



An introduction to Volt Pharma Associates 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."

Volt Pharma Associates (VPA) – Overview

OUR ETHOS

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

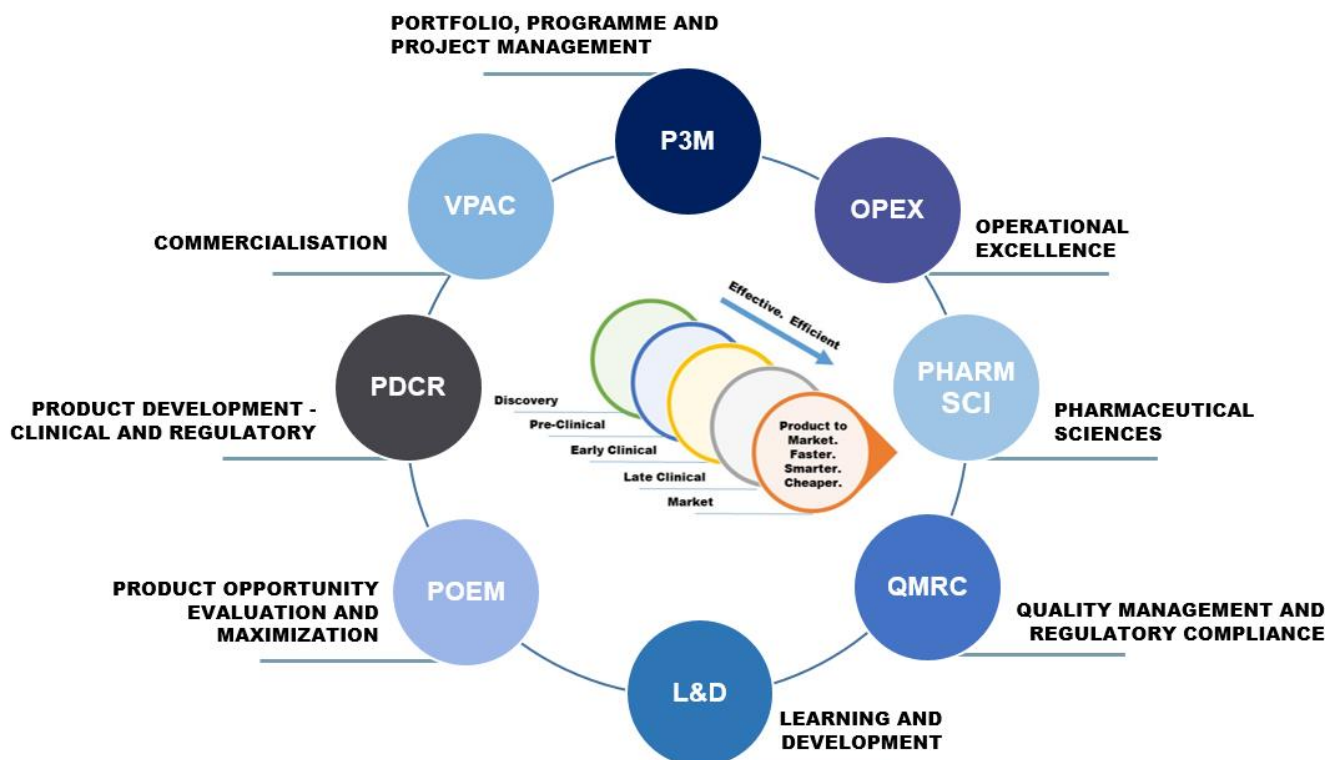
WHO WE ARE

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.

VPA is part of Volt Information Sciences, Inc., a global provider of talent, technology and consulting services. Volt is a highly successful, 6 Sigma company with offices in North and South America, Asia and Europe.

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 and organisations.



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. VPA 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 Volt Pharma Associates (VPA) 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

TEAM BIOGRAPHIES

Mike Florence PhD MBA



Mike Florence has over 20 years' experience in Pharmaceutical and Chemical industries delivering step change improvements and projects across manufacturing, supply chain, Research and Development and marketing companies. Mike is a winner of the European strategic risk award for building risk and lean into portfolio management and a sustainable business cycle. Previous roles include Global Project Manager accountable for leading cross functional teams to deliver large and complex portfolio of projects to decision points on time and budget. He is a full member of the Association of Project Management and the Institute of Risk Management. Mike gained a PhD from the University of Edinburgh, MBA from the Open University and is a registered practitioner of Prince2 and Management of Successful Programmes.

Paul Ilott BEng (Honours), MSc, PhD, Lean Sigma Master Black Belt



An experienced operational excellence leader, who has managed strategic change and productivity improvement programmes on an International scale in 3M and AstraZeneca (FMCG and regulated pharmaceutical environments). Operating at strategic and operational levels, implemented a Lean Sigma business improvement philosophy in the AstraZeneca Research & Development (R&D) organisation, establishing a vision and deployment strategy for 4000 people.

Achievements are based on his ability to create a clear vision within complex working environments and develop people / teams to deliver their maximum potential. Other skills include: Strong drive to learn and continuously improve from both a personal and organisational perspective. Ability to create strong working relationships with clients and people at all levels in the organisation.

Graham Finch BSc BEng MSc



Graham is a consultant to biopharmaceutical organisations providing strategic and analytical guidance to Research and Development and Business Development investment decisions. He has a background in product and portfolio strategy, commercial analysis and valuation, business development, due diligence and deal terms for licensing and acquisition, market and customer analysis, investment and risk analysis.

Graham has eleven years' experience working for a major pharmaceutical company and recent independent experience providing consultancy to biotech and mid-sized pharmaceutical organisations. He is a Graduate of Physics and Engineering with an MSc in Operational Research from the London School of Economics.

Preeya Beczek BSc, MSc, cGB



Preeya has over 15 years of regulatory affairs experience in contract research organisations and within the chemical and pharmaceutical industry. She holds a BSc in Chemistry and Management Studies and an MSc in Environmental Strategy from Surrey University, UK. She is also a qualified Lean 6-Sigma– Green belt. In her regulatory career, she has worked on products during development, submission, marketing and post-marketing in Europe and the rest of the world markets across all

regulatory procedures and regulations.

She has excellent project management and coordination skills and has managed various teams across regions for marketing authorisation applications, scientific advice, licence maintenance, clinical development planning, clinical trial applications, product labelling and process improvement initiatives.

She is a natural change leader for operational effectiveness and organisational change projects and initiatives. She has collaborated across functions and departments to lead and manage development, implementation and training of standard operating procedures for regulatory affairs departments.

Kevin Jackson BA, MA, FCIPD



Kevin is a consultant to multi-sector organisations providing performance-driven solutions to develop leader, team, culture and change capability. He takes a systems approach, looking for how people, teams, processes and activities connect to deliver. With a background as an internal consultant within a large, multi-national pharmaceutical company, Kevin has a deep understanding of the drug-development process and the real challenges that arise in highly complex, global businesses.

His consulting style is collaborative, with a coaching emphasis that empowers and generates sustained change. His goal is always to add value through evidenced performance & process improvement.

Kevin has 5 years independent consulting experience, with 9 years' experience working in a leading pharmaceutical company. Prior to that he held leadership roles in various public sector organisations where he played a key role in the implementation of Total Quality Management Programmes, including serving as an Assessor for the European Quality Award (EFQM).

Julie Evan, BSc, MPhil



Julie is an enthusiastic and dynamic individual who embraces change and relishes new challenges; a dedicated champion for continuous improvement to drive performance and delivery to better meet the needs of the customer. She is an accomplished project/programme manager, both leading and delivering through others in the effective coordination and prioritisation of resources to facilitate both strategic and operational planning to achieve timely delivery against targets and deadlines.

Julie is a confident external speaker, facilitator and perceptive communicator who cultivates excellent interpersonal relationships and actively encourages collaboration and commitment through the identification and development of supportive and effective solutions to mutual advantage.

An analytically minded problem solver and mediator who takes an objective overview, combined with diplomacy and an empathetic approach and a genuine desire to help. Julie has 25 years' experience working across the Pharma industry, from R&D to Operations, Commercial & Corporate IT. She graduated from Manchester Metropolitan University with a BSc in Applied Biological Sciences, followed by an MPhil in Applied Chemistry from Sheffield Hallam.

Julie pursued a career in science for the first 13 years before expanding her skill set to include Lean Six Sigma Black Belt and a Master Assessor in the EFQM Excellence Model; utilising these capabilities to help teams, projects and departments to improve Customer experience, realise efficiencies and savings, to deploy effective change as well as developing a Culture for Continuous Improvement.

Rowan Nidd, BSc, MSc



Rowan has years of experience working in many different scientific environments, both within the UK and internationally. Rowan is excellent at both working independently and as part of a team to achieve results. Most of his experience is in guiding and managing projects from start to completion as a subject matter expert, to achieve change. Rowan has experience in utilising Lean Six Sigma tools and methodology such as defining the project, designing the workflow, identifying measures (quality assurance and quality control) as well as implementing and identifying control points in order for the project to be continuously monitored to ensure compliance.

Rowan has also worked in regulatory compliance within the pharmaceutical industry. This involved change management and identifying areas of improvement by working with stakeholders to define and agree plans for the assessment, update, and implementation of license updates in line with local regulatory requirements.

Much of Rowan's client support experience includes scientific and strategic consultation, publications planning, managing professional relations with market leaders, organising symposia and meetings, financial budgeting and developing a range of projects. These activities have helped him develop excellent relationships with his clients through 1:1 interaction as well as stakeholder meetings and consultations. These strong relationships have helped support business development opportunities and knowledge management initiatives, produce targeted marketing presentations and provide analysis on markets and competitors.

Pauline Stewart-Long BSc PhD



Pauline has over 25 years' experience in the pharmaceutical industry with roles in clinical research, project management and portfolio management. After managing drug development projects in several therapeutic areas and all phases of development, Pauline spent 7 years as a portfolio director responsible for the respiratory portfolio at GSK. Moving back into project management to become the VP of Global Project Management she had a significant line management role as well as leading a major change initiative to define the practices and processes associated with the implementation of an enterprise project management system across R&D.

She has a special interest in the critical role of people in delivering projects and has been consulting since 2012 within the life science sector but also worked in finance, IT and education, regularly running in house master classes on many aspects of project management.

Pauline graduated in Nutrition at University of Surrey, has a PhD in Biochemical Nutrition from University of Cambridge and chairs the Pharmaceutical Industry Project Management Group executive.

Jay Makwana CChem FRSC



Jay has over 25 years' experience in the pharmaceutical industry (Glaxo, Boots Pharmaceuticals and Pfizer) delivering projects, innovation and continuous improvement in Analytical R & D. He has also considerable expertise of increasing productivity through innovation and continuous improvement.

Jay received a Global UpJohn Pfizer award for innovation and two global team awards. He led a number of collaborations, including a \$7.2m centre of excellence with academia, 18 Post Doc and 10 PhD projects delivering considerable advances in analytical science and technology.

He also chaired global continuous improvement teams, a site innovation team and safety teams, delivering 50%+ reductions in cycle times by stream-lining global workflows, implementing new technology and driving up multi-skilling. Jay is skilled in setting-up and running highly productive innovation, continuous improvement and change management programmes. Jay has a degree in Chemistry from the Royal Society of Chemistry, MRSC and a Fellow of the Royal society of Chemistry.

Mark Blanchard BSc, CA-AM, MCIPS



Mark is a chemist with more than 20 years' experience spanning the Chemicals & Pharmaceutical industries. A results oriented senior business leader who expertly brings people and processes together from across organisations to deliver sustainable business results. Consistently delivering results within the Pharma industry in senior roles with expertise in leading global, cross functional project teams within Drug Development. During 11 years with AstraZeneca, he held positions of increasing seniority in operations, procurement and R&D functions.

With strong commercial and business relationship expertise, he has established and managed new supply chains with strategic CMO & CRO suppliers and transformed existing relationships with key suppliers, enabling a step change improvement in project delivery and delivery performance.

Achievements include creating competitive advantage through the successful delivery of a strategically important \$60 million project to outsource a key clinical delivery service, exceeding deal value expectation within challenging timelines and organisational change.

As an Alliance and Integration Director, he played a key role in AstraZeneca's drive to be recognised as a "Partner of Choice" within the industry. He led the diagnosis of areas of improvement across the late stage projects portfolio and designed and delivered skills development programmes to senior alliance project leaders. He also leveraged his project management expertise in delivering a critical element of the integration of a \$4.3 billion acquisition deal. This was delivered at industry leading speed whilst effectively managing risk and cost.

Fraser Penny, BEng Chemical Engineering



Fraser has led effective programme management, supply chain and continuous improvement delivery in small operating sites and large global organisations for 20+ years. He helps clients to accelerate and maximise their return on investment from business and organizational change, typically associated with the introduction of new processes, systems and ways of working. He has an inclusive, hands-on approach which draws out the best in others whilst generating engagement and buy-in at all levels in a company.

Delivery skills include Workshop design and facilitation, End to end process capability mapping, metrics and measurement / Problem solving / risk identification and minimization / Project prioritization, initiation and management / Individual and team coaching and facilitation / Strategy definition and deployment / Culture and capability development / Lean manufacturing and change readiness assessment and Lean / supply chain awareness

Personal scorecard: 14 years supply chain programme and change management; 3 years supply strategy / design and new product introduction; 7 years manufacturing process design, scale-up and management. A lifetime connecting process and people.

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 VOLT PHARMA ASSOCIATES 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

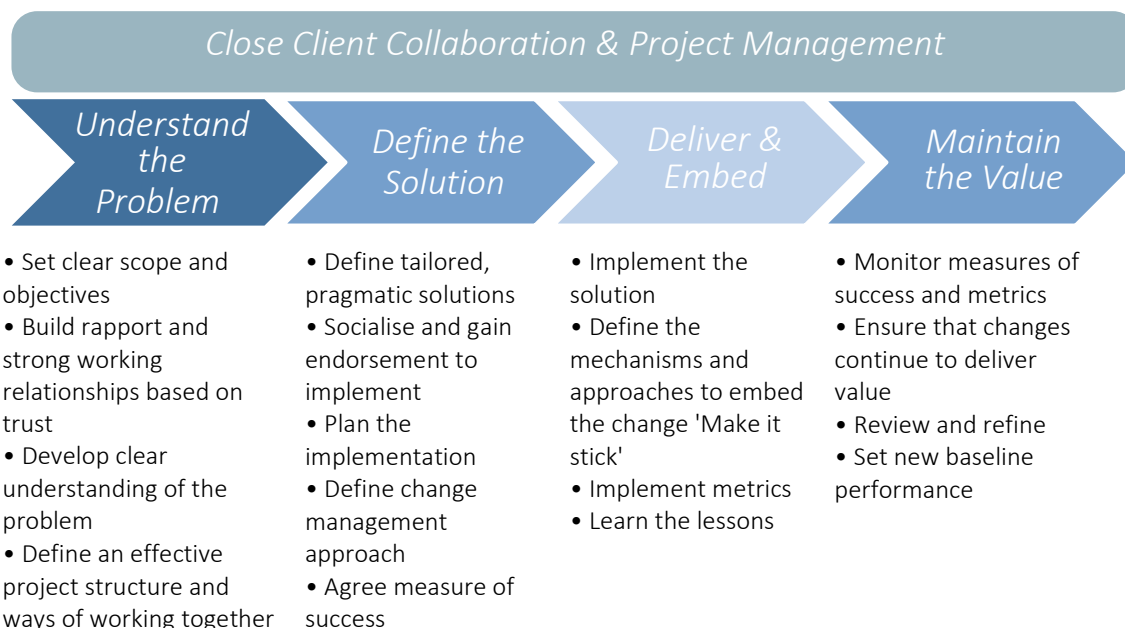
- Lead components of major projects
- Individual experts dedicated for extended periods

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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