



VALIDATION IN PARTNERSHIP LTD
YOUR INDEPENDENT CGMP & VALIDATION PARTNER

COMPANY CAPABILITY STATEMENT



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INTRODUCTION

Formed in 1995, Validation in Partnership (ViP) is a limited company specialising in the provision of validation and regulatory compliance services to the life science industries supplying the European and/or American markets.

As a completely independent organisation, we pride ourselves on the provision of an impartial, flexible, and pragmatic service with up-to-the-minute regulatory information and a commitment to adding value. The 'Partnership' in our company name represents the working relationship we forge with each of our customers.

Since the outset, we have been committed to:

Compliance, Consistency and Pragmatism

This commitment is demonstrated by our investment in the development of a range of in-house innovative compliance systems, and targeted personnel recruitment and development programmes.

We appreciate that time, resource and funds are not limitless and, therefore, compliance solutions must always be measured, focused and appropriate.

Scientific, risk-based compliance solutions can only be realised through the informed application of regulatory fact and product knowledge. Our partnerships with clients are forged as we fuse the applicable regulatory requirements with their unique product and process needs.

The last decade has seen ViP flourish and it is now an umbrella to a number of mutually complimentary compliance companies and products:

ViP PROJECTS manages our complete compliance project capability.

ViP RECRUITMENT is our validation and GXP compliance personnel recruitment agency.

ViP TRAINING provides on- or off-site validation and GXP compliance training courses.

ViP CONSULTANCY links us with an extensive network of consultant associates.

ViP DATUM is our unparalleled in-house searchable regulatory compliance database.

ViP SCRIBE enables the generation of compliance documents at the touch of a button.

Each of these makes a major contribution to our considerable range of capabilities summarised under the following headings:

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Everything we do in the field of regulatory compliance and validation is targeted at consistently satisfying the appropriate regulatory requirements in the most cost effective way practicable, (i.e. compliance, consistency and pragmatism). We believe that the key ingredients to successfully achieving this are through our **versatility, experience, impartiality, cost-effectiveness** and **regulatory knowledge**.

- Versatility:** We can partner you on site, from our office, or both.
- Experience:** The hands-on experience of our team of Specialists is unmatched.
- Impartiality:** Our independence ensures we are not deflected from our sole objectives of regulatory compliance and customer satisfaction.
- Cost-effectiveness:** With all our in-house compliance tools at our disposal, nobody can work more cost effectively.
- Regulatory Knowledge:** Our regulatory database ensures all the knowledge we need is always readily available.

Industry sectors so far benefiting from our capabilities include:

- Finished Pharmaceuticals
- Active Pharmaceutical Ingredients
- Biotechnology
- Veterinary Products
- Medical Devices
- Cosmetics
- Equipment Manufacture
- Engineering Design and Construction

SERVICES

At ViP, we continually strive to meet the challenges of our customers by providing innovative and economical science- and risk-based solutions to their validation and regulatory compliance problems. We achieve this through our unrivalled knowledge of regulatory requirements, unique operating systems and pragmatism.

VP PROJECT comprises a veritable arsenal of proven compliance problem-solving weaponry to meet any client's demands:

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In the execution of all these compliance project deliverables, the skill, knowledge and experience of our project personnel is second to none.

Consultancy

All too often perceived as an expensive luxury providing limited added value, the services of a compliance consultant, when directed at the correct level and at the appropriate time, can steer customers away from reinventing the wheel or repeating the mistakes of others and result in substantial cost savings, particularly during the early conceptual stages of a project.

VP CONSULTANCY is an active and ever-expanding network of industry specialists, with a vast amount of experience and knowledge gleaned from the satisfactory conclusion of myriad compliance projects in all segments of the life science industry.

Our customers are secure in the assurance that the employment of one of our consultant associates contracts not only the opinion of a respected expert individual but also the combined network and knowledge base of an entire organisation.

Project Management

“A full or part time resource responsible for the control, implementation and delivery of the compliance activities associated with a particular project scope.” (ViP)

In addition to providing ‘hands on’ resource, ViP also offers project management expertise to ensure that all compliance-related activities are completed to schedule and budget.

Our project managers, skilled and proven in the successful delivery of regulatory compliance projects, afford us the capability of a thorough assessment and understanding of a client’s specific project requirements and constraints. This information is fundamental in the development of an appropriate schedule and resource programme to manage a project to a satisfactory conclusion within an agreed budget and timeframe.

Effective document control is a key element in the successful management of validation projects and, to this end, ViP employs a tracking system based on the traffic light (red, amber and green indicators) principle to indicate the progression of documents. With a history of tried, tested and verified utilisation, this system is ideal for tracking the generation, field execution and reporting of qualification, validation and support documents.

Giving a clear indication of the exact status of all protocols, reports, etc., and the percentage outstanding for each, the tracking system also provides individual work allocation and productivity details, as well as overall ‘hours earned’ against those expended, and enables project execution efficiency to be accurately monitored.

A ‘System Owner’ approach to the project validation effort is encouraged, wherever practicable, with specific individuals being assigned the qualification/validation of critical equipment, systems and utilities on joining the project team. Continued commitment to an assignment, from protocol preparation through field execution and final report generation, maximises the benefits to be gained from the familiarity this achieves.

Process and Production Rationales

“These are formal statements of the importance of all parameters associated with each step of a defined process in terms of their potential effect(s) on final product quality.” (ViP)

The key to optimising time, resource and expenditure is to target those activities that will ensure the consistency and quality of the final product manufactured.

The first step in achieving this is to establish a clear understanding of the manufacturing process and document all the parameters that may have an adverse effect on the quality of the final product, if not properly controlled. The start point is a Process Rationale, which is written at development stage to evaluate risks to product quality. This formal compilation of the process critical parameters may comprise a variety of sources, such as technology transfer documents, and forms the basis of a series of risk assessments performed as the User Requirement Specification(s) and the detail of the full scale production model are being developed. This iterative process is documented in a Production Rationale, a step by step

analysis of the proposed production process and a compilation of all parameters that may have an impact on the quality of the finished product.

The finally agreed Production Rationale provides a complete list of all product quality impacting parameters at every step and, where possible, identifies all set-points and ranges or tolerances. The rationale deliverable is a justification for every subsequent process control measure, be it by facility, utility or equipment qualification, automation validation, calibration, in-process monitoring, standard operating procedure (SOP) or training. All static and dynamic attributes of the process are included. A parameter such as equipment product contact parts is assigned to Installation Qualification for verification, whereas the standing time for an off-loaded drum of material becomes the subject of an SOP. The charging of an ingredient into a mixing vessel, if a manual operation, is controlled by approved SOP, training and calibrated time piece. Dynamics such as mixing speed are covered by Operation Qualification. Thereafter they are monitored and trended, either by a suitably independently validated and maintained automated system or by manual measurements at specified intervals by qualified individuals trained in approved SOPs and using calibrated test equipment.

User Requirement Specifications (URSs)

“User Requirement Specifications are formal records of all pre-determined requirements.” (ViP)

The importance of the role played by User Requirement Specifications (URSs) cannot be stressed enough. They comprise all the known requirements of all stakeholders and are generated as a precursor to procurement of all facilities, utilities, equipment and operating systems. Non-detailed Project URSs can provide the master control over more detailed System URSs. Compiled as tender documents, they provide all the information necessary for prospective vendors to satisfy all the hardware, software and documentation requirements of the Quality, Production, Engineering and Maintenance departments. URSs cover not only the current requirements of GMP, GAMP (other GxP compliance issues, as appropriate), the registered process(es) and corporate standards, but can be expanded to become receptacles for all required deliverables.

Our experience has demonstrated that the more clearly these requirements are recorded, the more likely they are to be suitably addressed.

Traceability Matrices

“Traceability Matrices are living documents tracking the satisfaction of individual compliance requirements.” (ViP)

Traceability Matrices plot the projected delivery of every single user requirement, to ensure nothing is overlooked. Used prospectively they provide a detailed index defining precisely where each requirement will be verified as satisfied. But they can also be used retrospectively to identify the record sheets and reports documenting the fulfilment of individual requirements.

Reviews, Assessments and Audits

“Compliance Reviews are the mechanism by which design packages are confirmed to incorporate all applicable compliance requirements.” (ViP)

“System Impact Assessments formally document the impact of premises, equipment, utilities, instrumentation and automated/computer systems on the quality of the finished product.” (ViP)

“Risk Assessments formally document the risks associated with the proposed design or use of a compliance solution.” (ViP)

“Audits are assessments of the level of compliance against a predefined standard.” (ViP)

Compliance Reviews

Compliance Reviews perform the same function as the Enhanced Design Review advocated by the ISPE in their Baseline Guide on Commissioning and Qualification, and what some refer to as Design Qualification (DQ). Proposed designs submitted by prospective vendors in response to tender enquiries are checked for compliance with the user requirements. Each individual user requirement is verified as a deliverable of the proposed design by recording the precise location within the design package where the vendor's intention to comply is documented. Only then can an order be confidently placed.

Compliance Reviews are essential in the case of prospective validation, as it will be too late/expensive to eradicate any non-compliant aspects of a design at the Installation Qualification phase, leading to inevitable involuntary compromise. In recognition of this, Compliance Reviews are often performed for new or substantially modified systems throughout the design stage.

The number of Compliance Reviews performed depends on the complexity of the system design package. Prospectively, for complex systems, a review will generally be performed when the outline design is ready for approval, with additional reviews being performed at logical stages as the detailed design is developed. Simpler packages may only require a single review.

System Impact Assessments (SIA)

Complementing the FDA's risk-based approach to regulatory compliance, the SIA is the suggested method of assessing the impact of systems on product quality, as documented in the ISPE's Baseline Guide to Commissioning and Qualification, and determines whether or not a system is to be subjected to qualification/validation. The criteria provided by the ISPE and the Production Rationale are used to determine if Good Engineering Practice (GEP) standards alone will suffice or if they merely provide the grounding for subsequent validation activities.

The SIA provides a documented rationale for the scope of a validation project, a process traditionally undocumented. Historically, Validation Master Plans have contained matrices of systems and qualifications, but the decision making process has rarely been recorded.

At ViP, we have long recognised the importance of a system impact assessment process and have, for many years, encouraged the use of Process Rationales (explained above) to provide the necessary substantiation for the results of such assessments.

Risk Assessments

The proposed design and/or implementation of a compliance solution is assessed to determine all potential risks to such factors as data integrity, patient safety, product quality or, in the event of failure, to a company's business itself.

Rather than being performed as a single event, this formally documented activity evaluates risks at various stages throughout the design, development and implementation process. Successfully executed risk assessments should ensure the extent of validation/compliance activity is commensurate with the potential risks identified.

Audits

One of the most powerful outputs of our regulatory compliance database (ViP DATUM) is the compilation of customised audit checklists comprising all the latest regulatory authority requirements, guidelines and observations.

Where necessary, FDA and EC requirements can be compiled side by side and formatted in either the traditional or "Systems-Based Approach" styles.

These checklists, combined with our highly experienced audit team, ensure that all areas of compliance are assessed and carefully documented to correctly emphasise all applicable positive and/or negative compliance observations depending on the ultimate audit objectives.

Our impartial and unbiased involvement has proven particularly valuable in formally confirming the suspected existence of internal shortcomings.

Compliance Reviews by Email

In addition to performing compliance reviews against design packages, ViP also provides a service unique to the industry, that of CGMP Reviews by Email.

At a time when purse strings are being drawn ever tighter and regulatory compliance requirements are becoming progressively more stringent, companies are being forced to utilise internal or cheaper external resource to achieve their compliance objectives. Often unsupported and required to generate a vast array of compliance documentation, it is becoming increasingly beneficial to have their work reviewed by a subject matter expert prior to approval. We know, from years of reviewing plans and protocols generated by others, that personal history and experience can lead to the inclusion of inappropriate or unnecessary requirements and, more damagingly, the omission of essential criteria.

Where not available internally, ViP can provide impartial expert resource to perform such reviews on an as-needed basis, without the burden of costs incurred by travel time, or additional expenses.

Each of our in-house reviewers is supported by our unique compliance database, guidance documents and electronic library, and can provide the precise regulatory perspective.

Our customers simply purchase a block of review time and email their regulatory packages, or extracts from them, to us for a swift, but exhaustive, CGMP compliance review. By return email, we provide them with all of the necessary CGMP corrections/inclusions with supporting rationale.

Remedial Action Plans

“Remedial Action Plans are pre-approved programmes of work designed to eradicate areas of non-compliance.” (ViP)

Having successfully performed a Compliance Review, Assessment or Audit, the next step is to develop a meaningful Remedial Action Plan. The skill is to work alongside client representatives to develop the most appropriate compliance solution, with respect to commercial as well as regulatory risk, and to build this into a realistic programme.

Our extensive experience in the development of such plans, ensures that the appropriate level of regulatory compliance is achieved within the time, resource and financial constraints of our clients.

Site Validation Packages

“Site Validation Packages are compilations of plans, protocols, raw data and reports to support the qualification and/or validation of premises, equipment, utilities, instrumentation and automated/computer systems as well as cleaning/analytical methods and processes.” (ViP)

Where no corporate approach to validation prevails, we can assist a customer by providing a complete Site Validation Package. A fully documented and illustrated Site Validation Policy presides over a tried and tested modular system of stand-alone documents, its modularity minimising the impact and knock-on effect of any changes. The policy governs a hierarchy of validation master plans, subordinate validation plans, protocols, record sheets and reports, all supported by fully detailed Standard Operating Procedures incorporating example documents and training/evaluation sections, all of which can be generated at the touch of a button using ViP SCRIBE, our automated document generator (described below under [Products](#)).

The provision of clear, complete and consistent documentation is the ultimate objective of our work. We fully appreciate that, no matter how thorough the checking or testing, it is the manner in which these activities are documented, that will determine their suitability in the eyes of a regulatory inspector.

Validation and Good Engineering Practice (GEP) Policies

Validation Policy

“A Validation Policy formally documents a company’s approach to providing a high degree of assurance that its registered processes consistently result in products meeting their predetermined specifications and quality characteristics.” (ViP)

The Validation Policy is one of a company’s most important compliance documents. A clear, carefully documented policy demonstrates a commitment to validation and conveys the perfect message at the start of a regulatory inspection.

At ViP, we appreciate the importance of the Validation Policy, which formalises the approach to be adopted in the compilation of validation packages supporting the systems and processes that may impact on the final quality of regulated drug products and work carefully with our clients to integrate our own experience with their established systems and company culture.

GEP Policy

“A Good Engineering Practice (GEP) Policy formally documents a company’s approach to the compilation of foundation engineering packages for systems that may or may not impact upon registered processes.” (ViP)

The GEP Policy should complement the Validation Policy and formalise the compilation of foundation engineering packages to support the use or subsequent qualification/validation of a system.

A carefully constructed GEP Policy integrates the various user/supplier engineering activities, minimises duplication of effort during commissioning and qualification, and prevents the generation of unnecessary documentation.

Validation Master Plans (VMPs) and Validation Plans (VPs)

“Validation Master Plans/Validation Plans are structured, detailed plans of work providing information about how all of the validation work on a project is going to be controlled.” (ViP)

Whether for an entire Site, a single system (facility, utility, automated process, equipment item) or group of systems, we can assist in the development of high quality plans that integrate seamlessly within a customer’s established validation structure and formats.

Design, Installation, Operation(al) and Performance Qualification (DQ, IQ, OQ, PQ)

“Design Qualification is the provision of documented evidence to demonstrate that all key aspects of the proposed design package comply with the applicable user, process, CGMP and GEP requirements.” (ViP)

“Installation Qualification is the provision of documented evidence to demonstrate that all key aspects of the installation adhere to approved design intentions, that all applicable CGMP, GEP, user and process requirements have been addressed, and that manufacturers’ recommendations have been suitably considered.” (ViP)

“Operation(al) Qualification is the provision of documented evidence to demonstrate that the system under investigation operates as intended throughout its anticipated operating ranges.” (ViP)

“Performance Qualification is the provision of documented evidence to demonstrate that a utility/controlled environment consistently complies with the requirements of its specification.” (ViP)

The generation, execution and reporting of CGMP compliant Design Qualification, Installation Qualification, Operation(al) Qualification and Performance Qualification protocols remains the core of our company activity.

Our teams of validation specialists, project managers and subject matter experts can be rapidly integrated into projects in a variety of ways to suit our clients’ needs. Each team member is supported by a suite of ViP compliance tools, as well as having full access to our regulatory database and electronic documentation library, to ensure that all of the work performed is of an appropriate regulatory standard.

Computer Systems Validation

“Computer Systems Validation is the provision of documented evidence giving a high degree of confidence that an automated/computer system will consistently perform according to critical functional requirements and system specifications.” (ViP)

There are two primary objectives for computer systems validation. The first is to obtain a high degree of confidence that a system will consistently perform according to critical functional requirements and system specifications. The second is to establish documented evidence of the first objective, in accordance with company policy and all other current applicable Good Practice regulations and guidelines, based on current GAMP (Good Automated Manufacturing Practice) guidance.

Seamlessly integrated into the traditional process validation model, the design and development of complex or customised automated systems are measured for compliance with the System Development Life Cycle approach recommended in the current GAMP Guide to Validation of Automated Systems, whereas more simple systems may be subjected to the System Implementation Life Cycle series of risk assessments in the GAMP Good Practice Guide on Validation of Laboratory Computerized Systems.

Process Validation

“Process Validation is the provision of documented evidence to demonstrate that a registered process consistently produces a product, which meets its predetermined specification and quality characteristics.” (ViP)

Process Validation has traditionally been considered to be the manufacture of three consecutive replicate batches of product and requires qualified systems, validated cleaning and analytical methods, approved working instructions, trained personnel, and controlled documentation.

We recommend the expansion of this definition to encompass the trending of key/critical process parameters over time. This provides support for annual reviews and the associated rationales with respect to minimising the requirement for revalidation, while perfectly integrating with the FDA's Risk-Based Approach and Process Analytical Technology (PAT) initiative.

Although execution of Process Validation is the responsibility of trained company personnel, we can assist in the development of process validation protocols/programmes and the supervision of initial activity.

Cleaning Validation

“Cleaning Validation is the provision of documented evidence to demonstrate that cleaning processes consistently clean to predetermined limits.” (ViP)

The specific requirements of cleaning validation are all too often forgotten, particularly during the detailed design/equipment procurement phases of a project. We appreciate the complexity of this aspect of validation and have in-house experts, who can assist in the development of acceptable residue limits and compliant validation packages and advise on the most appropriate approach to the implementation of an overall cleaning validation programme.

Regulatory Compliance and Validation Training

ViP TRAINING controls our involvement in regulatory compliance and validation training. We are proud to have provided the course tutorship for the Validation Module of The University of Manchester Pharmaceutical Engineering Advanced Training (PEAT) Programme since its inception over ten years ago and also to be contributing to the Dublin Institute of Technology's "MSc Pharmaceutical Validation Technology".

We are committed to the advancement of companies through quality personnel development in current compliance solutions and, over the years, we have developed and delivered validation and compliance training in the form of educational courses, international seminars, academic papers, etc. and provided courses at all levels from the boardroom to the factory floor.

Our compliance training is innovative, targeted, informative and cost-effective. Our high quality training events combine essential information with real-life exercises to ensure all delegates depart better equipped to face their professional responsibilities.

Our on-site courses and seminar events provide an opportunity to access the wide-ranging expertise of our training team at a venue and time to suit our customers. With the support of our regulatory database, we guarantee the information we impart is up-to-date, targeted and scientifically referenced. Delegates are not subjected to any form of sales pitch and we use recognised industry subject-matter experts on all our courses and always attempt to secure a speaker from the appropriate regulatory agency, e.g. MHRA, FDA, etc.

By listening to our customers, understanding their training objectives and the target audience, we present focused learning, which delivers measurable improvements in knowledge, performance and confidence

On-Site Training

If the high costs associated with attending the usual capital city conferences are prohibitive to training budgets, customers can take advantage of our on-site training service and have factual, interactive courses, tailored to their specific requirements, delivered at their premises at a fraction of the cost.

Seminars

For companies with a limited number of delegates, our seminars are an economical alternative to on-site training.

By taking compliance training “on the road” we present our full complement of courses to delegates from different companies in convenient geographical locations, while still providing a cost-effective solution without compromising quality. Additionally, the rich diversity of company cultures and philosophies ensures an environment conducive to the positive exchange of information and ideas.

Standard Operating Procedures (SOPs)

“Standard Operating Procedures (SOPs) are approved documents providing clear directions for performing particular tasks, e.g. equipment operation, cleaning, maintenance, calibration, environmental control, sampling, testing, etc.” (ViP)

We have amassed a wealth of experience in the generation of a huge diversity of SOPs covering every conceivable topic area, from basic engineering to corporate Corrective and Preventative Action (CAPA) systems.

Our expert technical authors are accustomed to being seamlessly teamed with a customer's existing company resource to ensure the timely development of clear, concise procedures in their own established format and style.

PRODUCTS

Since our establishment in 1995, we have invested heavily in the development and maintenance of a unique suite of in-house compliance tools and solutions. Our extensive regulatory database (ViP DATUM) provides our team and clients with instant, searchable access to thousands of regulatory extracts, warning letters and citations, and our automated documentation system (ViP SCRIBE) ensures the rapid generation of high quality, uniform documentation. Combined with an ever increasing range of off-the-shelf audit checklists, guidance documents, policies, qualification texts and SOPs, we can support all compliance needs.

The list below outlines our currently available products:

Product:	Page:
- Regulatory Database (ViP DATUM)	14
- Automated Document Generator (ViP SCRIBE)	14
- Document Templates	15
- CGMP Audit Guides	16
- Compliance Guides	16
- Compliance Booklets	17

Regulatory Database



Regulatory compliance is a promise made by all providers of CGMP and validation services.

Traditionally this promise has only been delivered through the personal knowledge and experience of specific individuals. Compliance has been entirely reliant on limited retention of, and access to, all the current applicable regulatory facts. These limitations, and the inevitable resultant shortcomings, have time and again cost the industry dearly.

In recognition of the difficulties associated with remaining current in all areas of regulatory compliance, we have invested heavily in the development of an extremely extensive and comprehensive searchable regulatory database (ViP DATUM). Since its inception in 1997, this web-based application has provided our team and clients with up-to-the-minute regulatory facts, on which to make informed compliance decisions.

Automated Document Generator



Consistency and quality go hand in glove, and inspectors acknowledge that a consistent documentation package is indicative of the quality of the work it records. Achieving the necessary consistency across a manufacturing site, or even a single facility, represents a significant challenge. Achieving it, while employing outside contractors to generate compliance packages, can be virtually impossible, particularly where timelines are compressed.

In recognition of this, we have developed an automated electronic documentation system. Once entered into our system in the agreed client format, electronic masters of plans, protocols, reports, SOPs, etc., in fact, any standard document types, can be rapidly developed, assuring packages of unsurpassed consistency in unbeatable delivery times.

The benefits of this system include: efficient use of the validation personnel; consistency in the format and presentation of material; traceability of user requirements through the qualification process; effective management of change control process which facilitates maintainability of the validated status through the life cycle.

Document Templates

ViP has successfully developed and implemented complete Site Validation Packages, encompassing the full range of activity from development of Site Validation Policies and associated Good Engineering Practice Policies, through the generation of a hierarchy of Validation Master Plans and subordinate Validation Plans, down to the generation, execution and reporting of individual qualification and validation protocols.

This work has resulted in the compilation of a range of off-the-shelf document templates and supporting SOPs that can be purchased in either paper or electronic form. Alternatively they can be purchased as a complete suite of linked automated templates, enabling the user to generate all validation, qualification and related documents at the touch of a button, each of which is linked to, and updated via, an automated User Requirement Specification. Each document template can be provided with a complete document set, comprising a Standard Operating Procedure (including training section) and examples of all the associated plans, protocols, reviews, record sheets (pre-requisites, checks and tests) and reports, as appropriate.

Each document offers all the necessary alternative text options and specific instructions for every eventuality, e.g. success/failure, deviations resolved/outstanding, etc. The suite of documents currently includes:

Site Validation Policy	- to illustrate and explain a site's approach to validation
Site Validation Master Plan	- to identify all the VMPs and the products covered therein
User Requirement Specifications	- to document the requirements of the user, process, CGMP, etc.
System Impact Assessments	- to categorise each system according to its impact on each product
Compliance Review Protocols	- to verify design compliance with the URS
Traceability Matrices	- to project and confirm delivery of individual requirements in the URS
Facility Validation Master Plans	- for facility-dedicated systems and processes
Site System Validation Master Plans	- for systems serving more than one facility
Facility Validation Plans	- for facility-dedicated systems
Cleaning Validation Plans	- for facility-dedicated cleaning processes

Process Validation Plans	- for facility-dedicated production/packaging processes
Computer System Quality Plans	- for both developed systems and laboratory equipment
Computer System Risk Assessments	- for both developed systems and laboratory equipment
Computer System Specification Reviews	- for review of system design and test specifications
Computer System Validation Protocols	- for both developed systems and laboratory equipment
Equipment Installation Qualification Protocols	- for equipment and utility systems
Room Installation Qualification Protocols	- for rooms accommodating production and packaging processes
Facility Installation Qualification Protocols	- for facilities accommodating production and packaging rooms
Operation(al) Qualification Protocols	- for equipment and utility systems, cleanroom areas and the microbiological and physical environment within cleanroom areas
Performance Qualification Protocols	- for utility systems and the microbiological and physical environment within cleanroom areas
Cleaning Validation Protocols	- for systems used in production and packaging processes
Process Validation Protocols	- for production and packaging processes
Product Status Reports	- to summarise the validation status of an individual product or process

CGMP Audit Guides

One of the most powerful outputs of our compliance database, **ViP DATUM**, is the compilation of customised audit checklists comprising all the latest regulatory authority requirements, guidelines and observations. Where necessary, FDA and EC requirements can be compiled side by side and formatted in either the traditional or “Systems-Based Approach” styles.

Compliance Guides

We have prepared a range of regulatory guidance texts to support day-to-day operations for several major pharmaceutical companies. These compliance guides were originally developed for in-house reference but proved so popular with our clients that we were forced to publish them. What differentiates our guidance documents from the vast array currently available is that they are simply compilations of regulatory fact, with no additional interpretation. Using our extensive regulatory database, we extract all of the EC and FDA regulations, guidance and citations, associated with a specific topic and then combine them under logical subheadings in a single reference text. This provides our team and clients with a solid foundation of fact on which to base Regulatory compliance decisions.

Five ViP Guidance Documents are currently available:

- High Purity Water Systems
- Sterilisation Processes
- HVAC/Environment Validation
- Engineering Documentation Systems
- Cleaning Validation

Each document contains all of the American and EC regulatory points for consideration when either developing validation packages for the above systems and processes used in the manufacture of Finished Pharmaceuticals (Medicinal Products) and Active Pharmaceutical Ingredients (APIs), or for developing engineering documentation systems in support of manufacture.

Note: Additional Guides can be compiled to unique customer requirements.

Compliance Booklets

We have compiled a range of A6 pocket-sized regulatory compliance reference booklets including:

21 CFR Parts 210, 211 and 11 (Drug Products)

The Food and Drug Administration's (FDA) Code of Federal Regulations (CFR), Title 21 - Food and Drugs, Parts 210 - Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals. Parts 210 and 211 lay down the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the preparation, manufacture, processing, packing, or holding of drug products to be administered to humans or animals. Specific areas addressed include; building, facility and equipment design and construction, production and process controls, packaging and labelling control, laboratory controls, and records and report requirements. Part 11 - Electronic Records; Electronic Signatures, pertains to electronic records, electronic signatures and handwritten signatures executed to electronic records. This part also applies to records in electronic form that are created, modified, maintained, archived, retrieved or transmitted, under any records requirements set forth in agency regulations.

21 CFR Parts 600, 610 and 660 (Biological Products)

The FDA 21 CFR Part 600 – Biological Products; General, contains key definitions, establishment standards, establishment inspection requirements and adverse experience reporting requirements. Part 610 – General Biological Production Standards, sets forth tests required prior to releasing lots, general safety provisions, standard preparations and limits of potency, mycoplasma test review, communicable disease agent testing requirements, dating period limitations and labelling standards.

21 CFR Parts 820 and 11 (Medical Devices)

The FDA 21 CFR Part 820 - Quality System Regulation. This section lays down current good manufacturing practice requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labelling, storage, installation, and servicing of all finished devices intended for human use. These requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. Part 11 - Electronic Records; Electronic Signatures, pertains to electronic records, electronic signatures and handwritten signatures executed to electronic records. This part also applies to records in electronic form that are created, modified, maintained, archived, retrieved or transmitted, under any records requirements set forth in agency regulations.

FDA/EMEA Definitions

This booklet contains CGMP compliance related definitions and acronyms collected from a wide range of regulatory sources compiled from FDA Department of Health and European Agency for the Evaluation of Medicinal Products (EMA). For each term identified, the regulatory definition and cross reference to the documents where it originated are provided. The current edition contains definitions for over 600 regulatory terms.

DOWNLOADS

At ViP, we have invested heavily in the development of a comprehensive website, www.vipltd.co.uk, which provides up-to-date information on all of the products and services we offer, as well as details of how Document Templates, SOPs, Compliance Guides, Booklets and Email Reviews may be purchased. In addition, the following items are available via our website:

ViP Wall Charts

Our wall charts provide invaluable reference to anyone employed in the field of compliance. These wall charts can be downloaded (free of charge) as printable PDF or Microsoft Powerpoint files. Alternatively, laminated A3 size colour versions of the charts can be purchased for a nominal fee.

Route to Compliance Flow Chart

This Flow Chart was developed to define the sequence and interrelationships between the various site compliance activities. Primarily designed as an aide memoir in the planning of prospective validation projects, the chart can also be meaningfully applied to retrospective and concurrent compliance activity.

Cleanroom Classification Table

This table was developed as a single reference source for comparison of the different international cleanroom classifications. It identifies all the individual classifications assigned by international standard EN ISO 14644-1 alongside the European Guide to Good Manufacturing Practice and the superseded Federal Standards 209D and E, and British Standard BS 5295.

Updates by Email

We continually strive to heighten industry awareness of regulatory requirements and, to this end, have developed a list server, organised by geographic region, which we use to email updates on recent regulatory developments and trends in the healthcare industry to our existing and potential future clients, in fact anybody who requests to be registered.

Useful Links

Our index of useful compliance site links is continuously evolving. The links provided include organisations, associations and agencies within the UK, Europe and throughout the rest of the world.

OUR TEAM

Organogram

Figure 1 depicts the organisational structure of ViP.

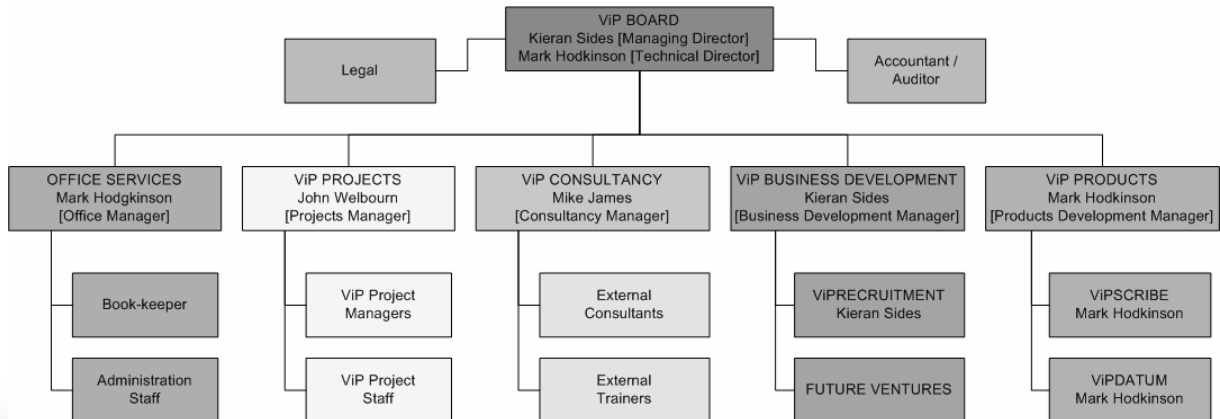


Figure 1 - Organisational structure of ViP

Staff

Our pragmatic approach to compliance is implemented by our highly motivated, knowledgeable, and extensively trained team of highly experienced Validation Specialists, Project Managers and Consultant, who are supported by a small group of office management and administration personnel. Team members are allocated to projects according to their experience, qualifications and the individual project requirements. We ensure that the right expertise is available at the appropriate point in the project.

Our validation staff have been specifically recruited to ensure that we can tackle any project regardless of content or size. With specialists in the qualification and validation of facilities, utilities, equipment and computer systems, as well as cleaning and manufacturing processes, no task is too onerous.

Our Managing Director, Kieran Sides has overall responsibility for the efficient running of the company.

The day to day running of the office and the provision of general office services, including Accounts, Payroll and IT support, comes under the responsibility of our Office Manager, Mark Hodgkinson.

The efficient delivery of validation projects is undertaken by our validation team made up of Validation Project Managers, Senior Validation Specialists, Validation Specialists and Technicians, and this area of the business comes under the responsibility of our Validation Projects Manager, John Welbourn. Currently ViP staff provide the nucleus for a number of site-based projects and their numbers are bolstered as and when required by contract personnel employed via our own agency, [ViP RECRUITMENT](#) (see below).

The training and technical consultancy arm of the business is operated through a select group of highly experience Validation Technical Consultants, either working as permanent staff, or, through partnering arrangements, this area of the business comes under the responsibility of our Training and Consultancy Group Manager, Mike James.

Product Development, including web based services is undertaken by our small in-house software development team. Additional software development resource is then bought in through several independent IT/Web design companies on an as-required basis. This area of the business comes under the responsibility of our Technical Director, Mark Hodgkinson.

Contract Personnel



Over recent years, the uncertainty inherent in an industry rife with take-overs and mergers, and the inevitable knock-on effect on the confidence of project budgets has contributed to more and more companies having to rely on contract personnel. We appreciate it is unrealistic to maintain too high a level of permanent staff, but to ensure we have ready access to an appropriate number of tried and tested individuals, we decided to establish our own dedicated regulatory compliance and validation staff agency, **ViP RECRUITMENT**. We started 2006 with some 40 contract personnel registered and have constantly been adding to this pool, relying on them not only to support our own compliance projects but also to provide temporary assistance to customers lacking their particular skills or requiring additional bodies.

Most of the personnel registered with us have worked closely with ViP for several years and are well known to us. On registering, they complete an induction process, during which their technical skills, and process and equipment knowledge are carefully assessed. We believe by these processes we can provide our clients with an assured resource pool backed up by unprecedented information about the strengths of each candidate.

ViP RECRUITMENT is the only agency that can provide thoroughly vetted validation and compliance contractors with the regulatory perspective at their fingertips. What makes it different to other agencies is:

- Since our establishment in 1995, we have enjoyed an enviable reputation for delivering successful validation and GxP compliance projects, satisfying EMEA and FDA regulators alike. We understand exactly what it is customers are trying to achieve and can provide them with scrupulously researched individuals, skilled in all necessary areas of validation and regulatory compliance, to help them realise their goals.
- The combined experience of our in-house staff and agency personnel, together with an extensive network of associates and contacts, ensures that no validation contractor is beyond meaningful scrutiny. Customers will never be presented with substandard personnel.
- We operate a policy of zero tolerance with respect to fraudsters, and any contractor submitting a CV we find to be deliberately misleading or misrepresentative is permanently blacklisted.
- For all personnel registered with **ViP RECRUITMENT**, we have profiles of their process and equipment knowledge, technology skills, and personality, all of which afford our clients unprecedented information relating to their individual strengths.

- Every contractor we promote has unlimited internet access to **ViP DATUM**, the most extensive and comprehensive searchable regulatory database available. All the time customers have one of our contractors on site, they too can tap into this unparalleled and indispensable resource. To assess the capabilities of **ViP DATUM**, we can set potential customers up with temporary access to the web site.
- An automatic link to our in-house project staff knowledge-base distinguishes our contract personnel from those more used to operating in an environment of isolation, and gives our clients the flexibility of agency staff with the security of a dedicated regulatory compliance partner.

and last, but by no means least ...

- Whenever customers contact us, they can rest assured that we fully understand their requirements; we are speaking the same language. Most agencies have a smattering of the acronyms and terminology, but no idea of what qualification, validation or GxP compliance actually mean in practice, and no way to stay abreast of regulatory changes. We have to, because it's what we do for a living. We can even provide advice to clients, who are not quite sure of the disciplines they need to achieve a particular compliance or validation objective.

CUSTOMERS

Client Portfolio

Our list of clients to date includes:

Amgen, Cork, Eire	Ivax Ltd., Runcorn
Angel Biotechnology, Cramlington,	Johnson & Johnson, Bracknell
Ashton Pharmaceuticals, Ashton u Lyne	Lonza Biologics Ltd., Slough
AstraZeneca, various sites	Lorien Engineering Solutions, Lichfield
Baxter Healthcare, Thetford	Macfarlan Smith, Edinburgh
Boehringer Ingelheim, Bracknell	Management Forum, London
BV2 bvba, Waver, Belgium	Manesty, Speke
CAMR, Porton Down	Microbial Developments Ltd., Malvern
Cardinal Health, Bolton	Micron Technologies, Dartford
CCL Pharmaceuticals, Runcorn	Norgine, Mid Glamorgan
Chemunex, Paris	Novartis, Horsham
Chiron Vaccines, Speke	Novartis, Speke
Cobra Biopharmaceuticals, Keele	Organon NV, Netherlands
Coopervision, Southampton	Partnership for Learning, Speke
Covance, Harrogate	Penn Pharmaceuticals Ltd., Tredegar
CP Pharmaceuticals Ltd., Wrexham	Pfizer, Dublin, Eire
Croda, Leek and Goole	Pfizer, Sandwich
Decorpart Ltd., Nelson	Presspart Manufacturing, Blackburn
Diosynth, Buckhaven	Puretech Process Systems Ltd., Redhill
ECEC, Liverpool	Roche Products Ltd., Welwyn Garden City
Elan, West Meath, Eire	Sanofi-Aventis, Dagenham
Eli Lilly, Kinsale	Schering Plough, Belgium
Eli Lilly, Liverpool	Serologicals, Livingston
Excell Biotech, Livingston	Smith & Nephew Ltd., Hull
GEI Collette, Belgium	SmithKline Beecham Ltd., Slough
Genzyme, Suffolk	SSL International plc, Cambridge
Genzyme. Waterford, Eire	Thermal Transfer Ltd., Glossop
Gilead, Dublin, Eire	Thornton Precision Engineers, Sheffield
GlaxoSmithKline, Barnard Castle	UMIST/University of Manchester
GlaxoSmithKline, Ulverston	Unidrug Distribution, Derbyshire
G-Pharm, Kent	Ventura Group, Chippenham
Honeywell Iropharm plc, Arklow, Eire	Vericore Ltd., Dundee
Hosokawa Micron Ltd., Runcorn	Wockhardt UK, Wrexham
Hyclone, Cramlington	Wyeth Pharmaceuticals, Havant
Ipsen Biopharm Ltd., Wrexham	Wyeth, Istanbul, Turkey
Isolagen Europe Ltd., London	

Customer References

ViP boasts an extensive customer portfolio and the true test of our abilities is reflected in the fact that repeat business forms 70% of our work. Our clients appreciate the fact that we listen and ensure their requirements are fully addressed. This focused approach, coupled with our experience and commitment to provide high quality services ensures that they need look no further for a compliance partner. Don't just take our word for it, here's what some of our customers have said about our project approach and our team:

"Validation in Partnership (ViP) have worked alongside Wyeth Pharmaceuticals in the UK to develop a robust but flexible validation process. All members of the ViP team involved with this substantial project have shown a high level of technical knowledge regarding the subject of validation. In addition the ViP team is able to effectively apply that technical knowledge within a tightly regulated environment, which leads to the development of validation packages that support the scrutiny of compliance inspections."

Brian R. Collins
Validation Manager
Wyeth Pharmaceuticals, Havant

"If you need excellent service, help or up to the minute advice on your validation needs - look no further, make ViP your first call! If a major Pharmaceutical likes the approach and content of the ViP validation package - why look any further? I found the ViP approach through the validation process to be highly professional, knowledgeable and user friendly."

Bert Calvert
Technical Support Manager
Presspart Manufacturing Limited, Blackburn

"I thought the course was well presented, backed up by a good mixture of validation 'real-life' experiences.....Detailed course notes are always a real bonus..... For a very dry subject this course was very good.....There was also a sprinkling of light hearted banter that helped gel the course."

Various Delegate Comments
SmithKline Beecham, Weybridge Site

"Validation in Partnership has been supporting AstraZeneca R&D Charnwood, (based in Loughborough) for the past 18 months in the generation of regulatory guidance documents on a range of topics. I have found these database reports invaluable in the development of qualification protocols and the execution of validation reviews. ViP has provided AstraZeneca R&D Charnwood with thorough information and a cost effective service that has been tailored according to our requests. Their proactive approach has helped us climb the inevitable learning curve when employing new members of our validation team."

Ian Johnson
PAR&D Business Support Manger
AstraZeneca R&D Charnwood

“The project scope covered the installation, commissioning and qualification of a 2000l purified water generation, storage and distribution system with O3 sanitisation. The system serving the Quality Assurance Building (QAB) at AstraZeneca’s Macclesfield Site. The qualification work was conducted by Validation In Partnership (ViP). Our previous experience of working with ViP promised an excellent working relationship, with them being prepared to make any extra effort required to support the project. ViP’s scope of work was to prepare and execute the IQ and OQ programmes for the purified water system, and to prepare a validation programme to cover the first year’s beneficial operation. The IQ/OQ and Validation programmes provided by ViP illustrated a comprehensive understanding of what was required in order to achieve regulatory compliance. Any reservations expressed by the project team were dealt with swiftly, and following consultation with the team by ViP to ensure that the detail of the reservations were clearly understood. Before execution of the IQ and OQ programmes, ViP’s representatives regularly attended the project team meetings for the purified water system. Possibly due to our vendor’s unfortunate internal difficulties during the project, the provision of supporting documentation by them was giving the team some cause for concern. Whilst sympathetic to the vendor’s position, ViP’s representatives were particularly tenacious in pursuing only completely acceptable standards of supporting documentation. This was achieved by them working closely with the vendor to ensure that their attention was suitably focussed. Initial experimental sampling of the systems highlighted a small number of non-compliances in terms of water quality. Here, the ViP representatives’ practical experience ensured that the issues were resolved by applying or recommending the most expedient, robust and practical solutions. The operation qualification phase of the project passed with little difficulty and the supporting reports were issued in good time by ViP to enable the earliest beneficial operation of the system. As stated earlier, previous experience of working with ViP had promised an excellent working relationship. Their tenacity, technical understanding and wealth of practical knowledge, plus working closely with their client, ensured that the service provided by them on the QAB project was first class and their services would be recommended for the future.”

Peter Sayer
Validation/Project Support Engineer
AstraZeneca, Macclesfield

“Validation in Partnership (ViP) has recently provided two Validation Specialists to support Ivax Pharmaceuticals UK in the qualification of a new manufacturing facility in Runcorn, Cheshire. Our previous experience of working with ViP promised a professional and flexible approach, with the ViP team being prepared to make any effort required to ensure project deadlines were met. During this project I have found ViP to be an excellent service provider whom I would utilise again. Ivax is happy to acknowledge that ViP made a valuable contribution to this project and would recommend their services to other companies.”

Matthew West
Head of Process Engineering
Ivax Pharmaceuticals UK Limited, Runcorn

“Just like to say that we all thought the above course was excellent. It was jam packed with useful information and presented in a simple and relaxed manner. We particularly enjoyed the case study and would recommend it for anyone starting out on the validation path.”

(Validation Basics Training Course)
Jan Clifford
Lonza Biologics, Slough

“Validation in Partnership have been involved with the Programme (Pharmaceutical Advanced Engineering Training, PEAT) since its inception in 1994. Their contribution to the teaching of module 12 is highly valued: their preparation for student workshops is totally professional and meticulous. ViP’s leading edge involvement with validation ensures that the teaching material contained within the module 12 is kept up to date.”

Dr. Rodger Edwards
Senior Lecturer in Civil and Construction Engineering
Director of the PEAT Programme
UMIST

“Diosynth Limited, a sub business unit of Diosynth bv, Netherlands have used Validation in Partnership on several occasionsto further the business’s knowledge on the important areas of Quality Assurance and Validation. We have found their team very responsive, knowledgeable and competitive in their approach to our requests. Their team has extensive and direct experience within the pharmaceutical industry and have made rapid and tangible benefits to our business performance.”

Alec Ingram
Managing Director
Diosynth Limited, Fife

“Very useful especially with respect to validation and swabbing methods, considerations etc. Contents of the course were very valuable and a lot of very useful information was given.”

(Cleaning Validation Workshop)
Medimmune Delegate

“For several years we have struggled with the validation process using contract staff – our bitter experience shows that they are generally engineers and lack the essential mindset of someone from a compliance background in manufacturing. We have turned that situation round by engaging ViP in an Alliance Partnership – the projects have sparkled since that decision, and the reasons are very clear to us;

- *They have a Regulatory Database that is second to none*
- *They have Automated Protocol generation and Guidance Documents*
- *They have Compliance Specialists from a manufacturing culture who speak our language*

We have worked together on a variety of jobs and find that their process focus complements our project focus thus affording a functional independence – our clients clearly agree with us as they use ViP independently on work that is adjacent to our own.”

Bill Miles
Pharmaceutical Sector Manager
Lorien Engineering Solutions Ltd

GLOSSARY OF TERMS

The following terms are used within the text of this document:

<i>Term:</i>	<i>Meaning:</i>
API	Active Pharmaceutical Ingredient
BS	British Standard
CAPA	Corrective and Preventative Action
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
Doc.	Document
DQ	Design Qualification
EC	European Commission
e.g.	(exempli gratia) for example
EMA	European Agency for the Evaluation of Medicinal Products
EN	European Norm
FDA	Food and Drug Administration
GAMP	Good Automated Manufacturing Practice
GEP	Good Engineering Practice
HVAC	Heating Ventilation Air Conditioning
ISO	International Standards Organisation
ISPE	International Society for Pharmaceutical Engineering
IQ	Installation Qualification
Ltd.	Limited
No.	Number
OQ	Operation(al) Qualification
PAT	Process Analytical Technology
PEAT	Pharmaceutical Engineering Advanced Training
PDF	Portable Document Format
PQ	Performance Qualification
Ref.	Reference
Rev.	Revision
SIA	System Impact Assessment
SOP	Standard Operating Procedure
UK	United Kingdom
URS	User Requirement Specification
ViP	Validation in Partnership
VMP	Validation Master Plan
VP	Validation Plans