

Process Validation Proposal Email, March 30, 2012 - Ducord

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From: Gavin, Denise K

Sent: Friday, March 30, 2012 5:25 PM

To: 'Amanda Parrish, Ph.D.'

Subject: RE: For Review: Duke/CCBB Process Validation Proposal

Amanda

I discussed the confirmatory HLA test with Mercy.

Her question to you is "Why do you do the confirmatory testing?"

She said you could drop it.

Please replace it with a prospective analysis of current data...i.e. how frequently has there been a discrepancy between initial and confirmatory HLA testing in HPC-Cs tested in 2011? were these investigated or how is the discrepancy handled?

Submit that data analysis along with your process validation report as supportive data.

thanks,

Denise

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