AUDITING

imarc
WE'LL EARN YOUR APPROVAL.

PREPARE FOR APPROVAL

- Verify that vendors have the experience to do their jobs through vendor qualifications and audits
- Identify and fix issues before the FDA finds them
- Be prepared for inspections by knowing what to expect
- Address compliance concerns and gain reassurance through mock inspections
- Prep your team with interviewing and coaching sessions

AUDITING SERVICES THAT WILL PASS YOUR INSPECTION.

- Real-Time Prospective Investigator Audits
- IRB Audits
- Sponsor/CRO Audits
- Vendor Qualification Audits
- FDA BIMO Prep Visits

Finally, being audited pays off.

With FDA and International inspections on the rise, so are stress levels of everyone involved in clinical studies. IMARC provides the specialized independent auditing support services you need to survive today's rigid regulatory requirements — not only to ensure compliance, but also to protect patients.

What your data doesn't know can hurt you.

IMARC Independent Auditors have experience reviewing clinical studies around the world, helping sponsors and sites focus on what is working and what needs work. That includes auditing in the U.S., Europe and Asia to assess processes, compliance and inspection-readiness.

There are many steps throughout our process designed to put you — and keep you — in complete control. For starters:

- ☐ **STEP 1**
  Assess performance against research requirements
- ☐ **STEP 2**
  Ensure the quality — and integrity — of data collected
- ☐ **STEP 3**
  Sync observations with regulatory compliance standards through corrective and preventative action recommendations
- ☐ **THE RESULT**
  Overall improved compliance, optimal readiness for inspection, and ultimately, high-quality studies that support marketing submissions

SITE GCP AUDITS

Utilizing FDA's BIMO checklist as a starting point, IMARC Auditors identify, analyze and address compliance issues including conformance with:

- Federal and Local Regulations
- Protocol Requirements
- IRB Policies
- Investigator Agreements
- Sponsor Requirements / SOPs
- Internal Site Procedures

VENDOR QUALIFICATION AUDITS

- Organization and Communication
- Personnel Qualifications & Training
- Standard Operating Procedures
- Records Maintenance
- Facilities / Equipment
- Project-Specific Requirements

SPONSOR / CRO AUDITS

- Organization & Personnel
- Monitoring Activity
- Quality Assurance
- AE Reporting
- Data Collection & Handling
- Electronic Records
- Product Accountability

Go from "PROVE" to "APPROVE" with IMARC.

Approvals are not just granted. They are earned. IMARC has experience preparing even the most sophisticated organization domestically and worldwide for FDA and International inspections. That includes everything from compliance checks and coaching to regulatory reviews, organization of documents, and more. Every move we make is strategically designed to earn your approval.

Waiting for decisions from the FDA or other regulatory bodies can be worrisome. Eliminate the worry by trusting IMARC auditors to make sure you have the highest probability of receiving a favorable outcome.

How prepared will you be for inspection time? Pass an IMARC audit prior to your official inspection and you will have a pretty good idea!

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