



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER 19900 MacArthur Blvd., #300 Irvine, CA 92612-2445 (949) 798-7600	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: <i>Kevin L. Keim, Ph.D.</i>		PERIOD OF INSPECTION 1/5-13/99	C. F. NUMBER
TITLE OF INDIVIDUAL <i>President</i>		TYPE ESTABLISHMENT INSPECTED Contract Research Organization	
FIRM NAME Quintiles Pacific, Inc.		NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 10201 Wateridge Circle		STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) San Diego, CA 92121		CITY AND STATE (Zip Code) Same	
DURING AN INSPECTION OF YOUR FIRM (WE) OBSERVED:			
THE OBSERVATIONS NOTED IN THIS FDA 483 ARE NOT AN EXHAUSTIVE LISTING OF OBJECTIONABLE CONDITIONS.			
1. The following observation(s) pertain to the monitoring of study protocol [redacted] at one study site (timeframe [redacted]).			
a. The time for preparation and approval of at least 7 of [redacted] site monitoring visit reports ranged from [redacted] months.			
b. Eight of [redacted] site monitoring visit reports did not contain review/approval signatures.			
c. The firm failed to document that all site monitoring visit reports were sent to the sponsor: 8 of [redacted] were not documented. <i>See KSK</i>			
2. The following observation(s) pertain to the monitoring of study protocol [redacted] (timeframe [redacted] at one study site <i>See KSK</i>).			
a. The time to approve 8 of the [redacted] available final reports ranged from [redacted] to [redacted] months.			
b. The firm failed to document that 6 of [redacted] available site monitoring visit reports were sent to the sponsor.			
c. No report was found for the site monitoring visit conducted on [redacted].			
d. No final report was found for the site monitoring visit conducted on [redacted].			
e. Following final approval, correspondence indicates that it took [redacted] months to submit 7 of the available reports to the sponsor.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Robert S.K. Young</i> <i>Stephanie E. Hubbard, CSO</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Robert S.K. Young, Medical Officer Stephanie E. Hubbard, CSO/Allen F. Hall, CSO	DATE ISSUED 1/13/99

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<p>3. Although instances of suspected misconduct were described in detail by one of the firm's monitors at one clinical site and repeatedly brought to the attention of his lead CRA and his supervisor, the firm's relevant SOPs were not followed and consequently no determination was made as to whether the suspicions were or were not in fact true. The SOPs were entitled: Handling of Suspected Scientific Misconduct and/or Possible Fraud in Clinical Trials (SOP#:1008/01, dated 5/12/95) and Handling of Suspected Scientific Misconduct and/or Possible Fraud (SOP#:0643/01, dated 5/15/96).</p>																																				
<p>4. The firm did not ensure that study tasks were properly delegated in studies [redacted] and [redacted] one investigational site. <i>See page 1</i></p>																																				
<p>5. The following observation(s) pertain to the monitoring of study protocol [redacted]</p> <p>The firm failed to submit finalized site monitoring reports to the sponsor within [redacted] weeks of the site visit as required by the Clinical Research Agreement (effective date 1/20/98). For example:</p> <table border="1"> <thead> <tr> <th><u>Study Site</u></th> <th><u>Date of Visit</u></th> <th><u>Date of Final Review</u></th> </tr> </thead> <tbody> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> <tr> <td>site [redacted]</td> <td>[redacted]</td> <td>[redacted]</td> </tr> </tbody> </table>				<u>Study Site</u>	<u>Date of Visit</u>	<u>Date of Final Review</u>	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]	site [redacted]	[redacted]	[redacted]
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DURING AN INSPECTION OF YOUR FIRM (WE) OBSERVED:			
			
FDA-483 ANNOTATIONS			
ITEMS # _____ CORRECTED AND VERIFIED			
ITEMS # <i>1^{a-c}, 2^{a-e}, 5, 3</i> , REPORTED CORRECTED BUT NOT VERIFIED			
ITEMS # <i>4</i> , _____ CORRECTIONS PROMISED BY			
<i>By 1/14/99 firm will initiate training and documentation activities to address application of current procedures.</i>			
			
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