Autumn Focus Workshop
Managing GCP in Regulated Bioanalysis

Feedback from EBF GCP Team discussions on learning from inspections

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15-16 September 2022 – Malaga, Spain

Guidelines diversity

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products

Guideline for good clinical
Step 5

Adopted by CHMP for release for consultation
Start of public consultation
End of consultation (deadline for comments)
Final adoption by CHMP
Date for coming into effect

EUROPEAN MEDICINES AGEN
SCIENCE MEDICINES HEAL

02 May 2022
EMA/INS/GCP/188326/2022
Good Clinical Practice Inspectors Working Group (GCP IWG)

ANNEX VII
TO PROCEDURE FOR CONDUCTING GCP I
REQUESTED BY THE CHMP: BIOANALYTIC
PHARMACOKINETIC AND STATISTICAL ANALYSES OF
BIOEQUIVALENCE TRIALS

Adopted by GCP Inspectors Working Group (GCP IWG)	29 April 2022

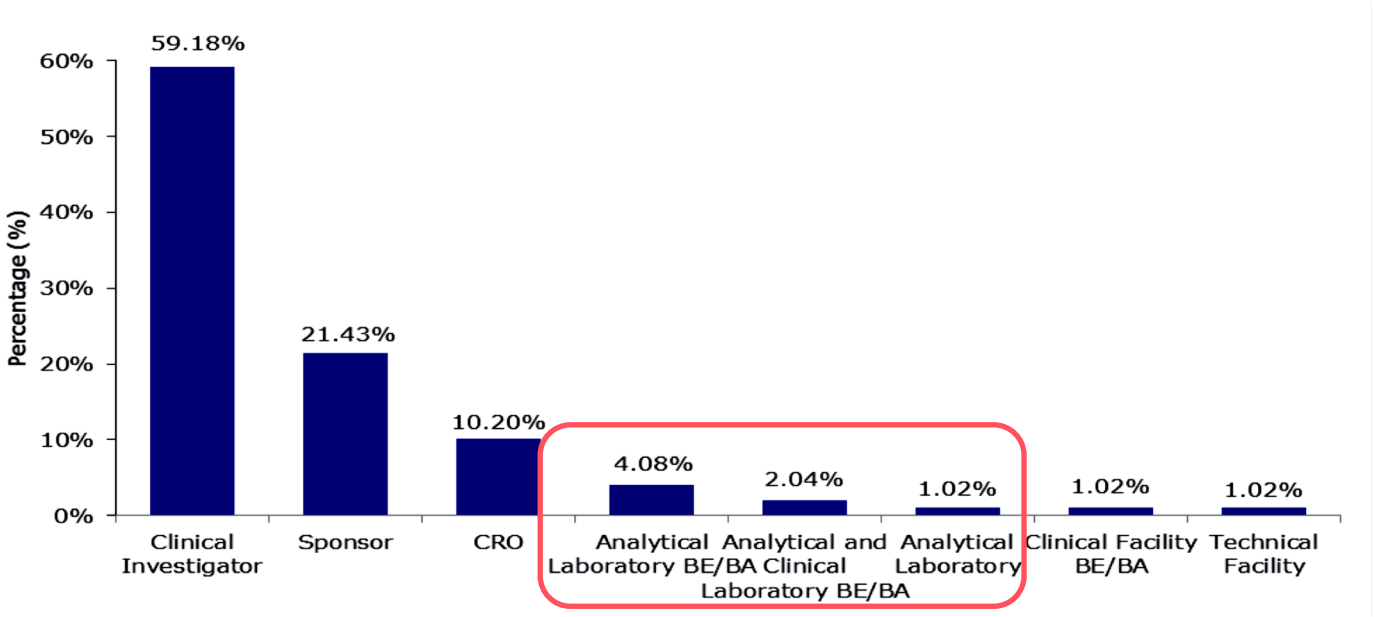
Keywords	***GCP inspection, bioanalytical part, pharmacokinetic and statistical analyses of bioequivalence trials***

2. ETAPA BIOANALÍTICA

2.1. INSTALAÇÕES - CONDIÇÕES GERAIS

Nº	Qual.	Itens
2.1.1	INF	Qual é a área física do laboratório?
2.1.2	INF	Existem fontes de poluição ou contaminação ambiental próximo da empresa?
2.1.3	N	Os arredores dos edifícios estão limpos?
2.1.4	N	Quanto ao aspecto externo, o (s) edifício (s) apresenta (m) boa conservação (isento de rachaduras, infiltrações, etc.)?
2.1.5	N	As instalações são construídas de forma a permitir a proteção contra a entrada de insetos e outros animais?
2.1.6	N	Pisos, paredes e tetos são apropriados às atividades desenvolvidas na área?
2.1.7	INF	A área é exclusiva para análise de material biológico?

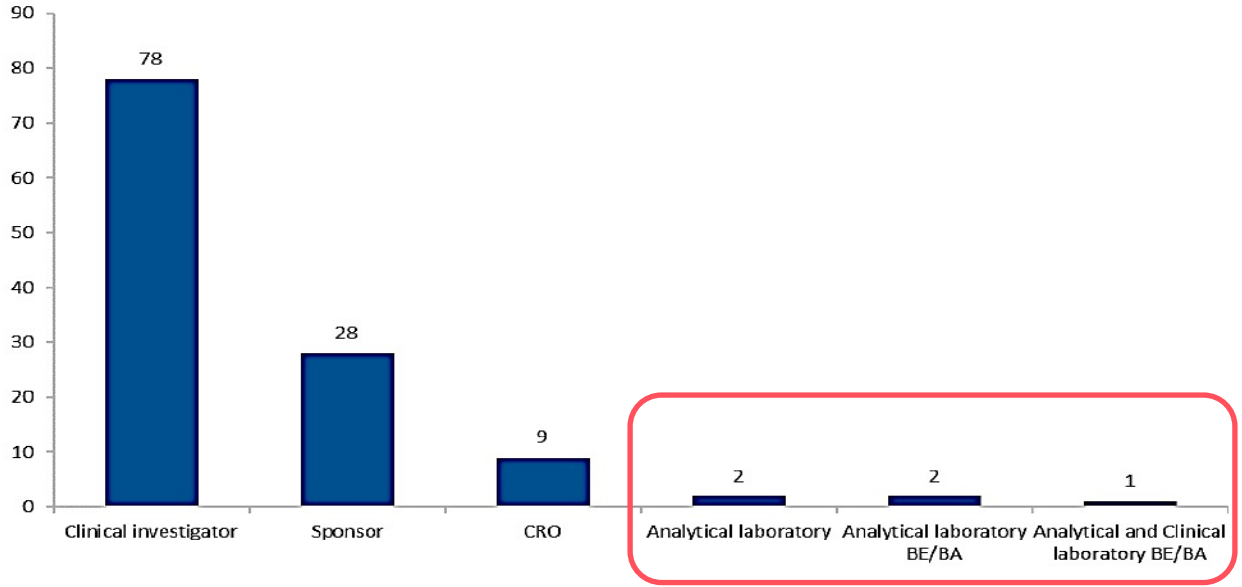
Looking on the regulators reports..



EMA Annual Report of the Good Clinical Practice Inspectors' Working Group 2018

And how they are changed

Figure 2: Inspections conducted per type of site



EMA Annual Report of the Good Clinical Practice Inspectors' Working Group 2019

And how they are changed

- In 2020 there were not any inspections at Bioanalytical facilities conducted by EMA

Let’s change the perspective

Picture removed

Let’s change the perspective

- In 2020 EBF GCP team conducted a survey to evaluate the challenges with regards to GCP implementation at BioA facility

- One of the topics included in the survey was related to the experience in GCP HA inspections

Survey Question

1. My organisation is
a. CRO
b. Pharma
2. In our lab we analyse samples from
a. Both GLP and GCP studies
b. Only GCP studies
c. Only GLP studies -
3. My laboratory is based in:
a. UK
b. Other

Outcomes

Question 1:

- 21 CRO
- 18 Pharma

Question 2:

- Both GLP and GCP Studies - 31
- Only GCP – 5
- Only GLP – 3

Question 3:

- UK - 8
- Other– 28

Survey Question

4. Are your laboratory being inspected by the regulatory authorities for GCP compliance?
a. No
b. Yes. (if yes, please specify by which HA)
5. If yes in question 4, is your laboratory being inspected:
a. As part of an inspection program. If so, which is the inspection frequency, every X year
b. As part of regulatory submission. If so, which type of trials are inspected?
c. Other, please specify.

Outcomes

Question 4:

- No - 21
- Yes - 15

(7 MHRA, 4 EMA, 6 FDA, 1 AIFA, 1 SwissMedic, 1 AGES, 1 Dutch agency, 1 Spain agency)

Question 5:

- As a part of inspection program – 11, (X=1-2-3) by MHRA, Spain Agency, AIFA, Dutch Agency, AGES
- As a part of regulatory submission – 4, BE studies by EMA, FDA and SwissMedic

Looking closer

- **AEGS** - GCP is only a “additional aspect" in the regular GLP inspections done in Austria.

- **AIFA** – inspections are part of accreditation process to confirm that the laboratories are able to perform analysis in support to the clinical trial including Phase 1 studies.

- **Dutch Healthcare inspectorate** - GLP inspectors are looking at the GCP aspects in the lab procedure

Looking closer

Lessons learned

- The experience with GCP inspection at BioA facilities is still limited
- Only specific inspection guidelines focused on BE studies are available
- We need to have an alignment between agencies on requirements on GCP BioA facilities
- GCP inspections conducted by GLP inspectors **– GCP is not GLP**

Acknowledgements

GCP Team

EBF Community

EBF Steering Committee

Contact Information

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European Bioanalysis Forum vzw

www.e-b-f.eu