A visual operational plan and facilitated team meetings made priorities clear, targets understood and issues identified with follow up support to resolve. This provided the flow for the material and, as importantly, identified the waste. Value stream mapping in action.
- ❖ Outcome: Lead times were reduced by over 50%; Working capital reduced by >\$m's; product was delivered on time in full; Increase contribution to the business; retain customers in mature competitive market; sustain performance improvement year on year.

Case study 2: Keeping products on the market by increase compliance from 20 % to 90 % in just 6 months

- ❖ Situation: A large leading pharmaceutical company needing to set up a new centralized team to manage labelling changes and compliance.
- ❖ Our Approach: Provide the region with labelling support for 22 markets in EMA region. Work with each local contact to fully collect local requirements, understand product portfolio and organise priorities into a label submission plan. Use current systems to manage changes in labelling – including updates and tracking of progress. Initiate and implement processes to increase compliance by integrating current approaches and join forces with the submissions and artwork team to optimise an end-to-end-process.
- ❖ Outcome: Work on and implement a strategic plan to bring each market from noncompliance to a business as usual model. Increase compliance from 20 % to 90 % in 6 months. Roll out strategic plan for other regions to follow suit. Requested to work on other departmental projects to help increase compliance and enhance processes.

Case Study 3: Successful implementation of high-value business improvement projects, including reducing supply chain delivery costs by 30%

- ❖ Problem Statement: A mid-sized global pharmaceutical company wished to engage senior leaders as change agents and to overcome functional and regional fragmentation. Additionally, it faced a number of significant operational challenges in order to deliver on an ambitious 10 year growth strategy.
- ❖ Our Approach: To design and deliver in in-house leader development programme targeting middle and senior people managers in a high challenge, high impact approach. Working as a cross-functional active learning set the leaders participated in 3 taught modules, senior executive-led business round-tables and carried out a major business improvement project. The most recent such project being the reduction of supply chain delivery costs by 30% accomplished through value-chain mapping, analysis, root-cause problem-analysis and solution implementation.
- ❖ Outcome: Two programmes have been delivered to date together with the successful implementation of

their high-value business improvement projects. The leader development programme is embedded in the business. Change capability across the organisation has increased (as assessed by Executives) together with cross-level management engagement. A number of off-shoot improvement projects are ongoing.

## 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

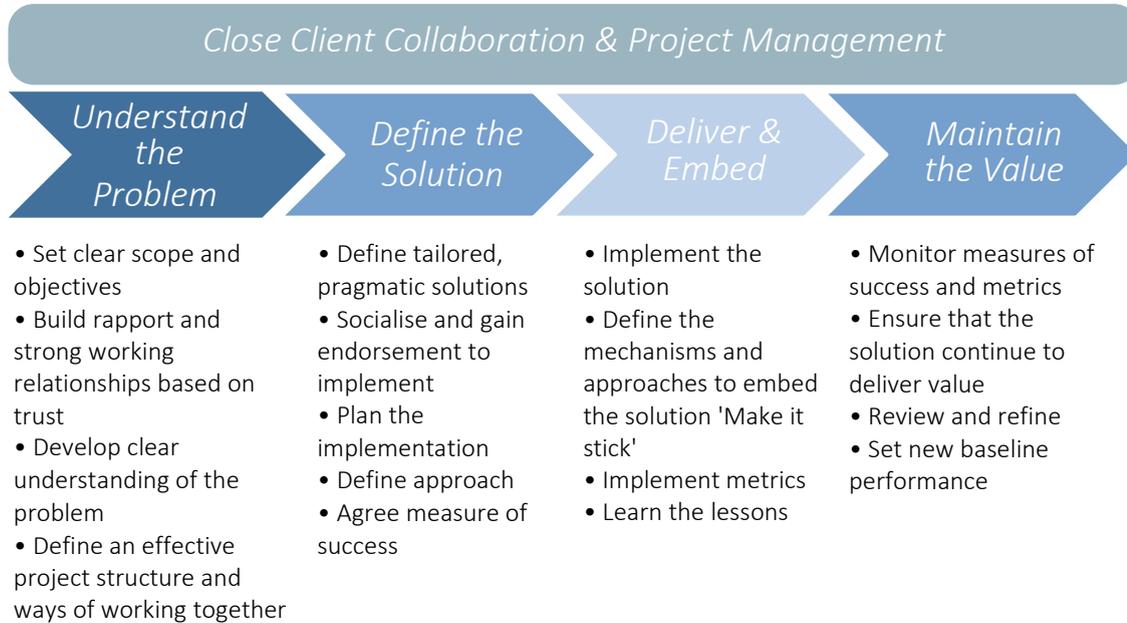
- Lead components of major projects
- Individual experts dedicated for extended periods

### 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



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