PROPHARMA GROUP®

Improving Patient Health and Safety

The Quality of Your Product Depends on The Quality of Your Data

Regulatory Agencies Expect Controls to Be in Place

Authorities have increased their focus on data integrity compliance since 2015. Data integrity essentially means that data are complete, consistent and accurate, which is crucial for proving the safety, efficacy, and quality of GxP regulated products.

ProPharma Group can lead your company to a fully implemented data integrity framework in which the complete data life cycle is in control.

ISSUE	CONSEQUENCE
Data lost or clearly incorrect	Inefficient way of working
Incorrect safety, efficacy or quality	Incorrect decision taken
Returned submissions or additional information requested	Too long time to market
Remediation activities on data processes	Loss of time, money, or no long-term remediation possible
Long preparation time for audits	Regulatory scrutiny

It's All About the Trustworthiness of Data

Data integrity is essential for GxP regulated processes. Therefore, data lifecycle controls must be implemented, and computerized systems need to be validated and ready for inspection at any moment. This enables you to demonstrate compliance with current regulations, best practices and company policies. ProPharma Group will:

- Find the data integrity gaps through our gap analysis and audit procedures
- Provide data risk assessments and mitigation programs
- Solve observations by implementing data controls tailored to your specific situation
- Give clarity around roles and responsibilities with respect to data integrity
- Teach how ALCOA+ can be used in everyday situations in every layer of your organization
- Allow you to be in control by implementing self-assessment programs at every level

Computerized System Validation & Data Integrity

Validation is an ongoing process. We can help you define your validation strategy to ensure this is continuously up to date, preventing unnecessary validation activities. Control starts with knowing what the status is of your systems. Your validation strategy is dependent on the intended use of those systems, as they will need to meet the requirements for the intended use. We can help you through your first validation and reaching from design to final performance qualification. We can help you to set specifications, write URS documents, and write validation documents.

Besides guiding you through every validation, ProPharma Group also provides:

- Perform GAP assessments
- Witness validation activities
- Create operational procedures
- Help you to keep the control during decommissioning

CSV for All Regulated Processes					
Validation of commercially-used systems and equipment	Validation of Medical Apps: Combine ISO 13485 with GAMP5	Validation of laboratory equipment in early research	Deliver IT QMS for software development	Validation of GxP and Non-GxP ERP systems	Validation of systems used for clinical studies

Improving Patient Health and Safety. At Every Step.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

Contact ProPharma Group today for a complete evaluation to ensure the quality of your data.

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