

Message

From: Tschirhart, Donald [REDACTED]
Sent: 3/10/2016 6:34:02 PM
To: Kingshuk Das [kdas@theranos.com]
Subject: RE: Day One

King-

I think that we will have this wrapped around our finger in no time. I am glad to have you!

See you Monday at orientation, we can talk more then.

Don.

From: Kingshuk Das [mailto:kdas@theranos.com]
Sent: Thursday, March 10, 2016 9:17 AM
To: Tschirhart, Donald
Subject: RE: Day One

Hi Don,

Yes, the "bulldog" type of person will definitely help--I think they may already have one: Sonia. Will definitely take time to get to know all the strengths/weaknesses of personnel here.

Visiting AZ lab should be fine, no one will object, I'm sure. I'd like to harmonize all the processes and documents across all the labs, including the new one on PA, but first have to implement a strong program. In my experience, 85% of inefficiencies are process, and 15% are people--and this lab has issues on both fronts.

I'm going to focus first on the QC/QA, validation/verification, and reagent/calibration issues, as those programs will ensure quality test results--and then go from there--much work to do.

Elizabeth and Sunny have been fully supportive, so there's absolutely no issues there. They share oversight, depending on the issue, and it's been seamless, so no worries.

-k

From: Tschirhart, Donald [REDACTED]
Sent: Thursday, March 03, 2016 9:01 AM
To: Kingshuk Das
Subject: RE: Day One
King-

I am afraid that I won't be there before the 14th. Things have not been easy here, and I am afraid it is getting to that point where I will have to walk away without really accomplishing what I wanted to. Through no fault of my own, mind you; but still not what I wanted.

After I come up to speed on the corrective action report, we can sit down together and come up with a reorganization plan. We should make every attempt to slot current people into the new org. I am afraid that I know nothing of their strengths and weakness, so we will need the help of someone with that knowledge. I have here and I certainly want a

"bulldog" in a high level position who can get things done. I can see that we may have to bring someone like that in, but we can discuss that after the 14th.

I do think that one of us should go to Arizona for a day. I am going to be a bachelor for a few months until my son finishes school and they come up to join me, so I don't mind going.

Your proposal makes ultimate sense. When we have our proposal together, we will present it to Elizabeth. We will let her decide if this is something she wants to personally oversee or if there is someone else that should manage the day to day of it.

From: Kingshuk Das [mailto:kdas@theranos.com]

Sent: Monday, February 29, 2016 1:12 PM

To: Tschirhart, Donald

Subject: RE: Day One

Hi Don,

Yes, 2 weeks to go, looking forward to working with you!

I'll be there full-time that Monday as well--I've been going there 1 day/week in the interim. I can tell you that the CMS deficiency response is quite comprehensive, and addresses all the basic infrastructure that was missing (a LARGE undertaking) quite nicely--the clinical consultants and legal team did an outstanding job putting it together--I'm most familiar with the patient impact assessments, since that was my focus. The initial response went to CMS on Friday, February 12--and there's a revision in the works that may go out as early as today, but probably within 1-2 days. All the SOPs, competencies/training have been addressed--however, as you know, they'll need to be reduced to practice and monitored, which will be just as difficult (evidenced by the proceedings in recent monthly QA/QC meetings). Based on the SOPs along, I've got a long list of tweaks to introduce, mostly involving verification/validation procedures, QC/QA protocols, and reagent/calibrator qualifications--but the bones have been put in place nicely already.

If you want a copy of the original response in advance of mid-March, email David Zifkin, he'll be happy to forward one to you. As soon as the revision goes in, I'll have him email you a copy of that too. It is a large document, as you would guess--but really highlights some overarching themes, which won't surprise you a bit, but good to note. Let me know if you have any troubles getting copies.

The AZ lab appears to function well--but the nature of the deficiencies in Newark point to more basic oversight and education issues--and will need to be remedied on those levels, including structural changes, as you said. If need be, I've enlisted a couple of my top lieutenants here at UCLA, just in case--but hoping I don't need to pull them up there.

Regarding sign-off by Sunny, that makes sense--I'm not sure exactly how that is planned. I know for sure that I report directly to Elizabeth, and sounds like you do as well--but I'm sure Sunny is involved. That's probably a question best left for Elizabeth.

I'll be there this Wed, and next Thurs--and next Thurs is a meeting to discuss SOP/QC/QA reviews and designees, so if you can make it out that day, would be great. Sonia Cendejas (Operations manager of AZ lab) is organizing the 1hr meeting (1-2pm), so we may get some insight into the AZ lab that way as well. I know Lisa (Helfend) will be there, and she's only on-site on Thursdays, so you would get the chance to meet her as well (I haven't met her in person yet).

Best of luck with the remaining preparations--I know I've got a lot to do as well. Exciting adventures await!

Regards,
king

From: Tschirhart, Donald [REDACTED]
Sent: Friday, February 26, 2016 8:35 AM
To: Kingshuk Das
Subject: Day One
King-

Good morning, I hope all is well. I am moving as quickly as I can to establish myself up north, which has been a surprising amount of work. I am sure you are the same. I believe that we will both be there on March 14, so I wanted to talk about some of the prelims.

Of course we will need to review the inspection deficiency response, as it will be our burden to make sure the specified corrective action actually takes place. I would like for us to do that together, if that works for you. I think we both know that most of what needs to be done will require a change in structure, but such things must be done cautiously. From our previous conversation, I am sure we are on the same page on that.

The other item that I would like to move quickly on is a database for our procedures, competencies and training. This I believe is something that any modern lab should have; and is a prerequisite for transitioning to being CAP accredited.

One of the good questions is how is the Arizona Lab handling these issues? If they are truly functioning well, perhaps there is merit to one or both of us going over there and understanding what they are doing.

The last sticky part is that both of us answer directly to Elizabeth; but as these are all operational issues, it seems to me that Sunny should sign off on the changes before we go there. Do you have a feel for this yet?

Two weeks 'til Newark!

Donald L. Tschirhart, MD
St. Vincent Pathology Medical Group
Tel: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

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