

Case Study

Partnering A Rapidly Expanding Oncology Focused Biotech Company



Client

- US-based oncology-focused biotech company
- Rapidly expanding portfolio and rich pipeline
- Increasing clinical trial case volumes



Challenge

- Managing scale
- Maintaining quality and regulatory compliance
- Completing partner reconciliations
- Successfully navigating inspections

Impacts

Achieved
100% compliance
with regulatory and
partner timelines

Successfully managed
volume fluctuations while
maintaining quality

Comprehensive visibility
into quality and
compliance metrics
for client

Delivered
positive inspection
outcomes

Positioned client for
seamless expansion
and future product
launches

APCER's Solution



Implemented phased transition
with US-India hybrid delivery
model to maintain quality and
compliance

Scaled team from 25 to 100+ while
optimizing processes over 6-12 months

Established regular Quality & Medical
review checkpoint connects for
continuous improvement

Improved data entry procedures

Took over submission/reporting
processes