



HIGH LEVEL VIEW GLP Laboratory Inspection List

Functional Area/Item/Process	Item	Comment
Facilities	<ul style="list-style-type: none"> • Facility schematics/floor plans 	
Specimen Processing and Log-In		
Lab and Reagent Refrigeration	Applicable SOPs	
Sample Storage and Archival	SOP for sample archival	
Lab Supplies and Storage	SOP describing: <ul style="list-style-type: none"> • Receipt and Storage • MSDS Receipt • MSDS File • Additional safety information 	
Matrix Storage/Use and Testing	<ul style="list-style-type: none"> • SOP • Storage Location(s) • Inventory • Log Books and Tracking <ul style="list-style-type: none"> ○ Source ○ Testing ○ Shipping/condition ○ Lot # ○ Screening records ○ Use log 	
Reference Standards	<ul style="list-style-type: none"> • SOP describing receipt, handling, storage and inventory • Assumptions made when Certificates of Analysis (COA) are not received • Forms for documenting receipt 	
Overall Lab security and Access	<ul style="list-style-type: none"> • Building security • Lab Access • Disaster recovery plan 	
Instrumentation	<ul style="list-style-type: none"> • Inventory • Capacity • Back-up instruments • Validation and change control when switching instruments or components 	
Lab Safety	<ul style="list-style-type: none"> • Safety Manual 	
Data Handling and Processing		

Report Preparation	<ul style="list-style-type: none"> • Report Template • Population of data tables <ul style="list-style-type: none"> ○ Run Summary (ref. stds. and QCs) ○ Individual sample concentration data ○ Reanalysis table 	
QA Data Audit	<ul style="list-style-type: none"> • SOP describing data/study audits • GLP Study audit (in-lab inspection) process and documentation to include % audited <ul style="list-style-type: none"> ○ % raw data audited ○ % report audit ○ % of GLP studies audited • Describe phase audits • Form used to report audit findings and record corrective action 	
Staff	<ul style="list-style-type: none"> • Training SOP 	
SOP Review	<ul style="list-style-type: none"> • Table of contents • Provide copy of individual SOPs 	
Miscellaneous		