PACT Web Seminar 13: January 29, 2009 "Qualification: Vendor, Equipment, and Supplies" Question & Answer Session Transcription
Speakers: Dr. Adrian Gee, Ms. Fran Rabe, and Mr. Chris Chun

Question 1: Can you provide examples of critical questions to ask on a vendor qualification checklist?

Fran Rabe: I think probably one of the most important ones would be; do you have a quality plan in place with your institution? I'd also ask questions like have you implemented all the core quality requirements within your institution and then spell each of those out individually: your training plan, do you have systems for equipment control, those types of things. Another important question would be related to their relationship with the FDA, had they ever had an FDA warning letter, things of that nature.

Question 2: How extensively do you perform a background check on an individual vendor the first time you plan on purchasing equipment from them and what sources of information do you use for this background check?

Fran Rabe: Well for purchase of equipment I think it would depend on how critical that piece of equipment is. Again I would probably do a risk analysis associated with that piece of equipment and based on that I would determine how extensive it is. With a really complex piece of equipment that's really integral to your operation and to your product, I might even do an on site audit of that facility or put together a really comprehensive checklist. I think Chris had some really good examples of some of those checklists, but as it relates to equipment you could ask very equipment specific types of questions.

Question 3: Regarding the vendor checklist and risk assessment, is there a standard checklist in use or does each facility devise their own?

Fran Rabe: I think in my own operations here, again, I had the different categories the A, B, C, and D and I think I would probably have at least a couple different levels of standard template questions that I would apply again depending on the criticality of that particular supply you are going to get from that vendor. And maybe you want to have the option on those templates of adding a couple extra questions that might be specific to that particular piece of equipment. I would control your checklist as a document, have these standard templates, but provide that extra flexibility by being able to add some additional questions that might be really specific to that particular vendor or that equipment or supply that you need.

Question 4: What is an approach to qualifying existing systems? Can the process be abbreviated and still be considered compliant?

Adrian Gee: For existing equipment, we still determine what the specifications should be in terms of performance and whether the performance in the past has met those specifications. We do try to keep the qualification abbreviated because particularly in retrospect you already should know that the equipment is performing. There are no hard and fast specifications as to what needs to be in the qualification, that's why I gave some of the examples from our own facility. Again, we put most of our emphasis on validation of a process, and performance qualification of

equipment for critical procedures. If we don't believe the procedure is really critical we keep it to the basics, as I showed in the operational qualification section.

Question 5: This question is in regard to the requalification after equipment changes. What should be tested after changes, for example, when the equipment is moved, repaired, or updated and what level of qualification is required?

Adrian Gee: Well again, it's a very good question and it's a difficult one to answer definitively because I think it depends on the extent of the move. If you're going to move it from one side of the bench to the other, you would do very little in terms of any kind of extensive requalification. If however the equipment has not been used for a year and has been sitting in one location and then you are going to move it three miles to a new facility, you would go through a much more extensive qualification. And again, the level of qualification will determine on how critical that equipment is to your process. So it's hard to be absolutely prescriptive in what should be done. I think it's a bit like the risk analysis that Fran presented in determining how critical is that equipment to you? If it's really critical, do you also need to go through a process performance qualification? If it's something that is less critical an operational qualification, just making sure that it still works to the manufacturer's specifications would be more than adequate.

Question 6: How often does a piece of equipment fail one or more of your five components of qualification and what action should be taken in response to a failure?

Adrian Gee: During the qualification procedure we've had very few failures. Most equipment, especially new equipment, unless it arrives in a damaged condition, usually works and passes at least the operational qualification. We haven't had, I don't believe, a piece of equipment fail a performance qualification, usually because we've been pretty critical before we've bought it as to making sure that it would meet our needs for a particular application. We'll talk to other users as to what their experience has been so the failure rate is fairly low. It again depends on the nature of the failure. If it's a mechanical failure we will get the vendor or the service that we're using to provide maintenance, to repair it and document what's been done. We would then go through either the operational qualification and/or a performance qualification depending on the nature of the problem that we have with the equipment.

Question 7: Is there a difference between validation and qualification?

Adrian Gee: Well, again I tried to allude to that in the presentation. There is a certain degree of overlap. I divided it in the way that we divide it here and I think it's open to interpretation by each particular center if you read the regulations. The validation really is of the process. We do a performance qualification which is really a kind of validation that that specific piece of equipment functions as expected within the process. So there is a gradation, a spectrum, between qualification and validation and that's why I recommend that validation is really directed more towards processes, and performance qualification is like a validation of a piece of equipment in a particular process.

Question 8: An additional difference between qualification and validation appears to be the word consistently. How many runs do you think is necessary to be consistent for a reliable validation?

Adrian Gee: To a certain extent again that would depend upon the criticality of the particular process that you are looking at. I think the minimum is three runs on anything to make sure that you have at least three examples where it's performed satisfactorily. If it's a really critical piece of equipment you may want to do something more extensive. It is not defined, the term consistent is not defined, and I think that's deliberate because it will vary depending on the critical nature of the equipment. If it's nothing that has a high risk impact, as Fran discussed then you will probably do it a minimum of three times. If it's something that is absolutely critical you may want to be more extensive.

Question 9: What have been your most common inspection problems with regard to qualification procedures?

Fran Rabe: I think one thing that's really important is to write your SOPs so they are flexible enough to handle different supplies and different materials. In other words, you wouldn't want to state in your checklist or procedure that all media should follow a certain line of qualification, so to provide some flexibility in your procedures. I think that people get locked in if they're too definitive and we all know the variations in different media. That's something I would suggest.

Chris Chun: Flexibility, yea I agree with you. The SOP that I provided, we wanted to be clear about what the qualification for that particular feature item was. Sometimes we got too carried away because we want to include all the information that our regulatory bodies say so we can cover ourselves, but as I've found in the Red Cross, it's very compartmentalized. We've got our own quality control/quality assurance unit that will come in, and even though we've developed them with the intent that we have, they'll come in and use those checklists and stick to the letter of the law. And quite often we can't go back and say "but this is what I meant," because as an independent unit, it's their responsibility to scrutinize those things. So provide a little bit of flexibility but still meet the intent of the regulation process.

Adrian Gee: I think the point that Fran made is absolutely essential. You don't want to lock yourself in because all of us use different degrees of assessment depending on the item; I gave the example of the criticality of different pieces of equipment. S o always bear in mind that you need to build in some flexibility into all of these procedures and all of the documentation that is associated with them.

Question 10: When potential suppliers fill out your questionnaire, how many unsatisfactory answers or responses to the questions would result in an unacceptable application to provide supplies to the American Red Cross?

Chris Chun: So again, in the Red Cross we have a whole sectionalized area of different areas but it does cross over into different departments that are applicable. Quite often those questionnaires will come back really not filled out as completely as we'd like, so the person who takes part in that, who's responsible for that, will go back and quite often have to coach them through. It helps us provide information as to exactly where they stand in their quality process as Fran indicated, even Dr. Gee. But we'll go back and continue to ask those questions. What's nice

about our process is, nationally we have a list of qualified supplies that we have undertaken and gone through. Disadvantage of that is when a new supply comes in, it has to go through the same rigorous process and so it's almost the urge just to go with whatever is on the qualified supply list, despite the fact that it may not be the exact thing that you want. How often does it come up short? Well we try to work with the supplier as close as possible to get the information that we need, and to feel and assure that we are going to have good quality not only from them but also from the product itself. I can't really off hand say because I haven't seen any real hard data and haven't been here long enough to get the sense of that. But if we really need something, it goes back out to what our colleagues are using and what has been their experience, and utilizing that information to help obtain what we need as well, especially if it's not on the qualified regulated supplies list.

Question 11: Do you verify every on-demand label against the template?

Chris Chun: You bet. Have to. In my previous facility we would print those labels and what we had found what I say needs to be verified and not outside of it's borders, is that we found a problem that when we were printing them certain individuals were printing on a different printer and the configuration would get thrown off all the time. So that is an example of you just can't trust what's coming off different printers. Well we finally decided we would stick to only one printer but that doesn't stop humans from being humans and using something that's more convenient. You bet. I take the regulation as that all labels need to be verified. We might take a bank of them that has been created in one certain time frame and maybe take the first, the fiftieth, the hundredth one and verify those in that batch but if we do, I mean each time that we create on demand labels we would. Definitely.

Question 12: For a supply qualification in determining whether validation is necessary, how do you decide whether a product or a process needs validation during a supplier qualification?

Chris Chun: Well, it all depends on the criticality, like both Fran and Dr. Gee were saying. How critical is it in the manufacturing process? And something I couldn't show you on this presentation nor do we have the time to talk about validation, obviously, is that we do have a validation checklist as well as it applies to certainly current good manufacturing practices. If it's critical in the situation that it needs to undergo a validation, then it goes through the checklist that determines; how many validations do we need, what kind of financial support is this going to take, so on and so forth. There are a number of different questions we have to answer to decide upon that. If it's something as simple as a new supply from a particular DMSO supplier or something, we would start off with three. First of all we would go out and obtain any documented evidence from studies that have been published. Working down from there, working with vendors and maybe getting their validation studies and then utilizing that as a template, but it just really all depends on what that supply is and what the criticality is.

Question 13: Do we need to request our vendors to comply with the FDA 21 CFR part 11 regulation?

Fran Rabe: Well certainly if you're purchasing any computer electronic systems that are integral to your operations you would want to do that. My understanding of the regulations is that it doesn't apply to things like your regular computer for doing excel and things like that. But say,

if you have a controlled rate freezer that's programmed or anything like that, any other programming, than yes you would want to confirm that they meet those FDA requirements.

Question 14: How much emphasis do you place on financial stability of a supplier as part of your vendor qualification process?

Fran Rabe: Wow that's a really good question, especially in this day and age. You know that's something I really never thought about. I think it really would be important because of the fact that you certainly want that longevity in that vendor. You don't want to commit to using just one vendor that might possibly not be around six months or a year from now. So I think that's a good point. I think that something to take into consideration.

Chris Chun: In our supplier qualification, those are the kind of questions we really want to get to because from a national standpoint it takes a great deal of work to get something to the qualified supplier list, so we want to ascertain that information to know what's the longevity or what's the potential longevity of this particular supplier, and in the instance we don't want to have to requalify or revalidate if we don't necessarily have to. It's not like we have a whole list of qualified vendors that we maintain for say DMSO, you know there's maybe one, maybe two. We want to make sure that we've done our due diligence in making sure that they're going to be around.

Question 15: Can we use any kit for cellular therapy testing that are not approved for screening but approved by FDA?

Fran Rabe: If we're referring to donor screenings or infectious disease screenings then those must be approved by the FDA and they must be approved for that function of donor screening. In other words, if you are doing infectious disease testing in a hospital or a clinic, frequently they're going to use a different type of test kit because they're not screening in the blood donor sense or in the sense of donating a product to another person. They're testing for diagnostic purposes.

Question 18: Can you comment briefly regarding the importance of having a back up supplier for supplies. Do you recommend having a back up supplier for all of your supplies?

Chris Chun: I'd love to have that at the Red Cross here, however it depends. It depends on the supply. Certainly throughout the nation there are different supplies that are used by different suppliers, so we have sort of a back up upon each other that we can go to and plus there's national contracts with us that makes it better in terms of ordering power or buying power. So we have that built in of sorts but there are esoteric things that we don't have that possibility to, especially in the cell therapy field where there might be only one or two. To undergo that extensive process might be too rigorous at the point in time that you want to, and usually it comes up at the critical point. So we'd love to have that in place if the money allows and the time allows but quite often it's not the case.