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Orthopaedics

April 30, 2009

Jeffrey Gassman President, Validation Plus, Inc. 14 Penwood Road Livingston, NJ 07039

Dear Jeffrey:

"Thank you" hardly seems adequate for everything you have done over the past eight months with us in the IT Quality department. As you knew coming in, we lacked a full-time resource to manage our computer system validation activities and we expected you to be a proverbial one-man-shop. You did not disappoint – and all with only three working days per week.

I want to say up front, and without reservation, that working with you has been the best consultant experience in my corporate career.

Thanks to your experience, professionalism, good nature and diplomatic skills you brought the entire IT Team to a better understanding of what computer system validation is and when it needs to be done, and demonstrated how it can be done both smoothly and efficiently. I believe one of your best skills is your ability to put people at ease with the reality of validation as a required and value-added business activity. As the "V" word was not popular around here at the time that was a fairly extraordinary accomplishment.

Beyond the excellent work done on development of validation packages and guiding them to completion, you also shared valuable insight into industry direction on computer system validations, how the FDA view aspects of validations and how we could improve our process and forms. You willingly shared samples of types of documents we did not have, many of which we were able to easily mold into something perfect for our environment – saving us much time and effort as we work to improve our quality system.

Thank you, also, for teaching me things that have made me a better manager of a computer system validation function. I have thoroughly enjoyed the time spent talking with you, working with you, learning from you and yes, laughing with you.

I wish you continued growth and success. You have a winning formula that will mean great things for Validation Plus, Inc. I sincerely hope that our paths will cross again. It has been a pleasure.

Best regards,

Bev Bertenshaw

Manager, IT Quality Systems