APCER
LIFE SCIENCES
Together for better health

BROCHURE

Together for Minimizing Risk

Pharmacovigilance Services

The successful development of any therapeutic product depends on numerous factors including the safety and efficacy profile, quality of clinical data, appropriate regulatory strategies, and timely regulatory submissions. Drug development is a long, complex process, which can span 10 to 15 years from the discovery stage through successful completion of all stages of clinical development to authorization. With the key objective of patient safety, the regulators are working to evolve in order to address increasing complexities of product types. As a result, the regulatory requirements are complex and dynamic, adding to the complexity of global end-to-end Pharmacovigilance systems. Biopharmaceutical companies are expected to adopt a proactive pharmacovigilance strategy as they seek market approval for their products.Therefore, appropriate risk mitigation strategies and pharmacovigilance processes should be in place as early as feasible.

Why APCER as a Strategic Partner?

Partnering with a provider who has strong expertise, understanding and adapting to global and regional regulatory requirements can be highly beneficial to ensure safe and effective use of therapeutic products as well as anytime inspection readiness.

As an end-to-end Pharmacovigilance service provider, APCER has the expertise to monitor the regulatory landscape and assess the impact to pharmacovigilance processes to ensure compliance.

Core Pharmacovigilance and Complementary Services

Pharmacovigilance

- Case Processing
- Signal Detection
- Aggregate Reporting
- QPPV
- Literature Search
- Safety Reporting
- Benefit-risk Assessments
- Risk Management

Medical Information

- Integrated & Global Response Center
- REMS Call Center
- Response to and follow up for Adverse Events, Medical Inquiries and Product Complaints
- Chat / SMS

Regulatory Affairs

- Regulatory Strategy and Planning
- Pre-Approval Services
- Submissions
- Life Cycle Management

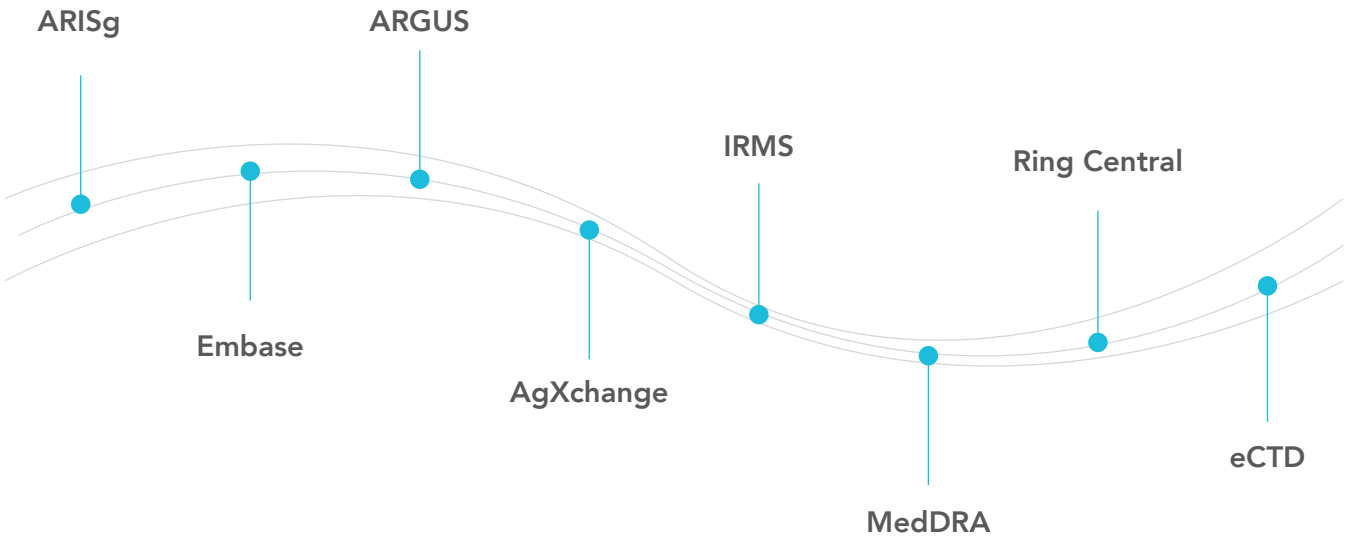
Medical Writing

- Clinical Writing
- Scientific Manuscript Writing
- Regulatory Writing
- Publications
- Scientific Communications
- Standard Response Letters
- REMS Communications

Quality Assurance

- Training
- Inspection Readiness
- Consulting
- CAPA Management
- Audits

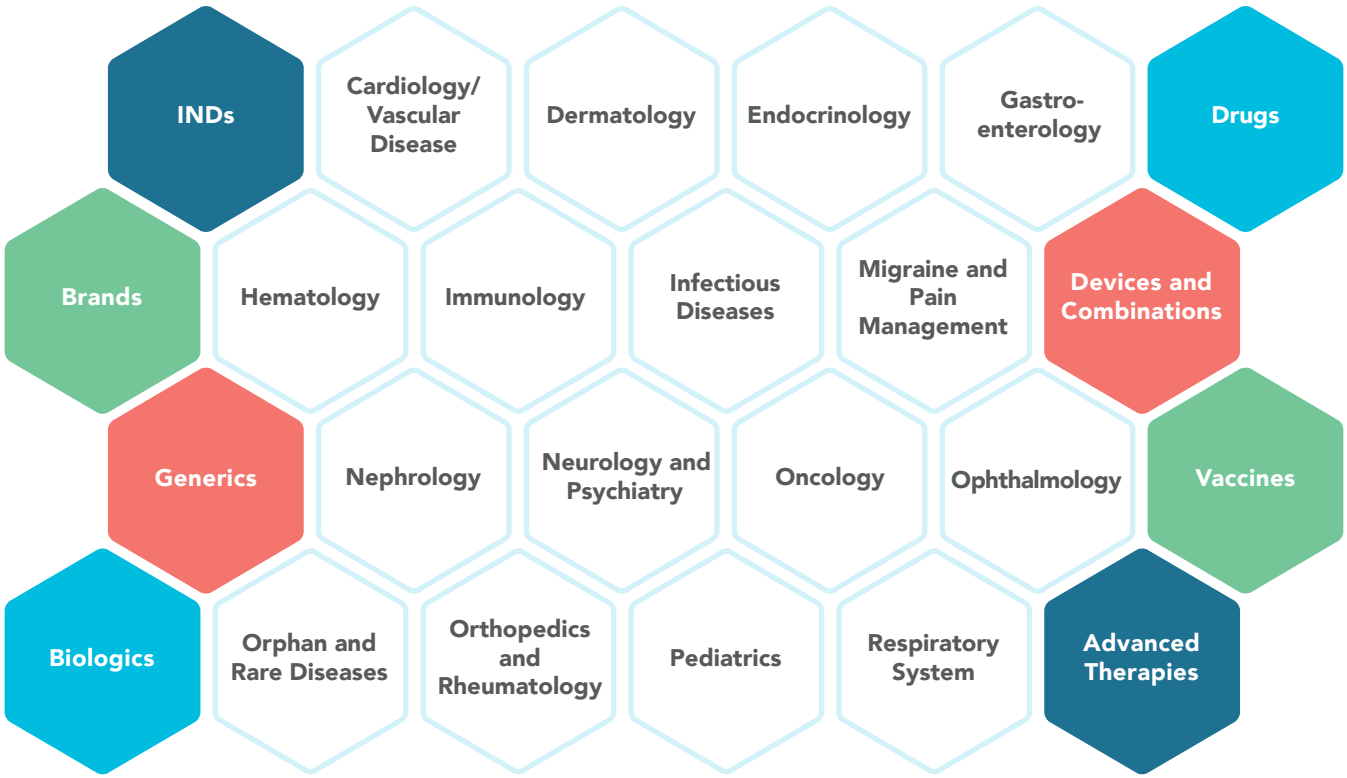
Technology Enablers

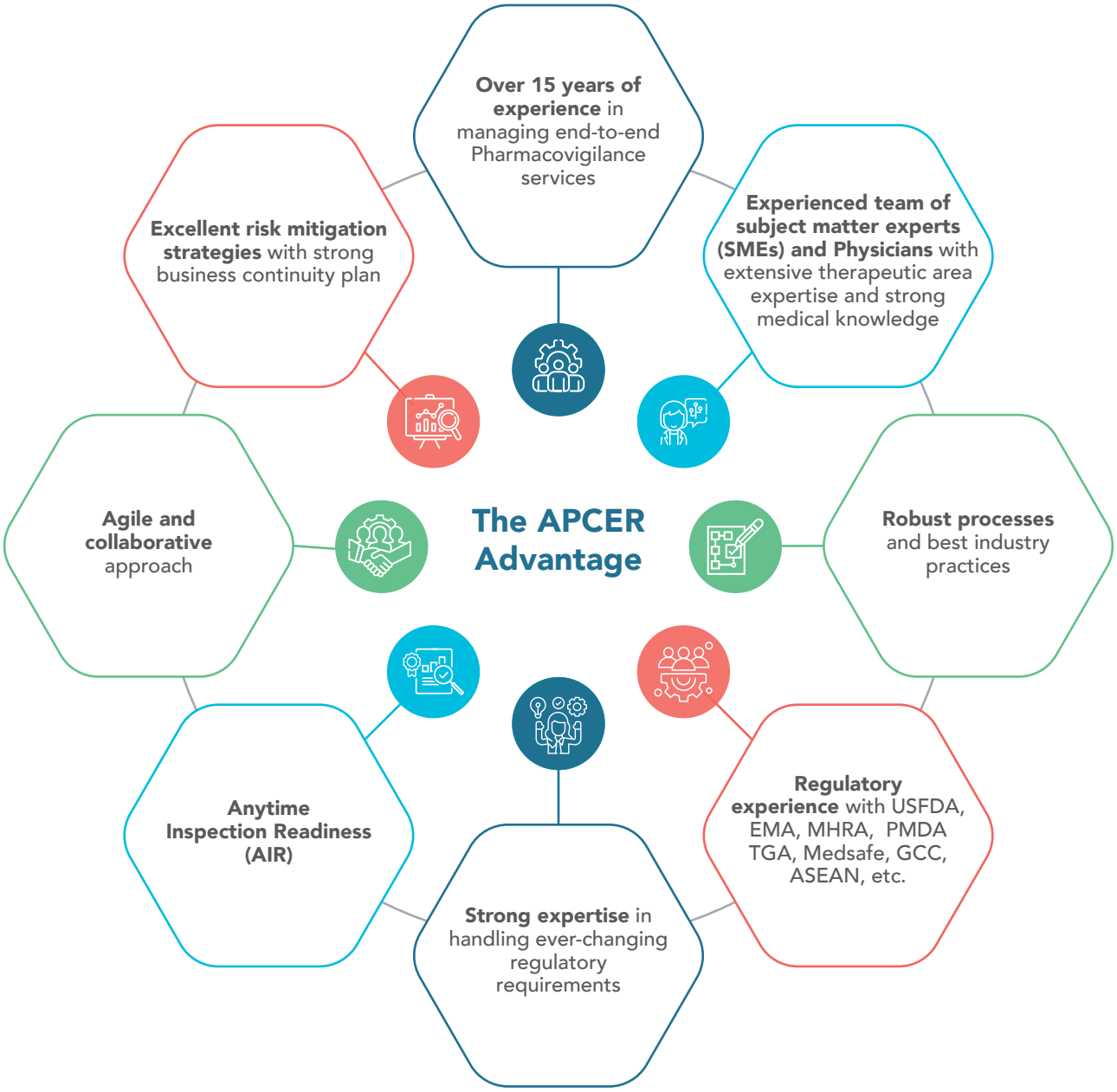


Therapeutic and Product Experience

Our expertise extends to every therapeutic area and covers a wide range of products such as Drugs, Vaccines, Biologics, Biosimilars, Medical Devices, Combination products, Advanced Therapeutic Medicinal products (ATMPs) and Cell & Gene therapies (CGTs).

Therapeutic experience across product types





APCER LIFE SCIENCES

Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2013, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com