An introduction to Volt Pharma Associates Product Development – Clinical and Regulatory (PDCR) Services

"VPA have been instrumental in providing clinical and regulatory support as we progress our lead compound into first in human studies both in healthy volunteers as well as patients. VPA have supported us with MHRA discussions, protocol design, selection of an appropriate phase 1 unit and CTA application. We look forward to continue working with VPA during the development of our lead compound." VPA client.

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.

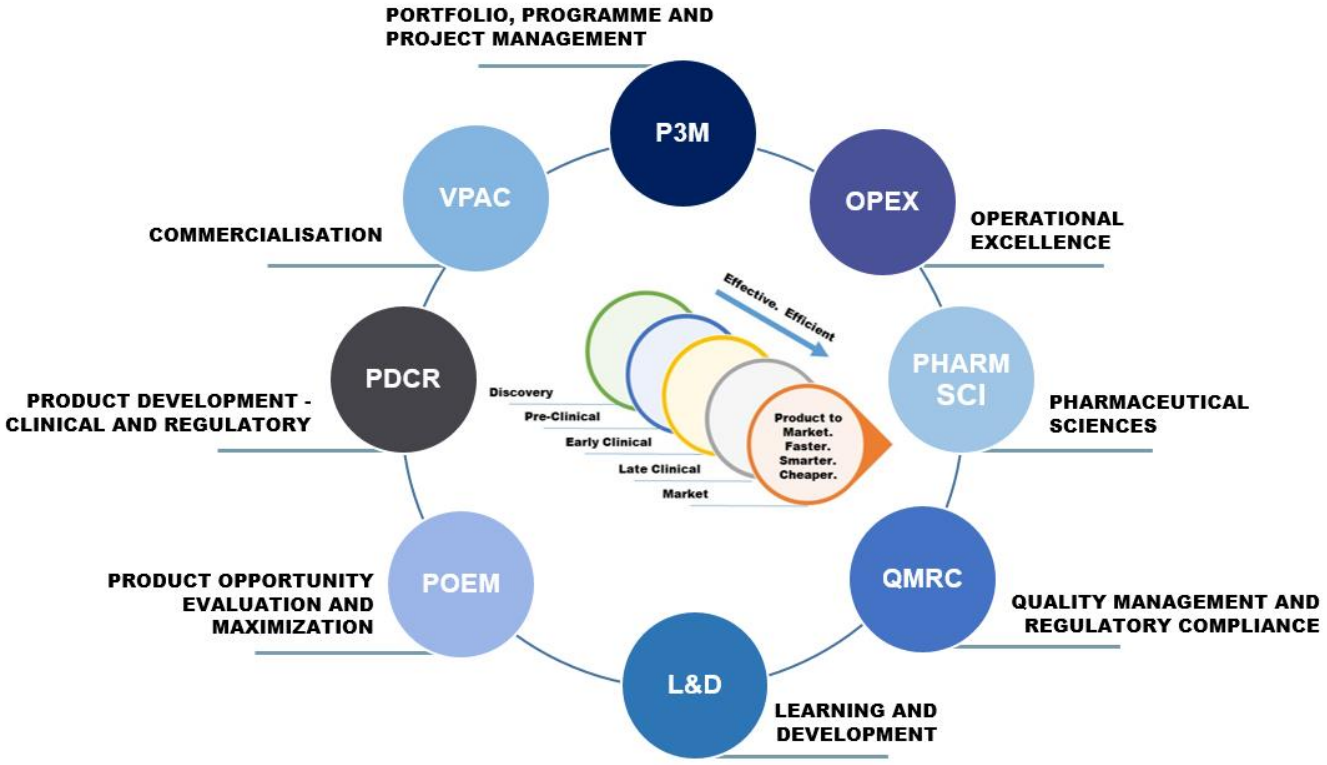
WHO WE ARE

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.

Product Development – Clinical and Regulatory (PDCR) Services

VPA's Product Development - Clinical and Regulatory (PDCR) practice is comprised of leading healthcare industry subject matter experts with a proven and well-established record of achievement across all phases of product development in a broad range of therapeutic areas. We have a passion for clinical development and a mastery of local and global regulatory issues, landscapes and guidelines.

We provide:

- strategic and operational input to start-up, biotechnology and pharmaceutical companies and other organisations engaged in the discovery, research and development of potential new therapeutic agents.
- close collaboration with clients to achieve targeted solutions and has flexibility to work for individual clients or as part of a multi-disciplinary teams.

Below is an overview of our PDCR services:

REGULATORY	*CLINICAL*	*CLINICAL PROJECT MANAGEMENT*	*BIOSTATISTICS*	*MEDICAL WRITING*	*QA & COMPLIANCE*
Liaise with HA, Regulatory Bodies, Advisory Boards & Patient Groups	Global Clinical Development Strategy	Project Management Plan Development	Design & Prepare Pre/Post-Approval & Marketing Clinical Trials	Clinical Study Reports, Safety Narratives, Protocols, IBs	Design GLP/GCP Compliance Strategies
Target Regulatory Strategies & Development Plans	Design & Implement Clinical Trial Program	Recruitment Strategy & Projections	Statistical Analysis Plans	Pediatric Investigational Plans	Perform GLP/GCP Audits
Regulatory Intelligence	Study Design	Liaison with KOLs and ACROs	Clinical Efficacy & Safety Summaries	Orphan Medicinal Product Designation	Training for Inspection Readiness
Consulting Services	Assess Trial & Programme Feasibility	Steering Committee, CEC and DMC Management	Data Mining & Predictive Analytics, Biomarkers Identification & Safety Signal Detection	Scientific Advisory Board Reports	Plan & Follow-up Corrective Actions
Medicinal Product Registration	Assess Clinical Pharmacology Studies	Vendor Selection and Management	Development Programming	Grant Applications for Public/Private Funding	Assess GLP-Compliant Development
Package Insert	Review Scientific Proposals	Risk Assessment			
Safety & Pharmacovigilance					

REGULATORY SERVICES

- Provision of Strategic Global Regulatory Advice
  - Regulatory Strategy
  - Clinical Development Planning
  - Strategic Planning
  - Compliance to global regulatory requirement
- Provision of Regulatory Intelligence and regulatory trend updates
- Creation of high-quality regulatory documents such as but not limited to
  - Orphan Medicinal Product Designation
  - Investigational Medicinal Product Dossiers
  - Clinical Trial/IND applications
  - Paediatric Investigation Plans
  - Briefing Books
  - Module 2 Overviews
- Review and risk assessment of all Documents supporting Clinical Trial Applications, Briefing Books, Marketing Authorisation applications and Post-approval follow up submissions as well as device documentation
- Interface with Regulatory Authorities as Sponsor contact, Health Authority lead and/or team preparation for Health Authority meetings. Support for Notified Body meetings and Health Technology Assessments
- Support for Consult with health authorities, regulatory agencies, advisory boards and patient groups
- Target regulatory strategies and development plans
- Regulatory intelligence
- Regulatory consulting services: Preparation and maintenance of clinical trial submissions (clinical trial application and investigational new drug application) and Support of marketing authorisation regulatory license documentation throughout Life Cycle
- Common technical document sections and modules for new product applications and line extensions
- Maintenance of compliance of investigational and registered products through their lifecycle
- Medicinal product registration
- Package insert adaptation
- Regulatory adverse event and serious adverse event reporting
- Manufacture registration
- Report compilation and publication
- Proof reading, rewriting and editorial support
- Support for legal representation

CLINICAL SERVICES

- Global clinical development strategy
  - Provide the global clinical development strategy for a medicinal product
  - Provide biomarker strategy and disease stratification approaches
- Design and implement clinical trial programme
  - Provide long-term goals
  - Incorporate adaptive trial designs where required
- Study design
  - Design studies from concept through to full protocol (from safety to confirmatory testing) to include production of investigator brochures, informed consent forms and other supportive study documents
  - Design prospective non-interventional studies, registries, post-marketing studies and

retrospective research to meet safety mandates, health outcome/economics, payer support and compelling publications

- Assess trial and programme feasibility
    - Assess global/site feasibility for clinical trials and drug development programmes
- Assess clinical pharmacology studies
- Review scientific proposals
- Other clinical services
    - Scientific advisory board formation, operational charter and minutes
    - Managerial oversight of the clinical group implementing clinical studies
    - Medical monitoring including data safety review
    - Training on study specifications

CLINICAL PROJECT MANAGEMENT SERVICES

- Project management plan development
    - Provide expertise and best in class project management practices to include all project planning
    - Development of comprehensive plans (timeline management, communication, budget management, risk management, resource management, quality and clinical monitoring)
    - Plans tailored to your needs and to also cover the scope of a full-service project from site selection to the final report including regulatory, clinical, data management, safety, biostatistics and medical report services
- Recruitment strategy and projections
    - Provide a full recruitment strategy including projections of first patient in and last patient out as part of the overall project delivery
- Liaison with Key Opinion Leaders, Steering Committee, Central Ethics Committee and Data Management Committee
    - Selection and management of steering, clinical endpoint and data monitoring committees
    - Charter writing and meeting management to meet project timelines and expectations
- Vendor selection and management
    - Vendor services sourced may include Clinical Research Organisations (CROs), drug supplies, depots, translators, imaging laboratories, electrocardiogram providers, patient and travel reimbursement agencies
    - Advise on sourcing strategy development to support drug development portfolio and business objectives
    - Conduct supply market and vendor profiling
    - Shortlist potential vendors
    - Cost model development and pricing benchmarking
    - Conduct due diligence
        - Regulatory Risk: to confirm vendor's appropriateness for the tasks being outsourced
        - Delivery Risk: to confirm vendor's experience and skills to perform specific tasks
        - Quality Risk: to define vendor's procedures and processes
        - Cost risk: to define what need can correctly increase risk of change order
    - Advise or lead agreement negotiation
    - Agreement implementation
    - Vendor performance management
    - Arbitration and dispute resolution
- Project Risk Assessment

- Identify Critical Project Risks, primarily categories associated with project endpoints and patient safety
- Assess measures of Impact, Probability and Detectability in order to generate a risk score for each category
- Plan a comprehensive clinical trial risk mitigation strategy

BIOSTATISTICS SERVICES

- Design and prepare clinical trials, post-approval studies and marketing initiatives
- Statistical analysis plans including tables, figures and listing shells
- Summaries of clinical efficacy and safety
- Planning, conduct and reporting of Interim, final, post-hoc analyses and meta-analyses
- Data mining and predictive analytics, biomarkers identification and safety signal detection
- Development programming and independent quality control and validation SAS programming

MEDICAL WRITING SERVICES

- Clinical study reports, safety narratives, clinical study protocols and investigator brochures
- Paediatric investigational plans, scientific advice documents, orphan designation applications and all other health authority contacts
- Scientific advisory board reports
- Poster presentations and slide decks
- Grant applications for public and private funding

QUALITY ASSURANCE AND COMPLIANCE SERVICES

- Design Good Laboratory Practice (GLP) and GCP compliance strategies to minimise safety risks to research subjects
- Perform GLP and GCP audits, including ad-hoc advice and inspection readiness training and plan corrective actions and follow-up to complete the actions
- Assess GLP-compliant development, supplied by contract research organisations, including validated pharmacokinetic, immunogenicity, pharmacodynamic (biomarkers) and cell-based assays

TEAM BIOGRAPHIES

Mauro Placchi Dott. Chimica, MSc

Mauro is a clinical development consultant with 25 years' experience in early to late phase development with major pharmaceutical companies and contract research organisations including Pfizer, Merck Serono, European Organisation for Research and Treatment of Cancer and Quintiles. He developed clinical studies in more than 20 indications in various therapeutic areas including multiple sclerosis, psychiatry, oncology, dermatology and infectious diseases. He is detail-oriented, dedicated and skilled in all aspects of Phase 1 to 4 clinical trials including planning, organising, implementing, leading, controlling and reporting.

He led international teams of up to 40 for more than 50 projects and achieved primary results for 6 Phase 2 and 6 global Phase 3 pivotal studies. He delivered complex clinical projects performed in Europe, Russia, Africa, India, Australia, North and South America with GCP/International Committee on Harmonisation standards. He worked across multiple technology platforms, including small molecules, therapeutic proteins, monoclonal antibodies and devices and in differently targeted environments, including prescription drugs and consumer products.

Charles Owen BSc, Cert. Pharm. Med (ECPM), MBA, PhD

Charles is a scientist with over 18 years' experience of the biotechnology and pharmaceutical industry, primarily with Novartis Institutes for BioMedical Research. He has extensive experience of drug discovery, translational research; clinical development and post-marketing activities. He has initiated several drug discovery projects delivering low molecular weight and biologic final drug candidates into early development, of which 4 reached at least first in man clinical studies.

He has extensive experience of therapeutic biologic compounds. He was the lead scientist for the anti-immunoglobulin E monoclonal antibody, Xolair for 16 years, developing it from Phase 2, through registration post-marketing activities, working across respiratory, allergy and skin indications. Prior to leaving Novartis, he was the scientific leader for the entire Novartis respiratory biologics portfolio, including the high affinity anti-immunoglobulin E monoclonal antibody, follow-up to Xolair.

He offers consultancy services through Epsilon BioConsulting Ltd to a range of clients. His particular expertise is in biologics strategy, discovery and development, scientific evaluation of clinical and pre-clinical studies and biomarker strategy. His disease area expertise includes respiratory indications, particularly allergy, asthma and other inflammatory indications.

Richard Phillips MBBS, DipPharmMed, MBA

Richard qualified in medicine at St Mary's Hospital Medical School, London (now Imperial College). After several National Health Service posts, he joined Pfizer as a Medical Advisor responsible for rheumatology and infection. He set-up their Outcomes Research Group after obtaining an MBA from Kingston Business School. In 1999, he founded the Goffin Consultancy to provide evidence-based health economics and data review for the healthcare industry.

His clients have ranged from start-ups, blue chip pharmaceutical companies, over the counter companies, medical device companies and private equity houses wanting to review potential investment opportunities.

He brings a wide background in clinical studies, economic analyses and meta-analyses following nearly 29

years in the pharmaceutical industry and wide experience in presenting clinical and health economic studies at symposia and for training. He has worked with several companies in the health technology assessment, pricing and reimbursement and market access fields. He is the author of numerous market, data and literature reviews and core-value documents.

Gary Muirhead BSc, FIMLS

Gary is an experienced pharmaceutical professional who has worked in the pharmaceutical industry for over 28 years. He started his career with Roche as a Team Leader and Senior Scientist in pharmacokinetics/drug metabolism. He later joined Pfizer and held positions of increasing responsibility over the subsequent 20 years. He managed the clinical pharmacologists and provided strategic leadership in the gastrointestinal, genitourinary/sexual health and antiviral therapeutic areas. He was also the Global Clinical Pharmacology Lead for Viagra, Celsentry and Geodon.

He was the Early Clinical Leader for several genitourinary/sexual health projects. He then became Sandwich Site Head for Clinical Research Operations and built a group responsible for the operational delivery of exploratory development, clinical pharmacology and clinical technology studies. In his final position at Pfizer, he was Vice President, Clinical Affairs Site Head for Specialty Care and managed the clinicians, statisticians and clinical pharmacologists, ensuring provision of quality resources and support to Specialty Care projects.

He is now Chief Executive Officer of Ixchelsis Ltd, which focusses on developing drugs in men's health indications. He also owns GJM Pharma Consulting Ltd, which provides pharmaceutical consulting services to a wide range of pharmaceutical companies from large multi-national to small biotechnology companies.

Brigitte Happ PhD

Brigitte has more than 20 years' experience in global regulatory affairs with the biotechnology company Serono and the pharmaceutical company Merck Serono. Her expertise covers a broad range of therapeutic areas including metabolic endocrinology, dermatology, oncology and auto-immune/inflammatory diseases and orphan drug development. She has worked on new drugs, biotechnology product development and full marketing authorisation applications. She has also managed product life-cycles, including device Conformité Européene marking, in the European Union, Switzerland, Japan, Canada, Australia and the United States. She has had successful interactions with international health authorities for marketed products and development compounds.

She has a strong scientific background and is able to bridge the gap between research and development. She is a lecturer for diploma courses at the University of Geneva and postgraduate courses at the Swiss Federal Institute of Technology in Zurich.

She has created Happ-Consulting, which offers strategic and operational regulatory expert advice to small and medium-sized biotechnology, pharmaceutical and medical technology companies.

Frank Freischlaeger Ger Dipl-Stat

Frank has over 25 years' experience as a clinical research statistician and has been a passionate SAS programmer for even longer. He worked in global pharmaceutical companies and more recently in contract research organisations providing specifically tailored statistical services to a range of large and small pharmaceutical and biotechnology companies.

He has managed multiregional teams of statisticians, clinical data managers, programmers, medical writers and electronic capture and information technology experts. He was Vice President at several service

providers, reporting directly to the respective Chief Executive Officer, responsible for all biostatistics and clinical data management activities. He has a wide experience of different systems environments, clinical indications and clinical trial designs and objectives, across all study phases.

He has the administrative, organisational, project management and business process management skills to master and optimise complex biostatistics and data management projects to GCP standards. He is the owner, Managing Director and Principal Biostatistics Consultant of Frei-Schlaeger Consulting.

Randa Zeitouni BSc, MSc, PhD, PMP, CSci FIBMS

Randa is an executive leader with 25 years' experience in academia and the pharmaceutical industry including 21 years in clinical research, initially as a clinician and, for the last 17 years in project management. She is a pharmacy graduate with an MSc in Clinical Biochemistry, an AES in Haematology and a PhD in Pharmaceutical Sciences.

She has led cross-functional teams for many full service large-scale projects and programmes for a variety of contract research organisations. She has successfully planned, directed and delivered several high profile global clinical trials, which have produced innovative breakthrough therapies and changed the standard of care. She has wide therapeutic area experience, particularly in cardiovascular, endocrinology and osteoporosis and expert knowledge in rare diseases, orphan drugs and enzyme replacement therapy, acquired through her PhD and clinical trials work.

Duncan Currie BSc, PhD

Duncan is a senior medical writer with 20 years' experience in large pharmaceutical companies and contract research organisations with a record of achievement delivering a range of high quality regulatory documents within tight deadlines and budgets. Previous employers include H Lundbeck, Pfizer and Pharmaceutical Product Development. He previously worked in academic research as a clinical pharmacologist at Surrey University and Dundee University, UK. His key strengths include writing clinical study reports across all clinical phases that fulfil regulatory requirements.

He has authored high-quality protocols that underpin clinical research projects; compiling safety narratives to report serious adverse events; assembling investigator brochures to supply study sites with high quality and up-to-date study drug information; and preparing advisory board reports that capture all key information obtained from healthcare professionals. He is the owner and Director of Maze House Medical Ltd. The company supplies quality medical writing to clients, specialising in regulatory medical writing, at the required speed and at a competitive price.

Gwyn A D'Souza PhD, DIC

Gwyn has 25 years' drug development experience in the pharmaceutical and contract research industry. Following her PhD in Drug Metabolism and Pharmacokinetics from St Mary's Medical School (now Imperial College of Science, Technology and Medicine), her career has spanned multiple stages of drug development from pre-clinical through all phases of clinical development and regulatory approval. She has worked in many therapeutic areas, including rare diseases and orphan drugs, with Wyeth, Covance, Astra Zeneca, Vanguard Medica and Pharmacia/Pfizer. She has worked on international project teams and teams collaborating with external alliance partners.

She has proven leadership of design, implementation, clinical oversight and reporting of complex adult and paediatric study programmes in North and South America, Australia, European Union, Japan, Eastern Europe, Africa, Russia, India, China and the Far East. She has expertise working with health authorities, institutional

review boards, ethics committees, investigational new drug/clinical trial approvals, new drug applications/marketing authorisation applications and paediatric investigational plans.

She provides consulting and contracting services to several pharmaceutical companies.

Marcus Benton BSc, MSc Quality, MBA

Marcus is an MBA-qualified quality assurance professional with extensive knowledge and 28 years of GLP/GCP expertise in quality management systems in the research, manufacturing and pharmacovigilance sectors of the pharmaceutical industry in Europe, Asia and the US.

He has worked for contract research organisations and pharmaceutical companies and is often able to see issues and hence create solutions, from many angles. He is a Fellow of The Research Quality Association and has implemented 7 Quality Management Systems and audited many more. He has hosted more than 12 Department of Health inspections. He is regularly invited to present at international conferences, round tables, UK and French university postgraduate courses on GLP/GCP, validation of computer systems, quality assurance tools and risk-based-quality where his laconic style is much appreciated. He has hands-on laboratory experience in developing methods for cryopreserving cells and tissues in the US and the UK.

Julianne Hull BSc, MSc

Julianne has over 25 years' clinical development experience and has held global leadership roles in vendor management/outsourcing and clinical operations for large and medium sized pharmaceutical companies (Pfizer, Wyeth, Marion Merrell Dow, Biogen Idec and Ipsen). She has been an accomplished manager and motivator of staff based in China, India, Japan, Europe and the US. At Wyeth, she developed, implemented and managed the key cross-functional governance body to drive successful delivery for inspection ready clinical trials.

In 2003, she strategically developed and implemented unique, quality and cost effective clinical data management outsourcing methods, which helped establish the ground breaking Wyeth Accenture strategic alliance. In 2010, she had business and operational oversight of the Wyeth/Accenture alliance through Pfizer's acquisition of Wyeth. She had critical roles at Wyeth, Biogen Idec and Ipsen to develop and implement effective service provider governance. She is an active member of the Drug Information Association, having been programme chair of the clinical forum in Paris in 2015 and receiving an award for service to the pharmaceutical industry in 2013. Since 2006, she has been on the advisory board of the Informa partnerships conference and is an honorary life member of the Association for Clinical Data Management. She is the owner and Chief Executive Officer of WenStar Enterprises Ltd, which provides clinical outsourcing and operations consultancy services to the pharmaceutical industry.

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.

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.

Colin Vickers BSc MSc

Colin has over 30 years' pharmaceutical research and development, 28 of them regulatory affairs. His speciality is regulatory affairs of emerging markets for which he is a recognised industry leader. He has extensive knowledge and experience of working in Asia, Middle East, Africa, Latin America and Europe and he has been head of emerging markets in global regulatory affairs, for The Wellcome Foundation, GlaxoWellcome, Pfizer and Eisai. He has provided independent regulatory intelligence and advice to companies on accessing new counties, new product regulatory strategy and product maintenance activities. He has delivered many robust product development, filing and approval strategies for company pipeline, established and in-licensed, products. Innovative regulatory strategies have often been developed to produce industry-leading application approval speeds.

For the European Federation of Pharmaceutical Industries and Associations, he has been chair of the International Regulatory Affairs ad-hoc group, chair of the Asia Regulatory Conference Organising Committee, a member of the Regulatory Policy and Technical Standards Committee and a member of the China Network. He is also a member of The Pharmaceutical Research and Manufacturers of America (China).

Gilles DELLA CORTE, MD

Cardiologist and Pharmacologist, after ten years of hospital practice, Gilles joined the Pharmaceutical Industry in 1990.

Since this date he worked for 9 companies including big Pharma (Rhone-PoulencRorer,

Servier and Solvay Pharma), Biotech (Serono and Merck-Serono), Startup (Anergis) and for CROs (Phoenix Life Sciences, Omnicare Clinical Research, Therapharm). He also held the medical responsibility of a Phase I site (Larime).

During this over 26-year career he held various senior R&D positions, mainly in Clinical Research from Translational Medicine / Phase I to Phase IV but also business oriented or managerial leading large Teams up to 35. This gave Gilles a large international experience in all aspects of Drug Development in several therapeutic areas as cardiology, rheumatology, endocrinology, allergy.

He is now CEO and Founder of DellMed Consulting, providing consultancy services to Healthcare companies around Clinical Development, Outsourcing, Safety, Due Diligence and Regulatory Affairs.

VPA CASE STUDIES

The following examples illustrate the experience and value that the VPA PDCR team can bring to our clients:

VPA SUPPORTED A VIRTUAL BIOTECH COMPANY WITH NO CLINICAL OPERATIONS EXPERTISE SELECT A SERVICE PROVIDER FIT FOR PURPOSE TO DELIVER THEIR PHASE I STUDY

- Situation: A virtual UK-based biotech company with limited knowledge of GCP requirements needed to source a service provider qualified to deliver their Phase I study with a potential biologic analgesic. They were unaware of the regulatory risks associated with lack of compliance, delivery, quality and cost when insufficient due diligence was ensured through a non-rigorous selection and capability assessment process.
- Services: VPA PDCR work with the client to define the critical success criteria for the selection of a fit for purpose phase I unit. They acted as the outsourcing department of the client developing a request for proposal versus the study requirements and critical criteria. They worked with four full-service, MHRA-accredited phase I service providers and guided the client through a robust selection process including capabilities assessment and risk assessment to enable the identification of the most appropriate candidate.
- Result: A Master Services Agreement was developed with the selected phase I unit. Contracts including key success criteria were developed for study start up and for full-service delivery.

URGENTLY NEEDED SPECIALIST WITH REGULATORY EXPERTISE AND ADVICE FACILITATES REGULATORY APPROVAL WITHIN ORIGINAL TIMELINES

- Situation: A mid-sized pharmaceutical company was in the middle of a de-centralised regulatory procedure when it suddenly needed additional expertise to complete the on-going procedure. There was a need to respond to questions, finalise the labelling and manage an unexpected complication due to a member state having raised national health concerns at the end of the procedure.
- Services: VPA PDCR partnered with the various departments of the client to prepare, review and submit the responses.
- Result: The client was provided with satisfactory responses which were handled in time through personal contacts with the health authorities. The company obtained the approval of the medicinal product in the EU according to their original regulatory plan.

EXPERT WRITING OF REGULATORY PROCESS DOCUMENTS FACILITATED CREATION OF A NEW AND EFFICIENT REGULATORY AFFAIRS GROUP

- Situation: A large leading pharmaceutical company with no experience in the Food and Drug Administration arena needing to setup a new efficient and strong US regulatory team to help it

expand.

- Services: VPA PDCR provided a team of experts to guide the development of more than 35 processes relating to Food and Drug Administration regulations and guidelines. Process mapping allowed process documents to be easily understood by new staff and thus increased process compliance. Processes provided a simple and deliberate approach to learning Food and Drug Administration regulations and guidelines and to easily understand language and instructions on regulatory requirements. Process-related report templates, tracking systems, forms and checklists allowed staff to immediately reap process benefits each time they were applied. Training of new staff was improved.
- Results: A large team of experts wrote processes which allowed clear roles and responsibilities to be defined that fed into the correct set-up on regulatory affairs team. The company received a full suite of process documents which new staff could be immediately trained on.

VPA SUPPORTED A SMALL PHARMACEUTICAL COMPANY ACTIVE IN RARE DISEASES TO RAPIDLY ANSWER REGULATORY QUESTIONS AND ACHIEVE DRUG SUBMISSION ON SCHEDULE

- Situation: A small European pharmaceutical company had filed an application for the treatment of a rare disease and had received a large number of clinical pharmacology (pharmacokinetics and drug interactions) questions from the centralised European Medicines Agency, rapporteur and co-rapporteur in the critical assessment reports. The responses to these questions were extremely time-critical to the overall filing and finalisation of the summary of product characteristics and the company realised they required additional clinical pharmacology expertise to complete these responses.
- Services: VPA PDCR provided clinical pharmacology expertise and, partnering with the client to prepare, review and submit the answers to the questions in a much contracted time.
- Result: The client was provided with timely responses to the extensive number of questions, which enabled the responses and the submission to be completed on schedule.

LARGE-SCALE LABELLING SUPPORT TO SIGNIFICANTLY INCREASE COMPLIANCE

- Situation: A large leading pharmaceutical company needing to set-up a new centralised team to manage labelling changes and compliance.
- Services: VPA PDCR provided labelling support for 22 markets in the European Medicines Agency region. We worked with each local contact to fully collect local requirements, understand product portfolio and organise priorities into a label submission plan. Current systems were used to manage changes in labelling, including updates and tracking of progress. Processes were initiated and implemented to increase compliance by integrating current approaches and joining forces with the submissions and artwork team to optimise an end-to-end process.
- Results: A strategic plan was implemented to bring each market from noncompliance to a business as usual model. Compliance increased from 20% to 90% in 6 months, with a similar strategic plan for other regions. VPA PDCR was requested to work on other departmental projects to help increase compliance and enhance processes.

A VALUABLE LARGE CLINICAL STUDY WAS RAPIDLY DEVELOPED AND COMPLETED

- Situation: A subsidiary of a large pharmaceutical company intended to launch a product for vaginal thrush. Marketing approval had been obtained but there were few data on product use in a real world setting.
- Services: A non-comparative study involving nearly 2000 patients was set-up in 4 months in 200 general practices and completed within a further 3 months and the results analysed. The whole

project from initial set-up to report for publication was completed in 9 months.

- Results: The study provided excellent efficacy and safety data, a publication, early experience among target General Practitioners and useful additional information in subsequent marketing materials.

REGULATORY MEDICAL WRITING WITH A TRACK RECORD OF CLINICAL STUDY REPORT WRITING

- Situation: A large pharmaceutical company developed a novel antiretroviral drug to treat human immunodeficiency virus. There was a need for a Lead Writer to author all clinical study reports for programme from Phase 1 to Phase 3.
- Services: Inputs were obtained from the drug development clinical team; all 15 clinical study reports were reported in a timely fashion from Phase 1 and Phase 2 through to complex, first pivotal Phase 3 study; and as key member of the drug development team, obtained approval and sign-off by Clinical Lead for regulatory submission.
- Results: the company gained rapid Food and Drug Administration approval which led to sales of £143 million in 2013.

FEASIBILITY ASSESSMENT FOR OUTSOURCING OF A REGULATORY AFFAIRS ACTIVITY

- Situation: The leadership team had identified a large operational/routine noncore process that they wanted to outsource against a target of cost savings and efficiency increase.
- Services: A feasibility study was initiated with the consultant ensuring the process demonstrated rigor and aligned to best practice business outsourcing practices. Using the output from the process mapping, the consultant led a market & external vendor delivery capability assessment resulting in a risk/benefit assessment of outsourcing the identified process.
- Result: The feasibility assessment showed that the outsourcing of the end to end process could achieve the targets, but the risk/benefit assessment conducted by the consultant identified a number of key risks and barriers that would undermine a successful outsource. The Leadership Team accepted the recommendation to improve the efficiency of the internal process before outsourcing should be considered. The consultant helped the client avoid outsourcing a process that was not outsource ready and avoiding a potentially costly failure.

HOW DOES 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

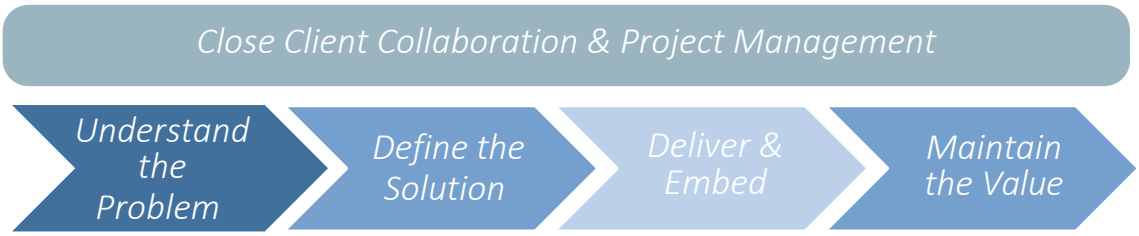
Full Outsourcing

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

HOW WILL WE OPERATE ON YOUR PROJECT?

VPA PDCR can rapidly assemble teams and ramp-up resources to integrate into the client's organisation to provide expertise and hands-on capacity to support client's needs.

We create tailored solutions and seamless integration to fit your product, needs and goals. These are not quick fixes. We aim to embed solutions that will have a lasting impact on your organisation.



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 change management approach • Agree measure of success	• Implement the solution • Define the mechanisms and approaches to embed the change 'Make it stick' • Implement metrics • Learn the lessons	• Monitor measures of success and metrics • Ensure that changes continue to deliver value • Review and refine • Set new baseline performance

CONTACT FOR FURTHER INFORMATION

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