VOLT®

An introduction to Volt Pharma Associates Pharmaceutical Science (PHARM SCI) Services

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

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.

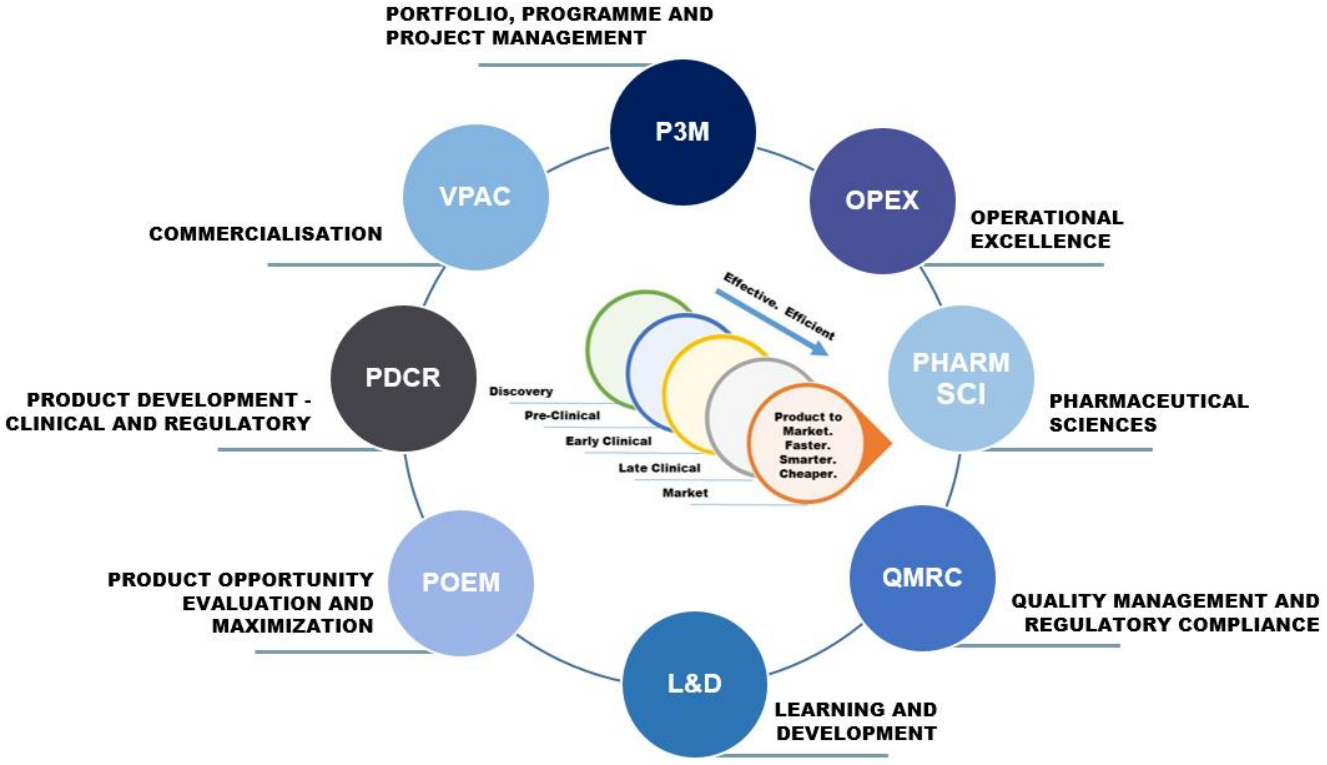
WHO WE ARE

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.

Pharmaceutical Science (PHARM SCI) Services

OVERVIEW

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

SERVICES

- CMC Strategy and planning
  - Defining overall CMC strategy for individual projects, including Quality by Design as required.
  - Defining programme /portfolio pharm sci. strategy.
  - Defining outsource strategy & plan.
  - Defining synthetic development & bulk supply strategy.
  - Carrying out due diligence so that CMC regulatory and manufacturability issues of potential assets are uncovered and understood
  - Developing regulatory and technical CMC strategy for 505b2 assets
  - Defining formulation development and formulation strategy
  - Defining analytical method development and validation strategy including analytical QbD.
  - Develop project plans for pharmaceutical science elements to integrate into overall project plan.
  - Ensure that the Regulatory CMC strategy is optimised and harmonised with the wider development strategy

- Outsource management
  - Choosing CRO / CMO
    - Capability audits.
    - Quality audits.
  - Monitoring and controlling outsource contracts.

- Process Improvement
  - Review / analysis of current processes.
  - Possible use of Lean six sigma capability.
  - Define solutions.
  - Quality by design / Right first time
  - Change management / implementation
  - Learning and organisational development synergy.
  - Metrics for measuring improvements.

- Tech Transfer support
  - Process
  - Analytical

- Pharm Sci Portfolio Review
  - Support for internal review of projects.
  - Support for developing understanding and managing priorities.
  - Keeping projects on track to meet goals

- Supply chain logistics
  - Pharmacy strategy
  - Packing and distribution advice

TEAM BIOGRAPHIES

Jeff Duke MSc C.Sci CChem FRSC

Jeff Duke has over 20 years' pharmaceuticals industry experience in both human and veterinary health in a wide range of Chemistry, Manufacturing and Control functions. Prior to becoming an independent consultant, Jeff held positions with a top ten pharmaceutical company such as Executive Director European Analytical Research & Development, Head of Strategy & Implementation for Pharmaceutical Sciences Asia Business Development, Head of Global Material Science and Oral Products as well as Director, European Analytical R&D Full Development. Jeff was involved in bringing 6 NCE drugs to the market.

As a consultant Jeff provides consultancy and interim management services in the following areas: CMC Strategy Development, Release testing strategies for drug products and API, Analytical method development, validation and inter laboratory method transfer, Integration of API & Drug Product strategies through development of Materials Science approaches. Supporting and optimising the R&D to manufacturing interface Change management within departments, particularly organisational and workflow design, upsizing, downsizing, continuous improvement initiatives and staff development, Selection and support of outsourcing partners and processes, both in western and eastern territories.

Alistair Swanson BSc DPhil FRSC

Alistair has over 25 years' R&D experience in Pharma and related industries in technical, managerial, leadership and consultancy roles, delivering projects involving colleagues and partners in the EU (UK, Germany, Italy & Belgium), US and Canada. As both a line manager and a consultant, he has completed numerous business process improvement and change programs, ranging from design and implementation of project management systems to business and portfolio integration following a take-over, organisational change and cycle time reduction.

Alistair has a deep understanding of drug development and P3M, together with extensive hands-on experience at a senior level of project and portfolio governance and project leadership. As EU CMC portfolio head at Pfizer, he was responsible for a portfolio of over 40 development projects, with an external spend of >$100MM p.a. and he managed the CMC development, industrialisation and registration of seven new medicines. He has a degree and doctorate in Chemistry and is a Fellow of the Royal Society of Chemistry.

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.

Amrit K. Judd, PhD, MBA

Amrit is a Senior-Level Pharmaceutical Consultant with more than 20 years of experience, combining quality, regulatory compliance, and pharmaceutical R&D expertise to prove an asset to pharmaceutical and biotechnology companies throughout the U.S., Puerto Rico, and Europe. Extensive QC/QA experience and knowledge in analyzing drugs for Safety, Identity, Strength, Purity, and Quality (SISPQ).

Her specialties include: Chemistry, Manufacturing, and Control (CMC), FDA GXP Compliance and Regulatory Affairs (cGMP, GLP, GDP), 21 CFR Food, Drugs, Cosmetics; APIs, Medical Devices, and Drug/Device Combination Products. Good Laboratory Practice for Nonclinical Laboratory Studies, and ISO13485 Compliance. Batch Record Review for manufacturing, GMP Compliance & Regulatory Affairs, Quality Compliance & Assurance, Deviations & Investigations Management under 483 and Consent Decree environment, SOP Documentation, CD Verification & Warnings, and Drug Certification, Pharmaceutical Research and Development.

Review BLA supplement, compose assessment report for FDA for regulatory strategy/pathway and conduct regulatory path. Coordinate and review Design Control document, Device Manufacturing File (DMF), Device History File (DHF), and Risk Management document. Monitor and review batch records for drug and API manufacturing, reporting observations and recommendations, review process and equipment validation, and recommend CAPA. Conduct GAP Assessment.

Paul Dickinson, B. Pharm. (Hons.) PhD

Paul has held several senior science leadership roles in Academia and Large Pharma for over 20 years. These roles focussed on applying the best science in projects to ensure optimal product performance in the patient, thus bridging pharmaceutical and clinical disciplines. Paul has extensive early development, late development and drug registration stage experience including written, teleconference and face to face regulatory interactions. This experience includes the delivery of several products to approval and commercialization and compounds awarded breakthrough status.

Paul has an international scientific reputation and is Chair-Elect of the AAPS 'QbD and product performance' focus group committee. Paul has been at the forefront of recent technical and regulatory advances in the understanding of dissolution testing and pre-defining in vitro performance criteria that assure drug product performance in the patient (clinically relevant dissolution).

Paul is currently Director of Product Performance at Seda Pharmaceutical Development Services a company focussed on delivering pharmaceutical development and clinical pharmacology services to the Pharma industry. Prior to joining Seda, Paul led the clinical pharmacology programs for several drugs in AstraZeneca's Oncology portfolio. Formerly Paul was a Principal Scientist within Pharmaceutical Development (AZ) leading both the global biopharmaceutics network and the Medicines Evaluation (early phase pharmaceutical development) science community. Paul has successfully developed, exploited, and out licensed technologies while at AZ and as a Lecturer at Cardiff University and has published extensively.

Marcel De Matas, BSc (Hons), PhD, FRSC, CChem

Marcel is currently Director of Product Design at Seda Pharmaceutical Development Services, a company focussed on delivering chemistry manufacturing and controls (CMC) and clinical pharmacology services to the Pharma industry. He has a track record of success over 18 years working in both management and senior scientific positions in industry and academia. Most recently he was a Principal Scientist in Product Design and Innovation at AstraZeneca, where he was responsible for introducing the latest science, new technologies (manufacturing and drug delivery) and product design thinking into the Product Development group.

He has led technical activities, provided project leadership and has managed product development teams responsible for the delivery of drug projects from initial concept design through late stage development, regulatory submission and launch. In addition, he has led teams at the drug discovery-development interface, assessing the level of CMC technical risk and defining product design strategies in early development. Project experience has covered projects across a range of disease and therapy areas with substantial experience in the oncology field.

Marcel also has notable experience in product innovation and the development of enabling technologies for pharmaceutical products. He has established a number of open innovation platforms, working across industry sectors, Pharmaceutical companies, Universities and SMEs spanning several international boundaries including China.

CASE STUDIES

Case study 1:

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

Case study 2:

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

Case study 3:

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

Case study 4:

- Situation: The Client had developed a new manufacturing process for a biotech drug substance, which improved the yield, reduced the cost of goods and removed the raw materials of animal origin. A regulatory strategy was needed to present the manufacturing improvement as minor only in order to save time and costs.
- Service: By careful assessment of the whole manufacturing process, restricting the changes only on critical process steps, maintaining the control tests and specifications and eliminating the need for additional clinical studies the improved process was validated.
- Result: The client had a clear regulatory strategy how to present and submit the manufacturing process improvement successfully as a minor process modification and get it approved in short assessment time by all major health authorities leading to the implementation of improved process earlier than anticipated.

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

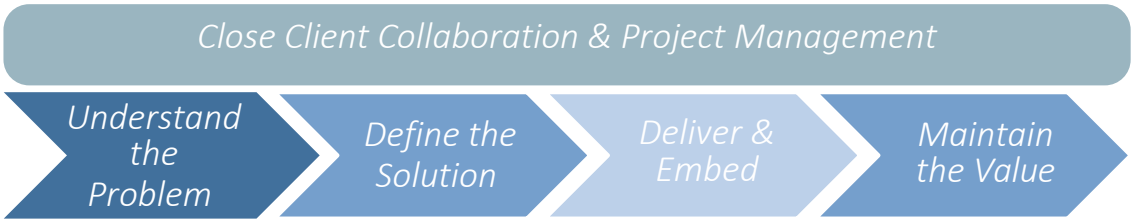
- Lead components of major projects
- Individual experts dedicated for extended periods

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.



- 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

Managing Partner: Claude Houet
Title: Head of Practice - Pharmaceutical and Life Sciences Industry
Telephone: +49 (0) 172 6340202 (mobile); +49 (0)761 600 69 355 (office)
Email: info@vpa.eu.com
Website: www.vpa.eu.com