



EXCELLENT ADVICE ON HIRING AND WORKING WITH A GMP CONSULTANT

There are numerous pharmaceutical blogs on the internet; some of them good, some bad and some downright ugly! There is one, however, which is consistently excellent and should be read by everyone with a true interest in pharmaceutical quality management – it is called The QA Pharm (theqapharm.blogspot.com). We have no idea who writes it, but he/she clearly has plenty of industrial experience and a clear vision of how quality should and should not be managed. We have reproduced a recent blog in full below, because we believe it encapsulates all that we believe in and contains perfect advice for all companies seeking to hire and work with a GMP consultant...

SEVEN SUCCESS CRITERIA FOR HIRING (AND WORKING WITH) A GOOD GMP CONSULTANT

The high layoff numbers in the pharmaceutical industry and poor job prospects in a weak economy have flooded the market with would-be consultants to Pharma companies that need extra help. Here are my suggestions for hiring and working with a good GMP consultant.

1. DEFINE THE SCOPE OF WORK

before you start scouting for a consultant. There is nothing worse than throwing a bunch of consultants at a problem without knowing the boundaries of the project or defining the expected results. Unfortunately, it happens all the time. It ends in frustration for all parties involved, and the tragedy is nothing gets better.

A formal Scope of Work (SOW) helps both the client and the consultant to set expectations of each other and agree on basic assumptions that are critical to success. A draft SOW is the basis of a discussion with the prospective consultant, and the final version becomes a formal understanding that both parties can agree to. Sometimes it is beneficial to have an initial scope of work that is limited to a survey of the present situation with recommendations for an approach to the problem and a breakdown into phases or discrete chunks of work.

2. DETERMINE THE HARD AND SOFT SKILLS REQUIRED.

Consultants have been everywhere and done everything. If you don't believe so just ask them. Résumés are inflated and each universally saved their previous client from the jaws of destruction. Many arrive like a one-person wrecking crew. Their know-it-all and negative behaviours will overshadow any remnant of dignity that your work group has left.

Explore the range of skills necessary to do the job and ask pointed questions about how the candidate's skills were applied to previous situations. Some skills may be hard technical skills, while others may be the soft skills needed to engender trust and collaboration with your team. In the back of your head you should be thinking: "Will the skills of my people be better as a result of having worked with this consultant?"

3. THEY REALLY MUST HAVE WORKED IN THE INDUSTRY.

With due respect to my FDA friends, especially those who are now consulting, it really is better to hire someone who has actually made medicine, not just conducted inspections. The reason that FDA experience is highly valued is because the client thinks that they will get some insider perspective on what the right answer is or what the FDA is looking for at the next inspection. There are plenty of people who can tell you what's wrong, but fewer people who offer a range of solutions or who had been responsible in their careers for results.

Inspection results have never been and never will be the true measure of future performance. Look for someone who understands the complexity of operational, technical, social, cultural issues that must be considered when resolving fundamental GMP problems. Nothing replaces specific operational knowledge.



4. AVOID CAREER QUALITY ASSURANCE CONSULTANTS.

QA experience is important, particularly when it comes to designing the interrelating elements of a quality management system. But I am sceptical when I see a résumé that is all QA experience. There is nothing like having operational experience to fully understand the practical environment in which GMP systems reside. If a quality system is not practical and useable, then users will find a workaround just to survive.

Explore the operational experience of the consultant candidate and ask how that experience has made them a better QA professional and consultant. Also, there is nothing worse than a consultant that has 25+ years' experience only in QA and all at the same company.

5. DON'T WRITE OFF FAILURE.

There are some consultants who have had failures in their career. Or it may seem like a failure to you, and feel like a failure to the consultant. Experience has taught me that good people have been terminated for wrong reasons. There are those who were fired for standing up to the company against doing the wrong thing. Also, many older folks who have valuable experience were the victims of layoffs just because they were high in the salary band.

I know it goes against conventional wisdom, but be open to the person who you sense has a "history" that he or she is reluctant to talk about, or gaps in a work history. It's just not unusual these days, particularly in QA. I would take someone like that in a heartbeat over someone who had been in QA his entire career at the same company. (Talk about someone who has learned to keep his head low!) It's more about the lesson learned, what they did next and whether it built character.

6. KEEP ENGAGED WITH CONSULTANTS AND OWN THE PROBLEM.

Unfortunately, some companies in trouble with the FDA hire consultants in the same way they would engage a contract manufacturer. You cannot sub-contract your problem. Just like a CMO, you are still ultimately accountable for results and managing the relationship. There will be no sympathy at the FDA District Office if you whine about your consultants.

The consultant and the client need each other to succeed, so keep the lines of communication open. Rarely can management solve a problem without some consultant help, and for sure a consultant cannot do it alone. Quite often, the underlying problem touches upon the bigger issues of company culture and leadership. The consultant needs the forum to openly discuss these issues.

7. DON'T OVERCOMPLICATE THE OVERSIGHT.

Consultants are typically involved in project teams that are comprised of client system owners and subject-matter-experts. While there must be management oversight, these project teams need to keep focused on getting the work done. The last thing you need is to have them distracted by preparing tedious PowerPoint updates and administrative activities to multiple layers of oversight and stakeholders.

I have always said that in the absence of real work, administrative activities will creep in and fill the void. Be sure that the consultant and your people who comprise the team are allowed to focus on what you chartered them to do.

We could not have put it better ourselves!

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