

**Recent Observations On
Performing GLP QAU
Functions At Non-GLP
Facilities**

**Jason R. Plaxco,
BS, RQAP-GLP**

Senior QA Auditor
Biotechnical Services, Inc.

Biotechnical Services, Inc.

❖ As QA contractors, BSI consults with a variety of different facilities.

❖ The GLP infrastructure can range from non-existent to rudimentary to fully developed.

Biotechnical Services, Inc.

❖ From these experiences, BSI has identified potential areas of concern for facilities that are new to GLP's.

Biotechnical Services, Inc.

Potential Areas of Concern

- ❖ QA / Study personnel relationship
- ❖ GLP Training
 - GLP Terminology
- ❖ SOP Development
- ❖ Reporting Phase
- ❖ GLP's at Universities

Biotechnical Services, Inc.

QA Relationship

- ❖ Typically, not accustomed to being inspected.
 - Very nervous
- ❖ No experience with the QA process.

Biotechnical Services, Inc.

GLP Training

- ❖ Attended by anyone who might be involved in the GLP study, including TFM.
- ❖ Includes Contributing Scientists.

Biotechnical Services, Inc.

GLP Terminology

- ❖ All labs think they use “good laboratory practice”.
 - Emphasize GLP’s are law, not classical lab techniques.
- ❖ Do they understand GLP terms?
 - Emphasize and explain critical terms: protocol, MS, SD, QA, Archive, etc.

Biotechnical Services, Inc.

SOP Development

- ❖ Personnel are hesitant to put their procedures in an SOP.
 - Don’t routinely train and review
 - Too much specificity – SOP deviation
- ❖ Stress that SOP’s are intended to control routine, repetitive procedures.

Biotechnical Services, Inc.

Reporting Phase

- ❖ All personnel must be cognizant of the steps (and time) it takes to prepare a GLP Final Report:
 - Data audit
 - Dbase prep / audit
 - Contributing Scientist Reports
 - SD Report

Biotechnical Services, Inc.

GLP at University

- ❖ Running GLP studies at universities can be problematic.
- ❖ Certain techniques are only being performed at universities.
 - Older or cutting-edge

Biotechnical Services, Inc.

GLP at University (cont.)

- ❖ Compliance personnel not familiar with GLP regs.
 - Contact Compliance Dept. prior to study start.
- ❖ Test Facility Management (TFM)

Biotechnical Services, Inc.

TFM at University

- ❖ TFM has to be most appropriate person – highest level individual with appropriate knowledge and authority.
- ❖ TFM has to have interest.
 - Must understand responsibilities under GLP – sometimes problematic

Biotechnical Services, Inc.

TFM at University (cont.)

❖ TFM needs to be aware of all on-going GLP studies, as does Compliance dept.

❖ Is TFM involvement apparent?

Biotechnical Services, Inc.

TFM at University (cont.)

❖ Research Admin. should also be aware of all regulated studies, not just GLP (any study that will be used to support submission to a regulatory authority).

Biotechnical Services, Inc.

TFM at University (cont.)

❖ Research Admin. has to be receptive to regulatory inspections & understand that they must participate, as needed.

❖ Recent experience indicates that Research Admin. participation during inspections is crucial.

Biotechnical Services, Inc.

Summary

❖ Be constantly aware that your understanding of the GLP's is probably not the same as the site personnel.

❖ TFM / Higher Mgmt. has to be involved and committed.

_____ Biotechnical Services, Inc.
