

Technical consulting, from route to release

Process R&D, analytical, quality and manufacturing expertise for pharma manufacturers, backed by 28 years inside the pharma supply chain.

Our clients often need technical help that sits one step beyond sourcing: developing a process, building a method that will withstand regulatory scrutiny, running a laboratory that passes audits, or scaling a product into the plant. VSP Pharma Services brings experienced specialists to each of these, managed by a team you already know. We work as advisers: we design the studies and review the data, and your team or a laboratory of your choice carries them out.

OUR SERVICES



Process R&D

Clear route and process recommendations for APIs, key starting materials and advanced intermediates.

WORKS TO

ICH Q8, Q9, Q11, Q3A/B/C/D, M7

- Route scouting and patent review, ending in a ranked route recommendation
- Proposed study designs, including DoE plans, for your team or a CRO to execute
- Paper-based impurity-risk assessment, including mutagenic-impurity and nitrosamine evaluation, with control strategy
- Solid-form and particle-size strategy: what to screen, why, and with which partners
- Review of your development data; process-description outline for DMF or dossier filing
- Cost-of-goods reduction and scale-up risk assessment



Analytical Method Development

A sound analytical strategy, with validation and transfer plans ready for your laboratory to execute.

WORKS TO

ICH Q2(R2), Q14, Q6A; IP, USP, Ph. Eur.

- Analytical target profile and method-selection recommendation for each material
- Validation protocol design with acceptance criteria and rationale
- Review of validation reports; method transfer protocol and acceptance criteria
- Impurity-control strategy for residual solvents, elemental and genotoxic impurities
- Specification setting and justification
- Reference and impurity standard strategy



Quality Control

A QC function whose procedures and data practices stand up to inspection.

WORKS TO

21 CFR 210/211, EU GMP Ch. 6 and Annex 11, GAMP 5, WHO TRS

- Review of QC organisation, workflow and responsibilities
- Data integrity gap assessment of procedures, records and systems (ALCOA+, 21 CFR Part 11)
- OOS and OOT investigation procedure, review of closed cases, and coaching
- Training curriculum and competency framework for analysts
- Reference standard, reagent and sample management procedures
- Laboratory SOP and record redesign

OUR SERVICES, CONTINUED



Quality Assurance

A quality system that is compliant on paper and in practice, with audit readiness built in.

WORKS TO

ICH Q7, Q9, Q10; 21 CFR 210/211, EU GMP, Schedule M

- GMP gap assessment and mock inspection (FDA, EU, WHO, Schedule M)
- QMS build or remediation: change control, deviation, CAPA, complaints, APR
- Supplier and vendor qualification, audit programmes, remote audits
- DMF and dossier quality sections; responses to inspection observations
- Internal auditor training and quality-culture programmes



Manufacturing and Production Support

Well-planned transfer from development to plant, with fewer deviations and better yield.

WORKS TO

ICH Q8, Q10, Q11; EU GMP Annex 15; FDA process validation guidance

- Technology transfer packages and site-readiness assessments
- Scale-up strategy and equipment-fit assessment
- Process validation strategy and protocol design; cleaning validation approach
- Yield and cost improvement recommendations from batch record and deviation review
- Continuous process verification plan: what to monitor and how to act

WHO WE WORK WITH

API and intermediate manufacturers

Formulation companies

Biotech and virtual pharma

Contract manufacturers

Testing laboratories

Overseas buyers qualifying Indian suppliers

HOW WE ENGAGE

1. Diagnostic

A short, fixed-scope assessment, such as a GMP gap review or route-feasibility study, with a written report and recommendations.

2. Project

Defined deliverables and timeline: a validation protocol package, a process recommendation report, a transfer plan.

3. Ongoing support

Retainer or embedded experts for audit programmes, remediation, commissioning and plant start-up.

- Specialists matched to your problem, with one accountable point of contact.
- Technical work joined to supplier identification, qualification and second-source development.
- Documentation built to ICH, GMP and pharmacopoeial expectations.
- Confidential, independent advice with clear scope and ownership of your data and IP.