



High quality, lack of quantity

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So, you lead a manufacturing plant and you are looking for a senior QA/QC professional to lead your quality team. You have heard about manufacturing sites closing left, right and centre, so you feel that the market must be flooded with quality professionals eager for a new role. However, you may be shocked to find that there is an industry shortage of “quality Quality people”. You should be reassured that you are not the only one who is struggling to find that dynamic character to implement new 21st-century quality systems across your plant. Manufacturing sites across Europe, in both pharma and biotech, are struggling to fill attractive senior quality roles with the right calibre of candidates.

As the industry looks to tighten its belt on costs and provide drugs produced at cheap prices, quality remains a hot topic. There is now not only the threat from generic competition, but also from emerging markets, where labour costs are vastly cheaper. The problem is simple: how do you keep the production costs of your drugs to a minimum, and yet maintain a very high level of quality?

In operations, we have seen the introduction and implementation of far eastern philosophies such as Kaizen as a solution to this problem. These processes, which have been long-standing in other industries, are aimed at reducing production costs and increasing throughput of products. Processes like Six Sigma are now common tools in the armoury of most operational managers within our industry, yet remain rare in the experience skills-set of quality assurance/compliance professionals.

Over the last decade, pharmaceutical companies have drilled quality and compliance into their QA staff, but now the industry is becoming more dynamic, quality is looking to catch up. Not only are QA professionals now required to have an intimate knowledge of the regulations, but they also need to be able to be strong relationship builders, to improve the perception of QA in the manufacturing environment. In fact, the way in which QA professionals are viewed has changed over the last couple of years.

Traditionally, the QA professional has been seen as the “police of the plant”. Working alongside but not with operations, the QA person ensures that everything is run according to the regulations. I have heard various stories of QA and manufacturing directors in headlock over operational processes; and such urban legends as senior QA staff lying-down in front of laden trucks leaving the plant, because they believed the batch was not regulatory compliant.

Recently, however, there has been a change in viewpoint of the quality function. There are now initiatives in place to integrate QA and operational staff better, so they work closer together. Through training schemes, production staff are becoming more quality-conscious, thus reducing the need for large QA/QC teams. Terms like Six Sigma Quality



are starting to emerge in the manufacturing environment.

In the highly-regulated life science industry, quality is of utmost importance in any manufacturing site. It is a very brave site director who does not treat quality with the highest priority, with some highly publicised cases of when quality standards fall. Despite there being some very attractive roles in the market, especially at executive level, there is a vast shortage of candidates who possess the type of experience recruiters are looking for.

Pharmaceutical companies are typically looking for their quality directors to not only possess a strong knowledge of the regulations, but also be dynamic leaders, who can initiate some of the aforementioned principles. They are expected to be fantastic relationship builders, with demonstrable experience of successful change/conflict management.



However, as many of the aforementioned ideas are novel in QA circles, there is a shortage of properly qualified professionals to fill key senior-level positions. The QA staff who are familiar with these new principles are often too light on managerial experience to take on the important, director-level roles.

The main problem is the lack of experience in certain areas within the industry. This problem has not come about due to a shortage of talented QA staff. The main reason for the low numbers of top-level candidates in the industry is the career path of the QA professional. With such a high demand for QA staff (especially those with QP status), many candidates have taken the contract/interim career route and now work as consultants. In these roles, they can attract far greater remuneration packages, as well as maintain a greater flexibility in their professional life; translating to a better quality of personal living. Once on an interim career path, it is very hard to tempt these candidates back into a permanent position.

An interesting point made by a site director I spoke with on this subject was as follows: "We have trained our QA people for years to know nothing but compliance. Now we want them to be dynamic, it is no wonder that we are struggling to get the right people".

So what is the solution to this problem? Is it something that can be sorted out by retraining QA staff to be more dynamic? Perhaps. However, much of the problems stems from mind-set: the phrase, old dog, new tricks comes to mind. So here are some of the solutions that I have seen in industry:

Technical QA: Managerial QA model

In this solution, two QA people perform the traditional QA Director role. The managerial QA professional will have the line and budgetary experience needed to provide adequate leadership of the QA team. The technical QA professional will lead continuous improvement projects within the QA function. This model is borrowed from manufacturing operations, where operational excellence staff champion projects to improve production. The technical QA position would be part of a QA manager's experience skills-set, on the way through to a senior line management position. This model is attractive, as it not only provides a short-term solution to the QA staff shortage problem, but also will guarantee the training of a whole pipeline of dynamic continuous-improvement-trained QA staff to fill the senior QA director's role in the future. The drawbacks will come from trying to integrate this role into the current QA team. If the technical QA position is made too junior, then no staff will want to perform the role. If it is made too senior, then the managerial QA position will feel under threat, and conflict may arise. However, pitching this role at the right level will ensure high quality is maintained, and production is improved.

The Rotation Model

If succession planning is not part of your business plan yet, and you are more worried about the present lack of staff, then the rotation model might be employed. As mentioned in the last solution, operational staff have been rotating in and out of operational excellence for years. Maybe this rotation could be expanded to include quality. This will mean that senior operational staff will have a secondment into a senior quality role before taking on a large director-level position. There are two main advantages of this model. There is a quick-fix solution to the lack of quality leadership, and your next-generation site directors will have experience of leading both quality and operations. This model would be a temporary fix, until the more junior QA managers can mature into a senior QA position.

The downside to this model is the morale of your quality team. Bringing in operational staff to lead QA functions may lead to unrest in your QA team. The type of candidate will have to have outstanding influencing skills and gravitas, in order to be credible in a function that is not their main profession.

The Interim model

As so many good QA professionals turn into interims, and as the shortage of staff is a short-term problem, then why not hire a good interim? There are several benefits for taking the interim route. An interim will typically possess more experience than the role requires, so there will be no problems about lack of gravitas etc. Also, as interims operate in many different working environments, they can bring the knowledge they have gained about best practices, and translate them into your manufacturing environment. However, all this experience does come at a price. A typical Quality Director may cost you (on average) £700-900 per day, perhaps more than that if you are targeting a specific skills-set.

These are all suggestions lifted from examples I have personally come across in industry. One hopeful sign is that problems appear to be short-term. As more people are trained in Six Sigma Quality and other new QA techniques, the gap in experience will close. Hopefully, this article will also highlight the importance of training and retaining your best QA staff. A solid training scheme and thorough succession planning may be costly now, but will save you months of time and money in the future. Appropriately incentivising your QA staff throughout their careers will ensure that less people are tempted by the interim career-route, and thus your senior-level quality positions will become easier to fill in the future.



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