DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Headquarters - White Oak - CDER/OTS/OSIS/DGDSI 10903 New Hampshire Ave White Oak, Building 51 Industry Information: www.fda.gov/oc/industry	01/27/2026; 01/28/2026; 01/29/2026; 01/30/2026
	FEI NUMBER 3003581184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Xun Wang, Ph.D/ Executive Director of Bioanalysis

FIRM NAME	STREET ADDRESS
QPS, LLC	3 Innovation Way Ste 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Newark, DE, 19711-5456	Biopharmaceutical analytical facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1: The firm did not follow SOP TLM-005. Specially, during study [redacted] (b) (4) 's sample analysis, sample [redacted] (b) (4) was initially assessed in run 206 and the concentration was found to be 438 ng/mL. Sample was re-assayed in error and then subsequently repeated three time. The repeating of the sample analysis three time is not consistent with SOP TLM-005 section 5.6.

Observation 2: The firm had source records with discrepant documentations that did not allow complete reconstruction of freeze thaw cycle in method validation QPS-997-1704 data. Specifically, the aliquots used to evaluate 3 and 5 freeze-thaw cycle were not recorded in the source documentation.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	SYLVESTRE K. DOSSOU -S Digitally signed by SYLVESTRE K. DOSSOU -S Date: 2026.01.30 12:08:42 -05'00'	Sylvestre K Dossou, Ph.D./ Biologist	01/30/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."