

Jeff,

I want to thank you for your assistance on the FFL Project. Your focus on the "big picture", your attention to detail, and your identification of potential problems was invaluable. You developed a strategy to reduce protocol cycle times by 7 days (per protocol) and you identified 36 conflicts in the project schedule and recommended strategies to resolve them. Your early identification of schedule conflicts helped to meet key project milestones.

You also stepped in to perform critical PQEs which helped the facility maintain a state of compliance and your work on a critical summary report was instrumental in resolving a time-critical issue.

Drafting of serialization protocols for the Validation Engineer responsible for this project was key to maintaining a very tight schedule for qualification of this complex new technology. Your help with this was greatly appreciated.

You became an important Validation team member as your transition into our teams was seamless. Junior engineers developed an important reliance on your experience and guidance for their projects just as I sought your trusted counsel on many occasions.

Your industry experience, no-nonsense approach to issues, and your ability to sift through details to help the Validation department maintain a "big picture" view of complex issues and new technologies was instrumental in meeting tight deadlines while always keeping cGMP compliance a priority.

I wish you all the best in your future projects and hope that we can work together again.

Sincerely,

Boyd Nightenhelser

Manager, Validation

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