VISSHWA
solutions

A TRUSTED
CRO PARTNER

www.visshwasolutions.com

About Visshwa Solutions

Visshwa Solutions is a trusted Contract Research Organization (CRO) specializing in clinical trials, regulatory compliance, and medical research. Founded by an entrepreneur with 10+ years of experience, we partner with pharmaceutical, biotech, and healthcare companies to bring safe, effective treatments to market. With a strong presence in India and an expanding international network, our professionals support every phase of clinical trials with speed, accuracy, and integrity.

We offer cost-effective solutions by leveraging deep industry knowledge and collaborating closely with clients to optimize processes and deliver tailored solutions. Our commitment to ethical standards and regulatory compliance ensures successful outcomes and lasting value.

Our Quality Management system ensures operations align with internal SOPs and regulatory requirements. The Quality Assurance Department, reporting directly to management, implements internal quality control to maintain excellence and compliance throughout all trial phases.

Meet The Visionary

Mrs. Dhanshri Amit Patil

Founder & Director

Visshwa Solutions is the sister concern of Visshwa Research and Healthcare Pvt. Ltd., founded in 2015 by Dhanshri Patil. The company is guided by her strong academic foundation and extensive industry experience. Dhanshri holds a degree in Biotechnology, a postgraduate qualification in Clinical Research, and an MBA from the University of Glamorgan, UK. Backed by a rich professional journey spanning over a 10+ years of period, she has continuously refined the company's operations to stay aligned with evolving market needs and industry dynamics.

Our Vision

A trusted Contract Research Organization (CRO), Visshwa Solutions specializes in clinical trials, regulatory compliance, and medical research. Collaborating with pharmaceutical, biotech, and healthcare companies, we help bring safe and effective treatments to market.

With a strong focus on quality, ethics, and innovation, we ensure seamless clinical trial execution, smooth regulatory approvals, and top-tier industry training. Partner with us to advance healthcare together.

Our Mission

Driven by a mission to uphold the highest ethical standards, Visshwa Solutions CRO is dedicated to delivering quality-driven services with unwavering regulatory compliance.

We aim to build trust and transparency in every engagement, creating lasting value for clients, stakeholders, and employees alike. This commitment reinforces our pursuit of excellence in the ever-evolving healthcare research landscape.

Our Values

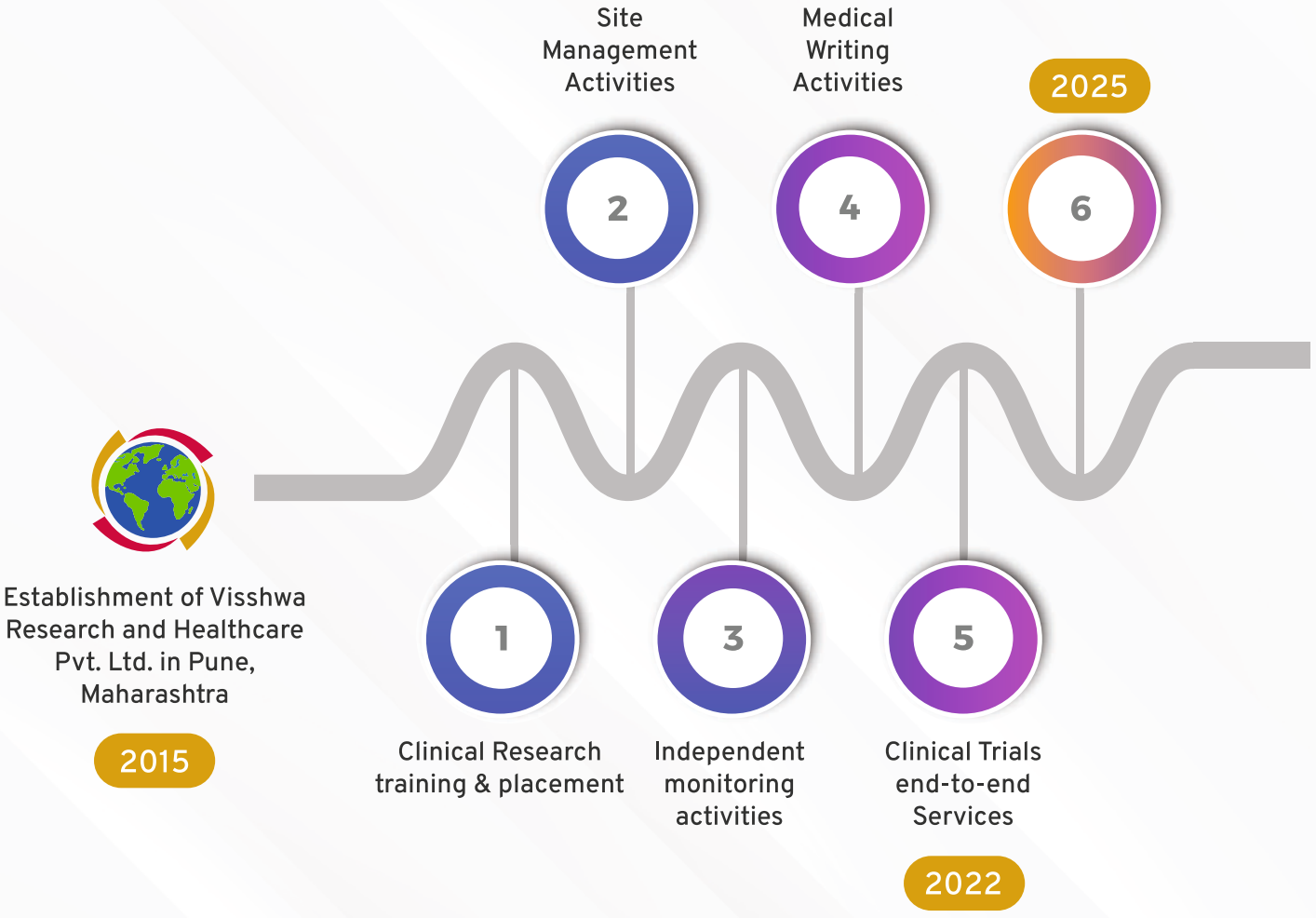
Our core values guide everything we do at Visshwa Solutions. We uphold **honesty and transparency** in all our interactions, maintain the highest standards of **ethics**, and foster **leadership** at every level of our organization. Our commitment to **excellence** drives us to consistently deliver quality outcomes and build lasting trust with our clients and partners. These values are the foundation of our culture and the key to our continued success in the healthcare research industry.

Our Strengths

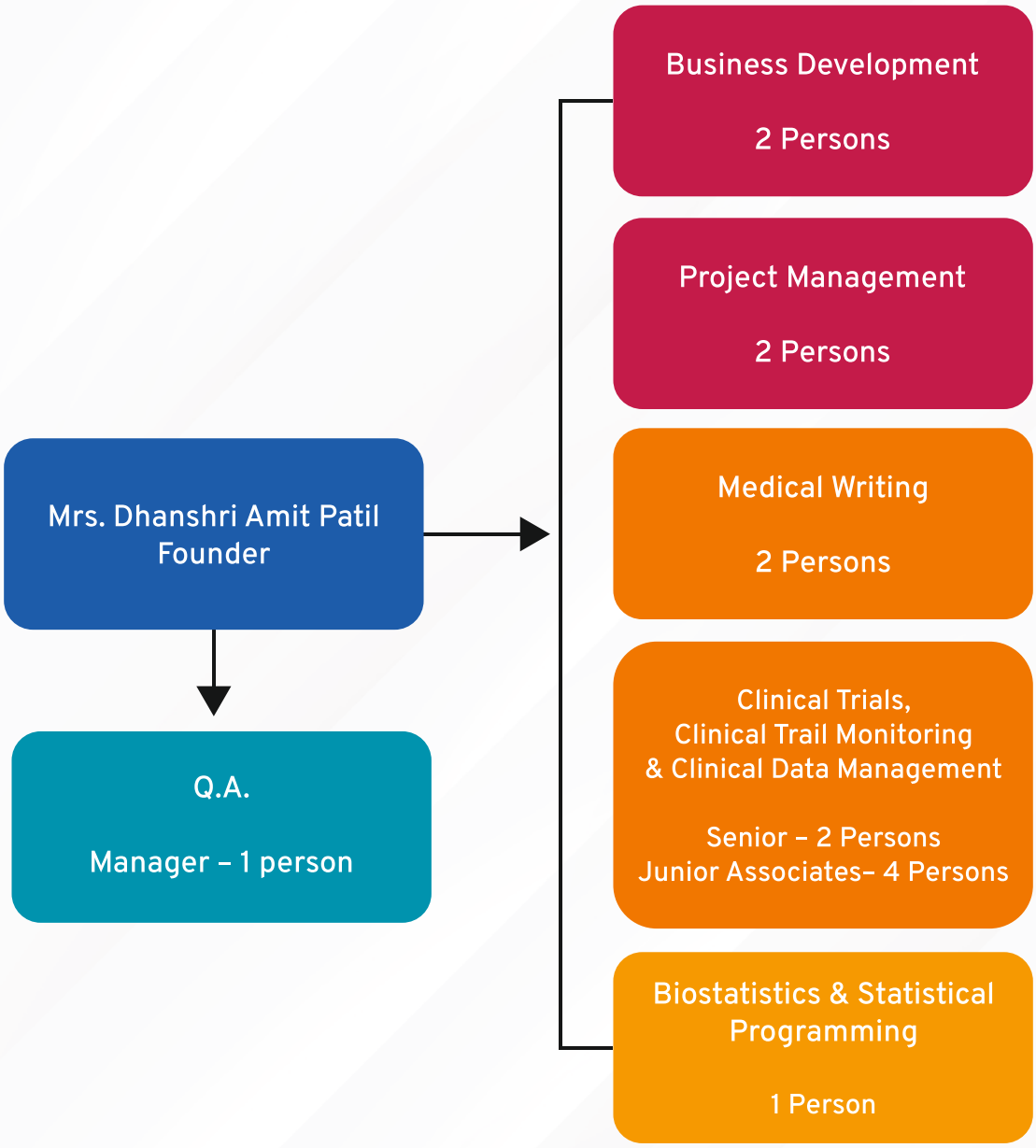
We focus on understanding client expectations and emerging needs to deliver tailored, cost-effective solutions without compromising on quality. With a team of experienced professionals and a strong network of investigators across India and internationally, we support all phases of clinical trials across therapeutic areas. Our wide patient base ensures robust recruitment and retention, driving successful trial outcomes.

Our Path

Visshwa Solutions is the sister concern of Visshwa Research and Healthcare Pvt. Ltd., which was established in 2015. Initially focused on clinical research training and placement, the company steadily expanded its services to include site management, independent monitoring, and medical writing activities. With a strong foundation in clinical operations, Visshwa advanced to offering end-to-end clinical trial services by 2022. Continuing its growth trajectory, the company is set to provide comprehensive pharmacovigilance services by 2025, reinforcing its commitment to delivering complete and compliant solutions across the clinical research spectrum.



Our Team


Business Development
2 Persons
Project Management
2 Persons
Medical Writing
2 Persons
Clinical Trials,
Clinical Trail Monitoring
& Clinical Data Management
Senior – 2 Persons
Junior Associates– 4 Persons
Biostatistics & Statistical Programming
1 Person
Mrs. Dhanshri Amit Patil
Founder
Q.A.
Manager – 1 person

Our Services

A professional with expertise in the pharmaceutical and clinical research fields, offering comprehensive support for clinical trials, medical writing, intellectual property management, and medical affairs. Skilled in clinical data management, patient recruitment and retention, and educational training programs. Dedicated to providing end-to-end solutions for drug development and clinical research activities.

- Clinical Trials End-to-End Services
- Clinical Data Management
- Medical Writing
- Vendor Management
- Recruitment & Retention
- Regulatory Affairs
- Educational Training

Why Visshwa Solutions

We are committed to ensuring on-time project delivery by providing a comprehensive solution for all clinical trial requirements. Our approach guarantees accurate, comprehensive, and reliable data at every stage, ensuring scientifically sound and trustworthy results. We prioritize cost-effectiveness without compromising quality, balancing efficiency and excellence. With a single point of contact, we simplify communication and streamline project management for our clients, offering a transparent and seamless experience. Our client-focused approach ensures tailored solutions, customizing project designs to meet specific client needs, whether by adjusting timelines, methodologies, or addressing unique challenges, ultimately ensuring the smooth progression and success of every clinical trial.

Clinical Trial Operations

Pharmaceutical organizations are continually seeking cost optimization strategies by leveraging efficient people, processes, and technology to overcome operational challenges, thereby reducing the time and cost of drug development. At Visshwa Solutions, our professionals apply their expertise in therapeutics, regulatory compliance, operations, and technology to consistently address the challenges faced by biotechnology and medical device companies.

Clinical Trial Services

Our Clinical Trial Services offer end-to-end support, including protocol writing, regulatory liaising, site feasibility, selection, and staff training. We manage site monitoring, closeout visits, and ensure seamless coordination throughout the process. Additionally, we provide project and data management, sponsor query support, and efficient regulatory inspection coordination, ensuring a smooth and compliant trial experience.

01 Protocol Writing

02 Regulatory Liaising

03 EC dossier Preparation

04 Site Feasibility

05 Site Selection/Collection of essential document

06 Site initiation/Training of site staff

07 Site Monitoring Visits

08 Site closeout Visits

09 Coordination of site Activities

10 Project Management

11 Data Management

12 Supporting Sponsor Queries

13 Regulatory Inspection co-ordination

Project Management

We apply classic project management principles to effectively meet timelines and project milestones by optimizing lines of communication.

As your single point of contact, the project manager will lead your study in:

- Timeline development and management
- Protocol and informed consent form (icf) development
- Study plan development
- Patient reported outcome diary development
- Site selection and vendor management
- Recruitment strategies for targeted populations
- Risk mitigation: includes identification, analysis, response, and quality control
- Study team, clinical research associates and clinical sites communication
- Monitor and site performance management

Therapeutic Areas

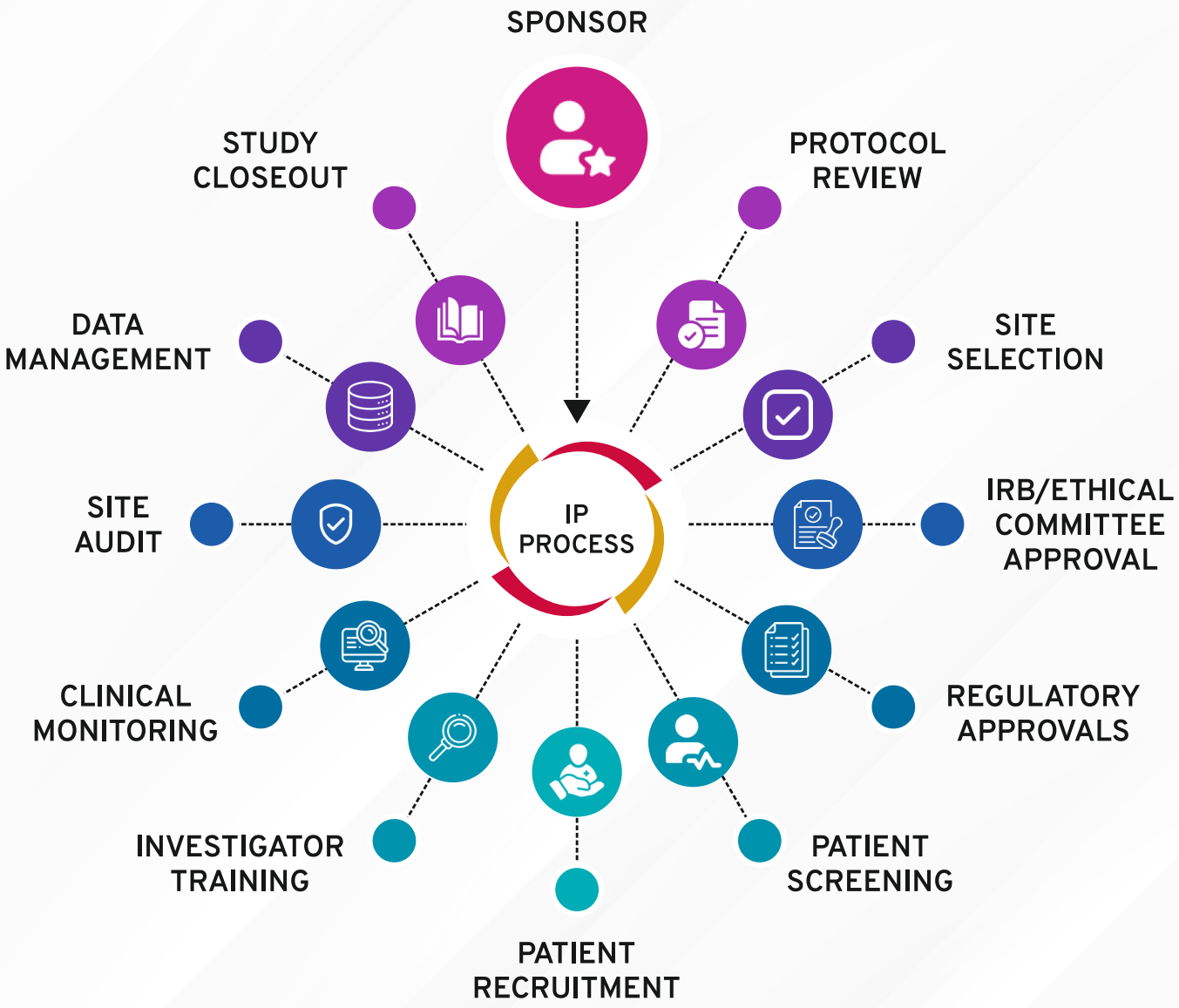
Top therapy areas include Cardiology, Neurology, Dermatology, Oncology, Endocrinology & Metabolism, and Ophthalmology. Other important fields are Pediatrics, Nutraceuticals, Gastroenterology, Respiratory Medicine, Vaccines, Immunology, Pharmacovigilance, and Nephrology. These areas represent a wide range of medical disciplines focused on the study, diagnosis, and understanding of human health conditions.

Clinical Trial QAE

Delivering comprehensive End-to-End Solutions, Visshwa Solutions supports every stage of clinical research with precision and expertise. Our services include Project Management, Medical Writing, Data Management, Biostatistics, Clinical Trial Monitoring, Risk-Based Quality Management, and Functional Support Provider support. Through seamless integration of these services, we maintain the highest standards of quality, regulatory compliance, and operational efficiency, helping clients achieve faster and more reliable clinical trial outcomes in a competitive global environment.

Work Flow Process

A seamless IP Process is critical to successful clinical trials, connecting key stages from Sponsor engagement, Protocol Review, Site Selection, and IRB/Ethical Committee Approval to Regulatory Approvals and Patient Screening. The process ensures smooth transitions through Patient Recruitment, Investigator Training, Clinical Monitoring, Site Audits, Data Management, and finally Study Closeout. Each step is carefully managed to maintain compliance, ensure patient safety, and deliver high-quality, reliable outcomes for every clinical study.

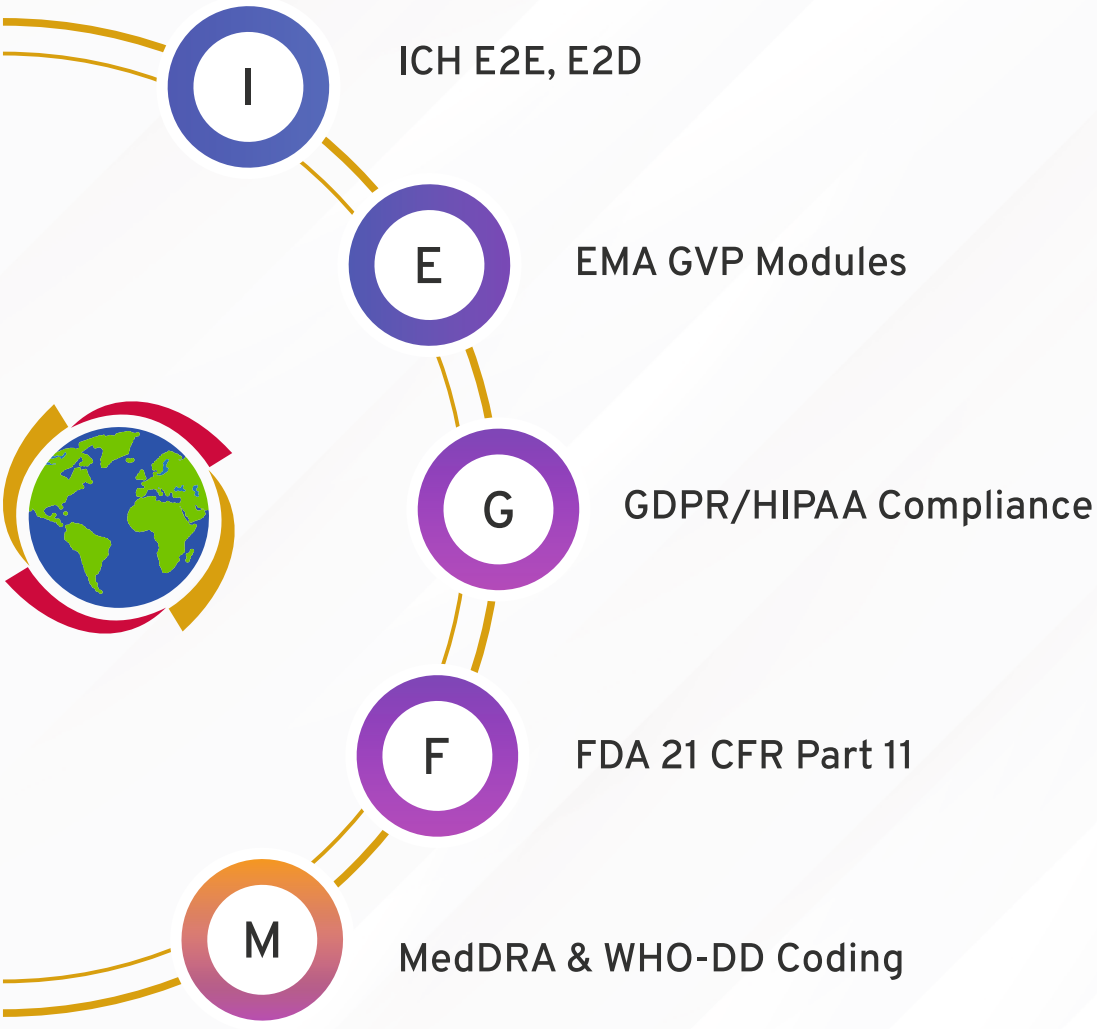


Pharmacovigilance Services

Visshwa Solutions provides end-to-end pharmacovigilance services to ensure drug safety and regulatory compliance. Our offerings include ICSR processing, medical review, narrative and aggregate report writing (PSUR, DSUR, PADER), literature surveillance, and signal detection. We also support PV system setup, audits and CAPA, training programs, and safety data exchange agreements. With in-house QPPV services and LRP/LPPV coverage across the EU, UK, and global regions, we deliver reliable and compliant PV solutions.

- ICSR Processing (Spontaneous, Literature, Solicited)
- Narrative Writing
- Medical Review
- Aggregate Reports (PSUR, DSUR, PADER)
- Literature Surveillance
- Regulatory Submission Support
- Signal Detection & Risk Management (RMP / REMS)
- PV System Setup & SOPs
- PV Audits & CAPA
- PV Training Programs
- Safety Data Exchange Agreement (SDEA)
- In-house QPPV EU and UK Region
- LRPs / LPPV EU, UK and Global Region

Compliance & Regulatory Standards



Our Service Models

Task Based Model

Tailored regulatory affairs and pharmacovigilance services based on clients' requirements

Headcount Based Model

Dedicated remote regulatory and pharmacovigilance professionals for your team.

Benefits

Expertise on Demand:-
Access specialized knowledge as needed without long-term commitment.

Time-Saving:-
Leverage our experience to navigate regulatory processes quickly.

Flexibility:-
Choose services that match your current project requirements.

Headcount Based Model

Dedicated Personnel:-
Full-time specialists working exclusively on your projects.

Scalability:-
Easily adjust the team size based on project needs without recruitment hassles.

Integration:-
Specialists work as part of your team, aligning with your company culture and processes.

Our Global Clientele

Clients Across US, UK, Canada, Australia, GCC RoW.

Serving Pharma, Biotech, and Medical Device Companies.

Strong Communication and Project Delivery Across Time Zones.

HAPPY ENDING :)

VISSHWA solutions

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