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To: Barbara Leczynski/DC/USEPA/US@EPA
cc: Rich Leukroth/DC/USEPA/US@EPA, david.menotti@shawpittman.com
Subject: R-5 QAPP for GLP Studies

03/15/04 01:51 PM

Barbara,

Thank you for the QA guidance you have given during recent ECA drafting committee discussions and for your plan to follow up on the issue of a potential redundancy or even conflict if a lab had to follow elements C1 and C2 of EPA R-5 QAPP guidance for a GLP study without the Agency giving prior study-specific guidance that work by the QA unit pursuant to Part 792.35 and related GLP requirements would satisfy what the Agency expects for elements C1 and C2 of a GLP study.

I look forward to our drafting committee discussion on the morning (8 am EST) of Monday March 29 and to any additional light you can shed on these issues via e-mail before then.

Thank you.

Best Regards,

Robert Giraud

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