EBF Autumn Focus Workshop - 1
Managing GCP in Regulated Bioanalysis - Considerations for Best Practices from the EBF
15-16 September 2022 - NH Malaga, Spain

Thursday 15-Sep-2022

09:45 10:00 Welcome and aim of the meeting

10:00 11:00 Session 1: Setting the Scene

10:00 10:20 *Philip Timmerman, EBF*
Introduction to the meeting

10:20 10:40 *Tsvetelina Ivanova, on behalf of the EBF*
Overview of EBF GCP Team discussions on GCP challenges

10:40 11:00 *Philip Timmerman, on behalf of the EBF*
GCP for Bioanalysis - Can we learn from GLP?

11:00 11:30 Coffee break

11:30 12:30 Session 2: Looking at the different angles

11:30 11:45 *Stuart McDougall, on behalf of the EBF*
GCP and MHRA - setting the bar

11:45 12:00 *Matthew Barfield, F. Hoffmann - La Roche*
GCP from and EMA/Swiss Medic perspective

12:00 12:15 *Lee Monk, UCB Biopharma*
GCP from a lab QA perspective

12:15 12:30 *Magnus Knutsson, Bayer (not released for publication)*
GCP challenges from a Pharma/CRO project management interface perspective

12:30 13:30 Lunch break

13:30 14:40 Session 3: Communication
During this big session we plan to go over the challenges related all aspects of study communication, incl. Issue communication / withdrawal/IC issues.

13:30 14:00 *Jo Goodman/Michaela Golob, on behalf the EBF*
FB from EBF GCP team discussions on communication with focus on stakeholder communication around study protocols, informed consent, sample disposition, study documentation & archiving/retention

14:00 14:20 *Tessa McDonald, Intertek*
Clinical Sample Handling – a CRO's challenge

14:20 14:40 *Sophia Christou, Drug Development Services Alliance Pharma*
Importance of Informed Consent Process and how it relates to Regulated Bioanalysis

14:40 15:00 Adriaan Tigchelaar, Janssen R&D
Effective communication in a bioanalytical lab environment

15:00 15:30 Introduction to round tables discussion 1
Round table 1: GCP communication requirements (pre, during, post study) in practice: challenges, responsibilities and accountabilities (with focus on IC)
Round table 2: What do GCP guideline/reflection papers requirements mean for BMV for the lab?
Round table 3: Communication around sample disposition, study documentation & archiving/retention

15:30 16:10 Coffee break

16:10 17:20 Round table session 1
Delegates split into round tables on above items. Moderators rotate to tables and consolidate discussions
Survey with pre-meeting questions can be part of the round table discussions

17:20 17:30 Short logistic break

17:30 18:30 Session 5: Learnings from inspections shaping our minds

This session discusses experiences from inspections/risk of confusing GCP and GLP requirements

17:30 17:50 *Tsvetelina Ivanova, on behalf of the EBF*
FB from EBF GCP team discussions on learning from inspections

17:50 18:10 *Stuart McDougall, Quotient Sciences*
FB from EBF GCP team discussions on learning from inspections

18:10 19:00 "SERT" - Sharing Experience Round Table
Delegates will be invited to share experience (round table). "Cases" will be gathered from a pre-meeting survey to all registered delegates. Moderators rotate to tables and consolidate discussions.

19:00 Day 1 close out

Friday 16-Sep-2022

08:30 10:20 Session 6: Diving in deeper on Equipment maintenance and validation, role of QA and training

During this session we plan to discuss the challenges of over interpretation related to CSV, equipment validation and maintenance, incl. SOP management

08:30 08:35 *Philip Timmerman, on behalf of the EBF*
Introduction to day 2

08:35 09:00 *Cecilia Arfvidsson, on behalf of the EBF*
FB from EBF GCP team discussions on Equipment maintenance and validation - inlcudes GCP relevant info from EBF e-data and Data integrity team

09:00 09:25 *Floris Bové, on behalf of the EBF*
FB from EBF GCP team discussions on the role of QA

09:25 09:45 *Lee Monk, UCB Biopharma*
Experiences - risk based audits…

09:45 10:10 *Tsvetelina Ivanova, on behalf of the EBF*
FB from EBF GCP team discussions on GCP training for the BA lab

10:10 10:20 **Introduction to round tables discussion day 2**
Round table 4: Role of QA/risk based audits
Round table 5: Equipment maintenance/validation and CSV
Round table 6: How to approach GCP training for BA?

10:20 11:00 Coffee break

11:00 12:30 Round table session 2

Delegates split into round tables on above items. Moderators rotate to tables and consolidate discussions
Survey with pre-meeting questions can be part of the round table discussions

12:30 13:30 Lunch

13:30 15:00 Session 7: Feedback from the round tables and building the EBF recommendation

During this close out afternoon session we will try to build 'best practices' recommendation covering several aspect discussed during the workshop round tables.
Round table 1: GCP communication requirements (pre, during, post study) in practice: challenges, responsibilities and accountabilities (with focus on IC)
Round table 2: What do GCP guideline/reflection papers requirements mean for BMV for the lab?
Round table 3: Communication around sample disposition, study documentation & archiving/retention
Round table 4: Role of QA/risk based audits
Round table 5: Equipment maintenance/validation and CSV
Round table 6: How to approach GCP training for BA?
Summary slides of the round tables will be added after the 15th Open Symposium

15:00 16:00 Close out & networking coffee break

Organising Committee: Tsvetelina Ivanova (Comac Medical), Joanne Goodman (AstraZeneca), Stuart McDougall (Quotient Sciences), Steve White (GlaxoSmithKline), Michael Golob (Nuvisan), Lee Monk (UCB Biopharma) and Philip Timmerman (EBF)