Autumn Focus Workshop
Managing GCP in Regulated Bioanalysis

Overview of EBF GCP Team discussions on GCP challenges

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15-16 September 2022 – Malaga, Spain

Once upon a time EBF GCP team discussions started

- EBF GCP team discussion started in 2020 and since then the team has arranged sessions at EBF Open Symposium to discuss the challenges of GCP implementation at Bioanalytical labs

- Initial survey to EBF community was conducted to check the challenging areas
  - Communication (unexpected results, ICF status, blinding)
  - Quality Management
  - Confidentiality

The first challenge

- Back in the early 1980s when animal testing laboratories modified their quality systems to incorporate GLP;
- In the early 2000s when GCP human analysis work was rapidly expanding and many GLP laboratories expanded their services to include these type of analysis;
- With the fact that ***GCP alone does not define laboratory analysis requirements*** and GLP focuses on animal testing. In 2012 EMA issued "Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples"

Reflection on the reflection paper

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 February 2012
EMA/INS/GCP/532137/2010
GCP Inspectors Working Group

Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples

Draft agreed by GCP Inspectors Working Group	10 June 2010
Adopted by GCP Inspectors Working Group for release for consultation	10 June 2010
Start of public consultation	23 September 2010
End of consultation (deadline for comments)	28 February 2011
Adopted by GCP Inspectors Working Group	28 February 2012

Keywords	Clinical laboratory, Laboratory analysis, Clinical Trial

Dicing the regulations

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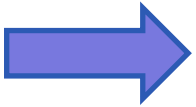

6. Reflection paper for laboratories that perform the analysis or evaluation of clinical trials samples

6.1. Organisation

Roles and responsibilities within a laboratory should be established and documented prior to the initiation of analytical work. These will include but not be limited to identifying personnel that are responsible for laboratory management, quality assurance, scientific analysis, reporting and archiving.

It is the responsibility of laboratory management to ensure that laboratory personnel are appropriately trained and qualified to perform the roles and responsibilities assigned to them.

Laboratory management should ensure that each individual involved in the analysis of clinical trial samples has a current job description detailing the individual's role and responsibilities within the laboratory.

Laboratory management should ensure that there is a Quality Assurance programme with designated personnel and ensure that the quality assurance responsibility is being performed in accordance with regulatory requirements.

The analysis or evaluation of clinical trial samples should be overseen by a named individual(s) who assumes responsibility for the conduct and reporting of the work. This individual(s) should ensure that all laboratory work is performed in compliance with the clinical trial protocol, clinical trial protocol amendments, the contract, any associated work instruction and standard operating procedures.

Prior to the initiation of any analysis, the persons designated as "laboratory management" should make provision to ensure that sufficient resources are available for the timely and proper conduct of the analysis in accordance with the clinical trial protocol, work instructions, associated methods and standard operating procedures.

Prior to the initiation of analytical work, lines of communication should be established and documented between the sponsor or their representative and the individual who is responsible for coordinating the laboratory analysis. It is particularly important that laboratory personnel know to whom they should report anomalous results which may impact on trial subject safety.

6.2. Personnel

Procedures and systems should be implemented to ensure that individuals involved in the organisation and conduct of the analysis or evaluation of samples collected as part of a clinical trial are appropriately educated, experienced and trained. Laboratory personnel should be fully aware of their roles and responsibilities with respect to the analysis or evaluation they are performing.

The risk of overinterpretation

Internal team survey has been conducted to evaluate the risk of overinterpretation by:

- BioA team
- QA
- Health Authorities

After a long discussions..

Overinterpretation risk area	Details
Communication	- Protocol deviations reporting requirements for Bioanalytical lab - Issue Communication - Informed consent status and data handling in case of withdrawal consent
GCP training	- Training requirements for GCP trainings at BioA
Quality Assurance	- Difference in QA activities between GLP and GCP
Equipment maintenance	- Difference in equipment maintenance activities between GLP and GCP

And more discussions…

Overinterpretation risk area	Details
Computerized system validation	- Difference in CSV activities between GLP and GCP
Accountability of BA team	- Data Management Plan - Expedited reporting
Contracting	- Contracts expectation within the same organization
Archiving (Retention period and e-archiving)	- Archiving requirements and applicable retention period for different type of documents

Is that all?

Survey all the way

Several surveys have been conducted for support the discussions within the team:

- GCP training
- Equipment maintenance
- CSV survey
- Protocol deviation reporting
- ICF status
- Monitoring activities at BioA
- Retention period (documentation)
- Retention period (samples)

Next steps

- (All) challenging areas to be discussed during these two days – ***we need your contribution***
- Feedback from this Workshop to be presented during EBF Open Symposium in Barcelona
- **GCP not to be a GLP** for BioA

Acknowledgements

GCP Team

EBF Community

EBF Steering Committee

Contact Information

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European Bioanalysis Forum vzw

www.e-b-f.eu