

Recent Veterinary GCP and University GLP Regulatory Inspectional Experiences:

A Comparison of Perceptions from Site Qualification to Site Inspection

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❖ BSI QA auditors recently supported a GLP and 2 vetGCP regulatory inspections.

❖ Initial site inspections/qualifications to in-progress study activities to the regulatory inspections.

❖ Lessons Learned

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University GLP

❖ BSI QA served as GLP Test Site QAU for activities conducted at a university lab.

❖ Site had limited GLP experience

- Training files, Org Chart, MS, SOPs, etc.

❖ GLP infrastructure in place

- Simple Org Chart : Mgmt. → PI(client) → Lab Tech

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University GLP-2

- ❖ Audit / inspection issues:
 - MS deficiencies.
 - GLP Mgmt. training file
 - CV not signed / dated per facility SOP
 - No JD per SOP and GLPs
 - No documented Mgmt. GLP training

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University GLP-3

- ❖ Regulatory Inspection:
 - No issues w/ lab or study documentation.
 - Inspection scope expanded to include entire university.
 - Inspectors went outside of GLP infrastructure
 - Requested interview w/ VP Research Admin

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Veterinary GCP study

- ❖ BSI QA functioned as overall study QAU for a vetGCP field efficacy study.
 - Participated in site qualifications
 - Performed in-life inspections and raw data & report audits
 - 2 of 5 sites were selected for regulatory inspection

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VetGCP site 1

- ❖ At qualification, no site SOPs
 - Documented procedures / practices as signed / dated NTFs before conducting study activities
- ❖ At in-phase audit, dosing records indicated that some animals rec'd an additional dose of IVP
 - Protocol deviation – 21 instead of 20 doses

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VetGCP site 1(cont.)

- ❖ Form 15A & B

Dose Record Form						
Study Number	Site Number	Investigator Name			Animal ID	
Syringe size used: _____						
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Calculated dose: 24 mg/kg x _____ kg h.w. = _____ mg = (400 mg/ml) = _____ ml.						
Day/Date	Dose	Time given (insert in military time)	Amount Given (insert in mL)	Environmental Temp. 30° (insert in °C)	All of dose administered? (If No, please describe and estimate amount lost)	Dose Admin. Initials
Day 0 ././.(MM/YYYY)	1 st				<input type="checkbox"/> Yes <input type="checkbox"/> No, describe:	
	2 nd				<input type="checkbox"/> Yes <input type="checkbox"/> No, describe:	
Day 10 ././.(MM/YYYY)	1 st				<input type="checkbox"/> Yes <input type="checkbox"/> No, describe:	
	2 nd				<input type="checkbox"/> Yes <input type="checkbox"/> No, describe:	

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VetGCP site 1(cont.)

- ❖ Regulatory Inspection:
 - Inspector had very strict, literal interpretation of protocol – “animal potentially needs discontinuation of dosing”
 - However, Study Monitor instructed CI to remove animals if they did not meet certain intermediate criteria
 - Inspector interpreted “potential” to mean that animals did not have to be removed.

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VetGCP site 2

- ❖ At qualification:
 - No documented GCP training
 - No CV's for some site personnel
- ❖ In-phase audit:
 - Documentation issues
 - Multiple personnel – training variations

VetGCP site 2(cont.)

- ❖ Regulatory Inspection:
 - Inspector asked what happened to animals upon removal – post-removal obs not stipulated in protocol
 - Inspector asked if animals were treated once removed
 - Treated with “benign neglect” – no positive documentation that animals were not treated

VetGCP site 2(cont.)

- ❖ Other site 2 issues:
 - IVP dispensing data not recorded contemporaneously – had to be transcribed from other records
 - CI used Attending Vets when unavailable
 - Attending Vet enrolled a pregnant animal – contrary to study enrollment criteria

VetGCP site 2(cont.)

- ❖ Attending Vet & other site personnel (not the CI) enrolled animals w/o having enough un-dispensed IVP
 - 3 animals dosed with previously-dispensed IVP: protocol deviation
 - “Robbed Peter to pay Paul”
 - Those 3 animals had to be removed from efficacy analysis

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Lessons Learned

- ❖ From GLP Regulatory Inspection:
 - Regulatory inspectors can ask to interview individuals outside of GLP infrastructure.
 - Mgmt. training is crucial!
 - Upper Mgmt. needs to take time for Regulatory Inspectors

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Lessons Learned(cont.)

- ❖ From vetGCP Regulatory Inspections:
 - IVP acct., animal welfare, & protocol compliance are stressed
 - Sponsor due diligence
 - Clinical Investigator oversight
 - Documented training

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❖ Thank you for your attention!
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