phetairos
Trusted partner for
pharma & life sciences

An introduction to Phetairos Quality Management & Regulatory Compliance (QMRC) Services

"From Uncertainty to Confidence through Compliance.

Define, drive and deliver your products successfully throughout their lifecycle."

Phetairos – Overview

OUR ETHOS

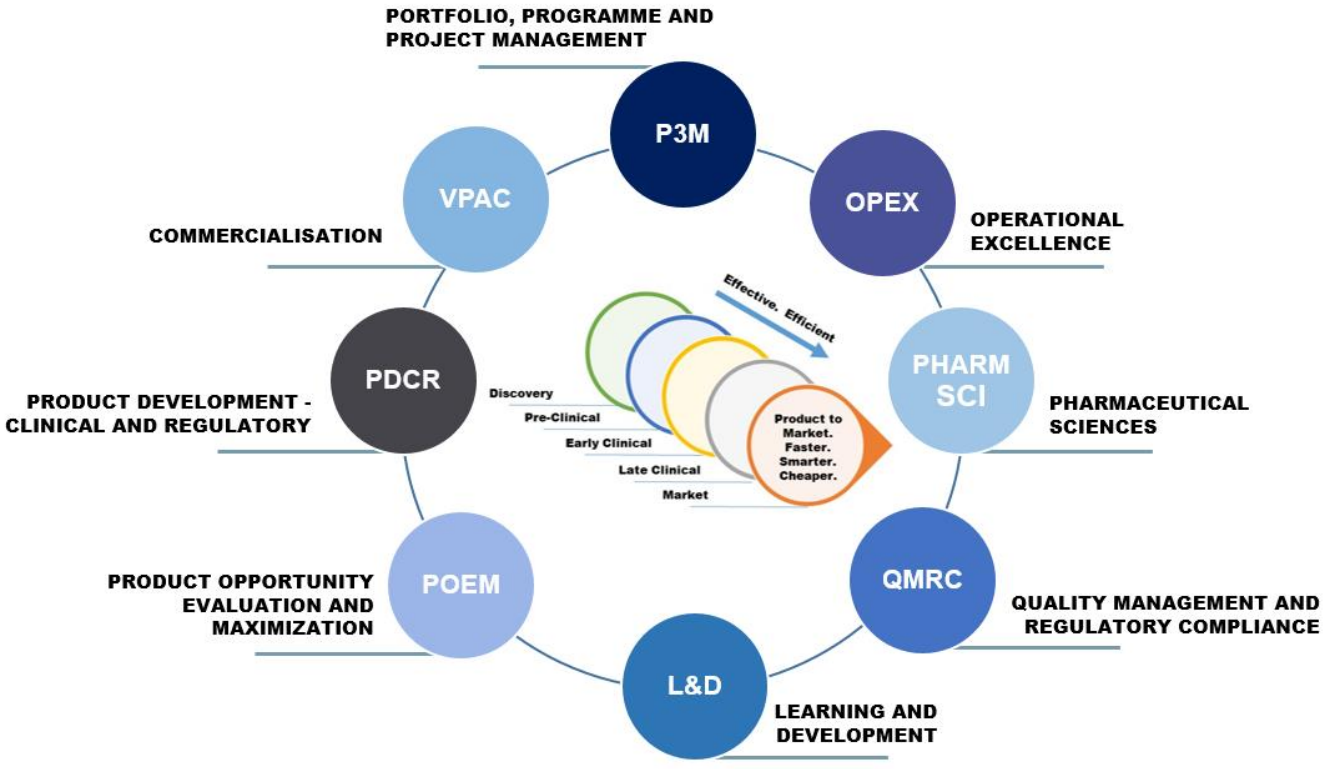
We are "committed to delivery through collaboration": Phetairos is dedicated to consistent delivery of successful client outcomes through collaboration, quality assurance, flexibility, cultural alignment, transparency and knowledge sharing.

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.

Quality Management & Regulatory Compliance (QMRC) Services

SERVICES

No pharmaceutical / biopharmaceutical / medical device company can afford an expense such as non-compliances, consequences may involve having a product withdrawn from the market or having a high-profile approval delayed. Setbacks associated with routine agency inspections, as well as more serious Warning Letters are costly and often result in approval delays, product recalls, harm to reputation, and adverse impact on shareholder value. PHETAIROS's experts can help with:

Auditing:

- GMP, GLP, GCP, Pharmacovigilance, Device Vigilance, Quality Systems, Management Controls, FDA / EMA / national agency -type Mock PAIs and Inspections, Verification Audits and Effectiveness Checks, Gap Analyses & Remediation, Vendor Audits, For-Cause Audits, (e)TMF Audit, PV DB Audit, Failure Mode & Effects Analysis (FMEA), Risk Analysis

Regulatory Compliance:

- 483/Warning Letter responses, IAG coordination and other correspondence, Consent Decree remediation activities, preparation for or attendance at FDA meetings, Serious Breach of GCP

Training:

- General & refresher GMP, GCP, GLP topics, EMA, FDA, national agency interaction and preparing for inspections, 1:1 mock interviews, auditing techniques, specific technical training

Inspection Management Process and Planning:

- Review hosting process and site presentations, tour routes, front/back room management, document management, employee coaching

Technical Writing:

- Validation Protocols and Reports, SOPs, Annual Product Quality Reviews, agency correspondence, audit responses, strategic plans, trend analysis reports, other technical reports, validation plans,

Data Trend Analysis:

- Collection, review, analysis and summary reporting for Deviations, OOS, Change Controls, CAPA, Complaints, Product Returns, root cause analysis

Project Management:

- For complex or long-duration Consent Decree or compliance remediation activities, multi- site/consultant audits, validation reviews
- Project Management of pre-clinical drug development through to manufacturing and supply of Phase 1 and 2 Clinical Trials drug product in multi-site operations, project management of device development
- Programme / Project Management of Capital Projects from building clean room facilities, Design for manufacturing assembly (DFMA), New Product Introduction (NPI), managing principal consultants and subcontractor teams, documentation such as User Requirement Specification, supplier evaluation, equipment procurement, validation, process validation.
- Operation Quality Management, managing teams, delivering required outputs, managing operational budgets, developing operations teams, continuous improvement plans, succession planning, development programmes for fast track staff.

CASE STUDIES

Case study 1:

- Situation: Pharmaceutical operations remediation to restore licence to manufacture from the regulatory inspectors
- Service: Interim operations management
- Result: The remediation team working to deliver operations and engineering systems remediation from an operations perspective as part of a Quality Management programme to pass an inspection to regain a manufacturing licence.

Case study 2:

- Situation: A pharmaceutical company looking to move to disposable systems and change the primary packaging
- Service: Project management of feasibility studies
- Result: The feasibility studies collated operational information, timelines, impacts and costs which allowed the management to decide on the acceptability of the projects.

Case study 3:

- Situation: Newly established Medical Device start-up company, developing a disposable in-line, arterial blood gas analyser (IVD).
- Service: Improved product design to the moulded device with manufacturing, assembly, cost and materials in-mind. Procured and established a manufacturing suite complete with cleanroom to enable low to medium volume product for use in Clinical trials.
  Project managed external supplier/contractors - Moulding manufacturer, Electronics assembly manufacturer, Final assembly / test & packaging, IV Bag development and supply.
- Result: Successfully manufactured patient compliant product for use in Clinical trials tests, phase I & II. Successful FDA 510(k) submission for premarket approval.

Case study 4:

- Situation: Established global healthcare and consumer electronics company, manufacturing systems regulatory compliance review.
- Service: Quality systems & Validation Consultant reporting to the Manufacturing Director, we were able to establish a “validated state” assessment report in readiness for an anticipated FDA audit. The report impacted all manufacturing sites within the business.
- Result: On completion of a full retrospective validation review, departments were able to identify specific areas for improvement and put the necessary tools in place to target specific areas for improvement, resulting in a successful external audit by third party auditors the following year.

Case Study 5:

- Situation: Vendor Audit for US FDA and EU/EMA compliance.
- Service: Prepared & conducted a vendor audit and submitted the Assessment Report to Qualify a Second Source of Device. Preparing an audit checklist for FDA and EU/EMA regulatory compliance. Reviewed BLA documents.
- Result: The strategy that was recommended to client was to obtain approval of a second source of the device is to prepare a comparability protocol and submit to FDA and EMA for review and approval. Once the comparability protocol is approved, client will initiate the testing and submit the package as a supplement/variation to its current BLA/MA for final approval to commercializing the new source of device.

Case Study 6:

- Situation: Review of Drug Manufacturing Batch Records for GMP and Regulatory Affairs compliance under Consent Decree environment.
- Service: Reported observations concerning Deviation, Process Validation, and GMP and Regulatory Affairs compliance.
- Result: Recommended Deviation Investigation Management and Corrective Action, Preventive Action, in some cases, in order to improve manufacturing process with respect to GMP and Regulatory Affairs compliance.

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.

Close Client Collaboration & Project Management

Understand the Problem	Define the Solution	Deliver & Embed	Maintain the Value
• Set clear scope and objectives • Build rapport and strong working relationships based on trust • Develop clear understanding of the problem • Define an effective project structure and ways of working together	• Define tailored, pragmatic solutions • Socialise and gain endorsement to implement • Plan the implementation • Define approach • Agree measure of success	• Implement the solution • Define the mechanisms and approaches to embed the solution 'Make it stick' • Implement metrics • Learn the lessons	• Monitor measures of success and metrics • Ensure that the solution continues to deliver value • Review and refine • Set new baseline performance

CONTACT FOR FURTHER INFORMATION

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