APCER LIFE SCIENCES

BROCHURE

Accelerate Your Path to Market **Approval with APCER**

Your Trusted Partner Through Every Step of Clinical Development

Managing clinical trials presents unique challenges: evolving regulatory landscapes, fragmented data systems, and the relentless pressure to deliver safe, effective therapies on time. The complexity can be overwhelming, but the right partner can transform your journey.

At APCER Life Sciences, we're more than a service provider. We're your friend, philosopher, and guide. Our integrated approach simplifies complexity, ensures regulatory compliance, and seamlessly scales operations as your programs advance toward approval. We offer integrated solutions for pharmacovigilance, regulatory affairs, medical writing, medical information and quality assurance to ease your journey.

With APCER by your side, you gain a true partner who takes end-to-end responsibility, adapts to your evolving needs, and stands ready to support you throughout your pipeline's lifecycle. From clinical trials to post-approval success, we're invested in your journey.

Get Yourself the APCER Advantage

One-stop support from clinical trials to post-approval.

Deeply experienced - multiple clients partnered through to market approval.

Scientific rigor and quality assured through 100% HCP teams.

Subject Matter Expertise across therapeutic areas and modalities

Seamless scalability as your programs grow in size or expands to new markets.

Excellence assured: ISO-certified,Inspection-ready, and >99% HA compliance.

Enduring partnership — APCER is here for the journey, not just a project.

Transform Your Scientific Data into Compelling Documents

Expertise in INDs, NDAs, ANDAs, and MAAs

Lifecycle management: variations, renewals, and change control

Global regulatory intelligence across 100+ markets

Transform Your Scientific Data into Compelling Documents

- Expert clinical and regulatory writing for all study phases
  - Authoring of Protocols, CSRs and Narratives, IBs, Briefing Documents and more
  - Multiple Manuscripts, CT Disclosure Documents, and CTDs created.
- Ensure global compliance and submission-ready documents.

Establish, Scale and Manage PV Operations Easily

- End-to-end ICSR case processing, Hosted Safety database included (Argus, Aris)
- Proactive signal detection, risk management, and aggregate report expertise
- >99% health authority compliance
- Global literature surveillance in 40+ countries, 170+ language

Build A Robust QA System to Mitigate Risks and Manage Regulatory Changes

- Expert support to set up and optimize your Quality Management System (QMS)
- Risk-based audits and proactive gap analysis to identify and address issues early.
- Guidance on SOPs, CAPA, and compliance for ongoing quality improvement
- Highly qualified QA professionals with proven inspection and audit success

End-to-end Services to Meet Your Every Need

	IND/CTA	Clinical Trials	NDA/BLA/MAA	Product Approval and Launch
Regulatory Affairs	• CMC/quality strategy Meeting support and participation • Authoring, review, and compilation of IND/CTA applications to US and EU health authorities e-CTD publishing and submission	• IND maintenance activities Safety-related support	• Review of the quality/CMC data • Authoring, review and compilation of the quality/CMC sections • Authoring submission modules E-CTD publishing, submission and submission management including handling queries	• Finalization of product labelling and artworks • Liaising with regulatory authorities/contact points to meet the national regulatory requirements Handling, submission, and management of OPDP materials to US FDA
Quality Assurance	• GCP, GCLP, QA and Audit Support	• GCP, GCLP, QA and Audit Support • Inspection Readiness QMS Consulting	• GCP, GCLP, QA and Audit Support • Inspection Readiness QMS Consulting	
Medical writing	• Clinical writing: Protocols, Informed Consent Documents, IBs • Regulatory writing: Briefing Documents for meetings with Agencies, Pre-IND submission documents • Strategizing clinical data for IND/CTA	• Clinical writing • Regulatory writing • Strategizing clinical data Scientific writing	• Authoring and compilation of Non-clinical and Clinical sections Paediatric Investigational Plan	• Regulatory Writing: SPC, PIL, PI, Medication Guide and artworks. • Scientific Writing: Posters and Manuscripts, Training Material, Leaflet and Promotional Materials- Authoring and Approval
Pharmacovigilance	• Safety document preparation for studies	• SAE processing & submission • Hosting and maintenance of safety database (Argus/ ArisG) • Safety database and clinical database reconciliations • Medical monitoring and support for DSMB • Aggregate repor preparation	• Pre-authorisation PV activities: literature management, QPPV, PSMF, Module 1.8 support	• Establishing PV processes • Safety database set-up, hosting, and maintenance (Argus/ ArisG) • Migration of ICSRs • Distributor and partner management including creation of SDEA
Medical Information				• MICC set up (toll free lines, fax line and telephony) Pre-launch medical inquiry handling

Streamline Your Path to Market with APCER

Your Trusted Guide:

We partner you through every step of clinical development and approvals.

Scalable Solutions:

Our services grow with your trials, ensuring smooth safety management worldwide.

Ownership of Outcomes:

We take responsibility for outcomes of our services, so that you can focus on your path to approval.

Proven Expertise:

Decades of experience and a global footprint make us a reliable partner.

Quality You Can Count On:

ISO certified processes and a robust Quality Management System that ensure excellence.

One-Stop Solution:

Pharmacovigilance, medical writing, and regulatory services - all under one roof.

Expert Teams:

100% healthcare professional teams with deep and wide therapeutic are expertise.

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 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices:
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