



Attitude to WIN with Sapience







The expansion of the pharma industry especially in the last two decades though has spearheaded progress of a healthy society but also brings with it the complex challenges of PV system. As we move forward in the era of evidence-based medicine, global regulatory challenges and nuances of therapeutics need to be overcome. Compelled by the need to balance robust PV systems with quality and cost effectiveness, MAHs are at crossroads. In this scenario outsourcing PV services has gained popularity, and this is attributed to the reduction in the upfront investment, resource flexibilities and ability to tailor services in accordance with complex regulatory requirements.

We at AWINSA Life Sciences have a good network of PV consultants worldwide with vast experience and cutting-edge capabilities who can help to consolidate and fortify your PV systems.

Also, our myriad of PV services can be tailored to suit your requirements thus offering you a customer friendly approach.

We are committed to an unrelenting pursuit of our goals: To deliver unparalleled PV solutions of the highest order.

Our Mission

Backed by a team of industrious individuals, we aim to provide the highest quality of services to our clients. Filled by passion and an indefatigable attitude, AWINSA envisions unparalleled solutions to all your requirements thus ensuring safe and efficacious use of the drugs for the society.

Our Values

- Passion and enthusiasm for our work provides us the necessary motivation to move on with grit
- Perseverance and commitment to excellence because productivity is never an accident
- Aiming for the highest **quality** in work outputs
- Integrity, honesty and transparent working style
- **Teamwork**: Individual efforts directed towards organizational goals in unison always ensures success

Pillars of AWINSA Life Sciences

Perseverance
 Quality
 Excellence
 Integrity
 Services

Case processing

Robust team to formulate the ICSR with utmost attention to all nuances and also ensure submission within the stipulated timeframes

Aggregate reports

Prepare complex aggregate reports compliant with exacting regulations. Precise well-articulated responses to regulator queries

Signal Management

Intellectually competent team who are adept at doing a critical analysis of the adverse event scenarios for correct identification of signal

RMP

Right set of tools, procedures and knowledge for requisite spatial framework and detailed modus operandi of risk management plan

SOPs

Help develop all PV related SOPs in accordance with the global regulatory requirements which will ensure efficiency, quality output and uniformity of performance at your facility.

Audit and inspection readiness

Conduct comprehensive walkthroughs of your facility by internal audit and pinpoint on troublespots which can have a momentous role in enhancing your operational efficiency and braces you for external inspections

Training

Well structured training programs to upskill your workforce

QPPV

QPPV to ensure that you not only have the services of the highest quality but they are incredibly cost effective

Medical Monitoring

Our Medical Monitors come from diverse therapeutic backgrounds and have the clinical and research expertise required to provide rigorous oversight of clinical trials from design through delivery

Medical Writing

Team of experts who besides having excellent writing skills can comprehend the technical jargon and tailor it to suit the requirements of the requisite document

Medical information

The team is well equipped with experienced Health care professionals who ensures very high-quality services and provide accurate and medically sound responses thereby complying to all regulatory requirements

Regulatory

Our intellectually competent team can provide strategic and operational guidance on all regulatory operations during product development process



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