15 DEC2020 PACT Web Seminar — Q&A Session

The following questions were asked during the PACT web seminar Q&A session but were not able to be answered live during the web seminar. For other questions and answers, please listen to the audio recording posted on the PACT website.

1. **How do your incorporate a biotech's SOPs into your own quality management system?**
   - ***Adrian Gee (AG):*** We would reformat them into our version and make any necessary changes – we would then send them to the company for review.
   - ***Allan Dietz (AD):*** Depends. If it has sufficient detail to meet our quality standards (but say differs in formatting), then we will put in the quality agreement an understanding that we will use it as well as confirm in our own quality system the ability to use it. Document control is difficult with external SOP, so this too (any future changes) has to follow mutual agreement and documentation prior to implementation. This is supposed to be a barrier to change to make sure we are all on the same page. Occasionally, we will transfer an SOP to our system. In that case we will have the company agree that our version of the SOP is equivalent to theirs. More work up front, but easier for document control and consistency in the lab.
2. **Can your customers use products you manufacture in your facility in trials within your own hospital systems or are there regulations that restrict this?**
   - ***AG:*** Yes we can use the products we made as long as we have a separate contract with them for their clinical trials.
   - ***AD:*** This is the primary reason we engage in contract manufacturing is to bring other novel products into our clinical trial testing portfolio. There are other benefits, but we are matching external tech, with our manufacturing to work with our clinicians to bring new therapies to our hospital.
3. **What would be a reasonable visit frequency by the biotech?**
   - ***AG:*** I think twice a year except in the case where problems arise.
   - ***AD:*** Depends. If we are talking about after all agreements are in place and we are executing on the manufacturing – then after the first product, after then on a regular interval (ie every fifth?) and/or annually whatever comes first. You have to have some trust but they also need to verify as well.
4. **Do you think it is absolutely necessary to have an FDA masterfile with respect to your facility metrics prior to starting contract manufacturing. Do your facilities have such a filing?**
   - ***AG:*** We have facility master files since we manufacture for so many INDs it was easier to generate the information in the form of a Master File. You are not required to do this.
   - ***AD:*** No. But what matters is what the company wants/needs. I think accreditation (ie. FACT) is probably better than FDA Masterfile.
5. **Do academic facilities need to register University/Hospital-based bio companies to make legal agreements and contract manufacturing?**
   - ***AG:*** Not to my knowledge
6. **What is a reasonable turn-around-time expectation for contracts, legal, budget?**
   - ***AG:*** It depends on the complexity but I would say AT LEAST 3 to 6 months at the fastest!
   - ***AD:*** 3-6 months.
7. **Can we get link for CE??**
   - CE credit is available to request for those who attended the live web seminar. If so, the link to complete the CE request and the attendee roster (only for those in a group/shared web seminar link), were provided in the email sent on 15 December. This must be completed by 22 December 2020.