

# Is the Integrity of Your Clinical Trials at Risk?

**Find out now with our GCP Auditing checklist.**

## Compliance

- IRB/IEC Approval obtained
- Annual Report completed

## Trial Monitoring

- Trial Master File maintained and complete
- Informed Consent properly handled
- Essential Documents complete

## Clinical Quality

- QMS processes followed and sufficient
- Quality Risk Management incorporated
- Business Continuity program established

## Vendor Management

- CRM/CMO Contractual and Quality Agreements established
- Vendor Audits and Site Visits performed, compliant, and on time

## Investigational Medicinal Product/Test Article

- Proper handling of Release
- Randomization, Blinding, Unblinding protected

## Safety and Data Management

- No Data Integrity gaps
- Proper Case Report Form, data handling and Clinical Study Report
- SAE Processing compliance

**Don't let a single oversight jeopardize the integrity of your clinical trials!** Contact our GCP auditing experts today for a complete evaluation.

## Who is ProPharma Group?

ProPharma Group is a global, independent, single-source provider of Life Science Consulting, Regulatory Affairs, Medical Information Contact Centers, and Pharmacovigilance services that span the entire lifecycle of pharmaceuticals, biologics, and medical devices.



## Our GCP Auditing Services

Our quality and compliance services include vendor qualification audits, mock regulatory inspections, gap analyses, quality management system development and optimization, and interim quality management.

## Why Choose Us for Your GCP Auditing Needs?

With an average of 20+ years of GCP auditing and clinical quality experience, our consultants seamlessly integrate with your organization to do more than simply identify potential risks. We provide recommendations to mitigate those risks and work together with you to implement improvement plans.

## Contact ProPharma Group

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