

The

7

Deadly Sins

of Quality Assurance and Quality Control

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Pharma IQ eBook

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# The 7 Deadly Sins of Quality Assurance and Quality Control

The Seven Sins of QA and QC are those transgressions which are detrimental to quality and profitability. You will probably commit some of them every day. We asked the global pharmaceutical community what they thought were the biggest sins that people commit in quality assurance and quality control and the same ones kept coming up over and over again.

- 1 Not detecting and addressing quality early in the project/product lifecycle before it becomes an issue**
- 2 Carrying out Internal audits after key people have left the organization**
- 3 Failing to cross train for “linchpin” functions**
- 4 Not carrying out gap analysis of QA/QC function in concordance with existing pipelines**
- 5 Failing to identify what is required from a process/product/analyzer etc and therefore how to test it, define acceptance criteria, and decide whether the criteria have been met.**
- 6 Not thinking from the end user side**
- 7 Documentation errors**

And one more for good measure:

**The willingness to accept a result you want, and not a result you don't want.**

So are you a QA QC sinner or saint? [Find out here](#)



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# Putting “Quality” Back into Your QMS

By Jon Wetzel

From a high level perspective a Quality Management System (QMS) is great but to the lab workers it's more like a pile of “red tape” that stops them from doing or improving their work. Here's what you can do to put the “Quality” back into your QMS.

**“Something is wrong if workers do not look around each day, find things that are tedious or boring, and then rewrite the procedures. Even last month's manual should be out of date.”**

*-Taiichi Ohno, former Toyota Executive Vice President*

**Forget the “suggestion” box and give them an “implementation” process.**

Great ideas are left on the lab floor because the workers are only told to make suggestions about improving the process but not given the empowerment to implement the ideas themselves.

Much of a QMS is about control. This control should rest in the hands of the people on the bench actually doing the work. They are your experts and have firsthand knowledge of how best to improve their work stations.

Give them a process by which they can get approval to test and implement solutions on their own. Remember: Workers manage the process...Managers manage the people.

**Streamline the approval process for implementing new SOPs.**

There is nothing more demoralising then to take someone's passion and hard work and give them the response “Thank you, we'll put it on the agenda for the quarterly QA meeting.”

Would you wait 3 months to implement a process that would make your job easier? I wouldn't, you wouldn't and neither do most other employees.

This is why most company SOPs don't actually match up with what is physically being done in the lab. Workers will normally just implement new improvements without tracking them.

You should have a target of 24-48 hr turnaround on signing off new SOPs. If that's not possible then you need to do some Value Stream Mapping on your SOP review process and discover what to change to meet or exceed that target.

**Employees are also the VOC (Voice of the Customer) for any QMS**

“Build it and they will come” works for Kevin Costner in “Field of Dreams” but it's not going to work for your QMS.

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For your companies QMS to function it needs to fulfill 3 main requirements:

- Satisfy compliance with: ISO, TQM, Baldrige, EFQM, GXP, FDA, CAP, CLIA, AATB or any other certification or affiliation you're working with.
- Adheres to your customers expectations in how you operate your business.
- Is simple enough to allow your workers to get their work done while wanting to improve their processes.

### Ready to take the temperature of your QMS?

Here's a simple test to see where your QMS really stands.

1. Go thru your active SOPs and find any that are older than 1 year.
2. Take the SOP to the work area and watch the process. (Going to the Gemba)
3. See how close the SOP is to the actual work being done.

### Are you running a high QMS out of tolerance fever?

- Don't freak out.
- Don't point fingers or play the blame game.
- Ask the workers what the best way is to get everything back up to speed.
- Empower them to get everything back on target.

**When you pay your staff to do a job with their hands you also pay them for their experience and intelligence.**

**It's your job as a company to find a way to harness that. That's what it takes to be "Best in Class".**

# 65.2% of Pharma Professionals Need Clarity on PAT and QbD Regulation Submissions

By Andrea Charles

Whilst companies seek to embed Process Analytical Technology (PAT) and Quality by Design (QbD) initiatives into their wider business to increase product quality and process efficiency, many still face uncertainty with regards to the regulatory review process.

### Regulatory uncertainty

A recent Pharma IQ survey conducted on behalf of the 8th Annual PAT and Quality by Design with key members of the community revealed that 65.2 percent of PAT and QbD professionals think more

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... clarification is required regarding PAT and QbD regulation submissions and that only 13.3 percent of participants have successfully filed using the principles of PAT and QbD.

### **Investment in process and operational excellence**

These regulatory challenges however do not seem to be deterring companies from investing in process analytical technologies. “The benefits of implementing PAT will not be dramatic in the short term. It is an essential investment for companies that seek continuous quality improvements and sustainable development over a long-term period,” said Rajabhadur V Arcot and Piyush Dewangan from the ARC Advisory Group, in [Process Analytical Technology Helps Pharmaceutical Companies Capture Process Knowledge and Achieve Operational Excellence](#).

### **Many companies already recognise the benefits of PAT to help them achieve process control and increase product quality.**

In a recent Pharma IQ interview about the effects of applying PAT to pharmaceutical manufacturing and PAT validation, Martin Warman, scientific fellow, analytical development, Vertex Pharmaceuticals said: “The number one impact is much more robust processes, not only is there a great control over variation, causes of variation. It actually means we have a degree of understanding in the process, parameters and the impact on the product”.

PAT is helping companies to attain their QbD goals, as the study revealed 25.6 percent of survey participants are already actively applying PAT tools and QbD principles to multiple products and 15.6 percent are applying PAT tools and QbD principles to one product.

According to Frost & Sullivan report entitled [World Process Analytical Instrumentation Markets](#): “The pharmaceutical industry's process analytical technology (PAT) initiative and global green environment initiatives supported by regulations are poised to drive the demand for process analytical instruments in the next couple of years.”

“The competition in the total process analytical instrumentation market is intense, with large conglomerates competing with niche market participants. Multinational participants account for more than half the share in this market,” said the report

### **Greater QbD adoption**

The industry is also poised for greater QbD adoption. Nearly 70 percent of the survey participants said that their company had a specific change management strategy in place for better QbD adoption throughout the company. QbD is also receiving attention from regulatory bodies such as the FDA and EMEA who are now actively seeking applications with QbD concepts. Successful communication between both parties will be key for the success of QbD implementation.

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# Ensuring High Levels of GCP

By Helen Winsor

Amer Alghabban, head of GCP Auditing Group at Merck Serono, joins Pharma IQ to discuss the implementation of GCP and effective auditing of clinical trials.

**Pharma IQ:** Amer, hello and welcome. I'm pleased that you could join us. Now first of all where do you think that the main challenges are in ensuring high levels of GCP at the moment?

**A Alghabban:** I'll start with the top of the pyramid downwards and I would think, in my professional opinion, that the consistency between the regulatory alternatives on the compliance with GCP and the implicit and explicit interpretation of the regulation would be the first challenge that we have been facing in the past few years.

The second one would be a consistency among us GCP professionals in the same way. You would always hear from auditees if you were collecting feedback that... certain auditors who have done the same audit of the same scope, they come up with different results and this tends to pose a challenge to us in the sense that we are regarded as very credible people who look at the compliance and interpret it in a certain way. The expectation is that we interpret it more or less in the same way. That doesn't always seem to happen, but it is the same issue as you find between regulators and even between different inspectors, regulation inspectors, and their interpretation.

The third one I would say would be the lack of consistency in the training that we provide to GCP auditors, for example. There is not set requirement. There is no set auditor qualification.

People have been working on the concept, but I don't think we have reached the point where we could say that we have a universally accepted role.

The fourth one I would say that unfortunately still in the GCP-affected industry we do not have quality built in the GCP affected systems and processes. GCP professionals, they tend to come right at the end of what's been implemented as a process or building of a system and therefore it is a bit late in the day to correct things and we are seen as people who clean and correct processes and systems. Whereas if our input is taken right from the beginning, many of the mistakes or the non-compliances with GCP wouldn't even have taken place.

**Pharma IQ:** And what technologies and solutions do you employ over at Merck in order to address these different challenges?

**A Alghabban:** Not all of these things, of course, can be addressed from the pharmaceutical point of view working in the pharmaceutical industry, for example, how the regulators interpret their own regulation and the inter-inspector differences. But at Merck Serono we are working on auditor specification, for example, to have harmonisation.

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As with any big organisation like Merck Serono, we have GMP auditors. We have GOP auditors. We have GCP auditors and the peripheries. So we are currently working on auditors' certification so that we have some harmonisation at least in the training of the auditors to be.

We also take the chance of being involved in forums like yours, the one that has been set up by your organisation, the IQPC, and having dialogue with the health authority representatives on certain issues, on certain grey areas in GCP, for example.

And we have also taken many initiatives in building quality in the form of starting the processes and systems so that quality assurance is always involved from the start of a clinical trial rather than at the end when we come just as auditors. So these are kind of a few of the solutions that we have... that one should adopt in confronting these challenges.

**Pharma IQ:** Thank you. And obviously there's a lot of hype in the market about quality-based risk management. Is this something that you think will provide benefit when auditing?

**A Alghabban:** Indeed. Of course, risk-based quality management is a relatively new concept to risk mitigation. In the end, one has to identify the critical linkage to the requirement and to the requirement to civilities. In developing these requirements, you have to consider both the business and the IT risk of the various capabilities. And if it is not a quality based, to be honest, I would wonder what it would be based on. Risk management, at least within our world of GCP, has to be with equality of the clinical practice. And if it is not risk based, the scope will be far, far too wide, and there will be huge inconsistencies between professionals working on risk management.

**Pharma IQ:** And can you tell me about your experience with the application of electronic data capture?

**A Alghabban:** Yes. As you know, the ETC has got electronic data capture. Now, it's becoming almost a standard. In my last years of audit management, to be honest, I can't even remember when was the last time we have done an audit on a trial which was still paper based. So electronic is definitely here to stay. I think we are past the teething phase of ETC, but there are still a few challenges that one has to counter and face.

**Pharma IQ:** Sure. What are the main challenges in satisfying regulatory criteria during audits, and how do you ensure first-time approval?

**A Alghabban:** By which, do you mean the regulatory criteria and their satisfaction, the health authority criteria in how we do audits, is that what you're referring to?

**Pharma IQ:** Yes.

**A Alghabban:** As you know, the health authorities have never stated what sort or capacity of the audit plan you would need to pursue in your organisation to be what is called, 'satisfactory'. Each organisation has adopted its own standard. Just to give you an example, some would say, 'well, for Phase II trials, we would do 10% of size generating one-third of the data'. There isn't any standard that the authorities have provided that the industry can follow.

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So the industry has followed its own and it tries to reach a level where in its quality assurance opinion it is satisfactory.

And they use, in general, similar criteria in that they cover the site which has adequate data generation capacity to ensure that they have a good representative sample. And that is really, at the end of the day, the argument that one would put to the health authorities to say, our audit lab, for example, has covered size which generated at least 30% of the data. Also, I don't think any organisation can reach that, or at least between 10% and 30% of the data generating aspects should be covered by the audit.

**Pharma IQ:** And I guess this really merges with the next question. Please could you explain to us the different approaches that you've used in the past to ensure regulatory compliance, giving the various steps that you would recommend to others?

**A Alghabban:** Compliance, in the past, used to be something that one would refer to the quality assurance side and say, 'is this compliant?', and by means of auditing, as you know.

But the way forward, as I alluded to earlier, is to ensure that quality assurance is involved at the very early stages. You would hear stories where auditors would tell you that they go to a site. Say, for example, an independent external auditor would be recruited by a sponsor to go to a site and he or she will find that the flaw is actually not of the wrong doing of the site. It is rather the complexity or the way that the protocol has been set up.

So what that means is that one would wonder whether quality assurance had been involved right from the beginning, right from the set up of the trial, from the concept sheet, from the protocol design. You would find a lot of the times that findings, or non-compliances by clinicians, for example, are mainly due to the fact that the complexity of the study was just almost designed to have faults rather than completely exclude them. So that's where the involvement of quality assurance is absolutely paramount in all the stages of the clinical development.

**Pharma IQ:** Thank you. I'm sure that's going to be of real interest to our audience also, so thanks for that. Now, the Clinical Trials Directive is currently up for industry review, with the potential of an updated document being published in 2012. In your opinion, what needs to be brought up to date and what are the likely implications of the revised directive?

**A Alghabban:** The Clinical Trials Directive, when it came out initially, we all knew, of course, that it will have to have many changes and sculpturing to ensure that it is a workable regulatory tool, in that it was the first of its kind. The GCP was lagging behind GMT in producing statutory instruments for the industry to use.

But in summary, of course, nobody's unanimous on these opinions, but in general what you hear in the field is that people would hope that the improvement or the update of the Clinical Trials Directive would include the allowance for a single clinical trial application for multinational trials. Hopefully it will have the implementation of a single clinical trial application dossier.

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It will have an amendment of the Directive to allow core sponsorship. It would have a regulatory oversight proportionate to the risk of the clinical trial. It will have a single ethical opinion for Europe with a national input rather than each country having to have the approval of its own central ethics committee.

If we are working towards a regulatory approval in a single point in all of the European Union, it makes only sense that we have the ethical approval in the same way. It would have a single application into a central database rather than individual databases and hopefully there would be an agreement on the definition of the investigation of medicinal product, substantial amendment for known interventional trials and also for the financial support for infrastructure and insurance requirements for academic trials not pharmaceutical as a sponsor.

And one would also hope that there would be something like a governmental support for insurance requirements to cover trial protocols.

**Pharma IQ:** And moving onto effective communication and relation management with CROs and trial partners, do you have any tips for effective communication and what are the implications of poor communication?

**A Alhabban:** Indeed, the CROs are considered by the health authorities as the sponsor. There is no distinction in the regulatory terms, in the eyes of the regulator, between the sponsor and the CRO. As such, the sponsor on their part should really consider CROs as an extended arm of their company and they are indeed an extended arm because they have delegated powers which they otherwise would have done themselves.

So the quality of selection of a CRO to start with is absolutely paramount. The selection process is therefore immensely important and it is also looked upon by the regulators during the inspections very thoroughly indeed and quite rightly so because if we are dedicating a very legally regulated task to a third party, one would have to ensure that the entity that you have selected is capable, has a quality built in and so forth.

Taking that into consideration, once you have gone into an agreement with the CRO, the communication is paramount, you have to have what is called a preferred partner and indeed it would be a partner - and with a partner one has to have, logically speaking, absolute good trusting and transparent communication.

If communication goes wrong, one has to remember that while they are an extended arm, while they are a partner they are still a separate legal entity, they have their own systems.

They have their own way of doing things. They have their own personnel. You are not really involved in the hiring and firing in that organisation. One has to have continuous transparent communication to ensure that this bridge is absolutely functioning all the time and indeed it would materialise in what one would call an extended arm.

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**Pharma IQ:** Yes. And do you have detection and escalation strategies in place?

**A Alghabban:** Indeed. This is an absolutely important aspect here because what you find is that if there isn't a very solid water-tight escalation process, that an issue might be identified by the personnel of the CRO.

This might be escalated within the CRO organisation that if that escalation process is not jointly agreed upon by the sponsor and the CRO, this would not reach the sponsor in time. You will have actions being taken that the sponsor probably might not have agreed to and this would of course lead to a huge non-compliance in the eyes of a regulator inspector.

**Pharma IQ:** Obviously at the moment there are a lot of cost-cutting pressures, industry-wide. Where do you see the areas that you can cut cost during clinical trials and auditing and what different measures would you say that you can take?

**A Alghabban:** Again it's a very sensitive issue here. As most, if not all, of the quality assurance GCP professionals will tell you that they work in a very under-resourced environment and as we have alluded to earlier in the previous question as to what is the regulatory expectation from the industry with regard to the auditing, you will see that in most cases the quality assurance resources are never in full swing as it were in trying to achieve the increasing demand, increasing involvement of quality assurance GCP professionals.

As we said earlier, the involvement should be much earlier and, of course, if they are not involved just in auditing, but they are involved in the clinical development processes and in auditing the documents as they evolve, of course this all means resources.

So I would really categorically say that cutting resources in quality assurance and GCP quality assurance would be very detrimental and it would be very, very counter-productive because to correct mistakes at the end of the day it's far more costly than correcting them or preventing them right at the beginning.

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# Getting to Grips with Stability Testing and Regulatory Compliance

By Helen Winsor

Find out more about the challenges in pre-and post-release stability testing and formulation. In this Pharma IQ interview, Claire Willsher, head of analytical development at Lifecycle Pharma, discusses the technologies being employed by Lifecycle Pharma to pre-empt these challenges. Willsher also offers her perspective on [Quality by Design](#), cost-cutting and how to achieve regulatory compliance.

**Pharma IQ:** Claire Willsher, head of analytical development at Lifecycle Pharma, joins Pharma IQ today to discuss [stability testing](#) requirements. Welcome, Claire. Thank you for joining us.

**C Willsher:** Hello.

**Pharma IQ:** So, Claire, just to start off, where do you think the main challenges are in pre-stability testing at the moment?

**C Willsher:** I think the main challenge at the moment in pre-stability testing is the fact that we tend to focus a lot on chemicals, for the chemical side, for the chemical stability. And we don't really look at the physical attributes so much in pre-stability. And I think that this is an area that we really need to work on. We need to work hard to look at polymorph and active pharmaceutical ingredients (APIs), excipients, etc, and that kind of thing. And I think that that's the main challenge at the moment.

**Pharma IQ:** What are the key challenges in stability testing and formulation, and also, what technology do you employ in order to pre-empt these different challenges?

**C Willsher:** Challenges in stable formulation, making a stable formulation - that's a challenge in itself - or, in reality, the key challenge. So, identify your most stable formulation as early as possible during development. We want to do this to avoid formulation changes at a later stage, that can lead to really costly bioequivalent studies.

So, during formulation of your products, it's important to identify early on compatible excipients; and know the degradation pathways, so that you understand your API as much as possible, then that way you can identify the best formulation routes and initiate any stabilising compounds where you can see that there may be possibility issues.

There are a number of tools available for you to look at this kind of thing, and I think those utilised most are forced degradation of excipient compatibility and stability as early as possible. One thing again I'd comment on is to remember to monitor both the chemical and physical attributes, especially when you're using fluid systems.

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As I said, we tend to focus on the chemical stability, and it can lead to some not-so-nice surprises at a later stage. To do those kinds of things, obviously you need have an effective chromatography system in place. It needs to be a stability indicating method. At the early stages, it doesn't have to be as vigorously qualified as it does at later stages, but you still want to ensure that you can monitor all impurities and get reliable results.

All the challenges include the normal cost versus stage of development, return on number of samples – that kind of thing. And when to perform those kind of analysis varies from company to company. The use of ultra high pressure liquid chromatography and improved common chemistry nowadays means that sample volume is becoming less of an issue. I think in research and development it's always going to come down to where we can get the most information for the smallest cost, both monetary and resource.

What we do have to remember is that we need to be disciplined and avoid the temptation to say, oh well, it's not so stable, but we can do something about the packaging to do that. We need to choose our most stable formulation; it might not always be the nicest formulation, but I think the best companies, they have the best decision-making skills, and they're not afraid for the quick-kill approach.

**Pharma IQ:** There is a lot of hype in the market about Quality by Design throughout the product lifecycle. Now, specifically within stability testing, is Quality by Design something that you think will provide benefit?

**C Willsher:** Quality by Design - or QbD, as we know it - is the new buzzword. The authorities undergo cutbacks just like the rest of us. They're looking for features that can assist them and make their lives easier - something that we all do. I can see the benefits within manufacturing of employing Quality by Design or PAT testing; however, specifically within stability, I'm not so sure that it's something new that will revolutionise the way that we do things.

If you look at what is QbD really, it's a way of looking at factorial design of experiments, and using your scientific knowledge to ensure that your product quality is maintained, and what you're putting in is a quality product. However, if you look at ICH (International Conference on Harmonisation) guidelines, in particular Q1D, this discusses how to utilise bracketing and matrixing to minimise the amount of samples required to gain your maximum amount of knowledge about your product. This guidance has been around for nearly a decade or so now. I'm not sure how that differs from the description of what Quality by Design is. I think within stability, we're already doing Quality by Design as much as possible.

If you took the absolute description of Quality by Design to its absolute maximum extent, you perform the majority of your stability on scientific knowledge: one strength may be a couple of pack configurations, tutorial designers, five or six strengths in three or four pack configurations. Do we really think that the authorities are going to approve our product? So, I don't know if it's true. I'm not sure that Quality by Design is something that's going to be new and revolutionise the way we do things in stability.

**Pharma IQ:** What are the main challenges in maintaining regulatory compliance for post-approval pharma products?

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**C Willsher:** I think there are a number of challenges in post-approval compliance, and I think that many of them are area-specific; whether it be chemistry, manufacturing and control or clinical, we have different challenges. One of those that a lot of people trip up on is the constant improvement of analytical technology, and everybody wants to be cutting-edge. If it's not broken, don't fix it. It's not always a great idea to constantly change your methods or your processes just to keep up with the new trend.

However I think for me, personally, what I find the most challenging is classifying what is a major change, what is a moderate change, what is a minor change to the product, and then how to handle that change with respect to your filing or contacting the authorities.

Both the [Food and Drug Administration](#) and the European Medicines Agency do have a general description of what the changes should be classified as in their guidance for post-approval requirements; however, these descriptions are a little vague and they're not very specific. So, that's where I find the most challenge.

**Pharma IQ:** Please can you explain some of the different approaches you have used in the past to achieve constant compliance?

**C Willsher:** I think the simplest thing that you can use is a good change control system. Other valuable tools, I found, are REMS – the risk mitigation evaluation strategy – the use of decision trees to lead to creations and documentation evaluations, and finally, the actual implementation of the change, I think, helps in many situations. There's one thing that I really like about this process – and it's really interesting and often very inspiring – it's the meeting of minds from different viewpoints.

Often in these processes you have representation from a number of different departments or specialities, and it could be really interesting to see how the different people from the different viewpoints can brainstorm and bring things forward that you don't necessarily see or you hadn't even thought about. I'm not saying it's always easy, but it definitely helps that process along.

Again, the final piece of that process - the implementation of the change - is eased along by a good change control system. I'm sure there are very many other valuable tools out there, and I think the ideal one is to find something that works for you.

**Pharma IQ:** Obviously at the moment stability testing is an area where there are a lot of cost-cutting pressures. What do you see as areas where you can cut costs and what different measures can you take?

**C Willsher:** I think in today's financial climate with big company mergers and small biotechs folding under the strain of cost-cutting, it's part of everyday life. When you compare the cost of a phase three clinical trial to the corresponding stability support or primary stability, the cost concerned with stability, it's a drop in the ocean. However, it's often the stability that is the place where you have to find ways to save money. To maximise your cost efficiency, you've got to look at a number of things, I think, including the possibility of outsourcing large chunks of your studies.

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Sometimes that gives you advantages compared to utilising the resources you have in-house. Where this may seem contradictory within itself, if you've got a good relationship with your contract manufacturing organisation (CMO), then for large amounts of work they'll provide reasonable rates, especially at the moment.

They're also feeling the effects of this financial climate and they're also looking for work. One thing I do want to point out here is that there are a number of CMOs being started at the moment in the wake of all these redundancies in the business, where I would say the majority of them are really good. There are an increasing number of not-so-good ones, shall we say.

So, I'd say, when you're outsourcing your stability, cheapest is not always necessarily the best. Also, looking at the quality requirement, and the study that you're performing, often you can charge less for GMP studies, but still perform according to ISO or GLP, and it's worth taking advantage of that, if you don't require full GMP requirement.

I'd say that also one of the things that we have to focus on during the lifecycle of development is learning the difference between the nice-to-have and the need-to-have. I'm an analyst, and I know as an analyst, all formulators, they want to put everything onto stability, and one formulator can, on average, create enough work for at least two or three analysts.

When your cost-cutting measures are imposed, they're nice to have if they take on less priority, as much as, myself included, we all hate to go against our scientific interest. We need to leave those exciting, interesting studies behind, and focus on the resource we have, both monetary and time and personnel and on the absolute studies required to move your product towards filing, because at the end of the day we all need to have a return of interest, and to do that, we need our product marketed.

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# Best Practice Ways to Overcome Common Challenges in PAT

By Helen Winsor

Rakhi Baj, Technical Project Leader at Abbott Diagnostics, joins Pharma IQ to offer some best practice ways to overcome common challenges in PAT.

**Pharma IQ:** What do you think are the major challenges that hinder the progress of increased process understanding and control?

**R Baj:** One of the key challenges that I come across quite often is a lack of understanding of the actual tools. People are inherently wary of mathematics and statistics and they get the perception that they're really difficult and that really it should be left up to the statisticians to work away in the corner and come up with the answer. But I think both scientists and statisticians need to work together to get a better understanding of the process; what are the issues; where are the bottlenecks, and then decide on the best approach. I think it's really important for statisticians to get a better understanding of the process and for scientists to get a better understanding of statistics, and that way the two groups can decide on the best tools to use for that specific area.

**Pharma IQ:** So, expanding on this, do these challenges differ when working in the diagnostics field, and if so, how?

**R Baj:** Not really. The challenges stay the same, but the processes are different, but I do believe that with increased communication and working across the functional groups, a better understanding of the process can be achieved, and therefore better control.

**Pharma IQ:** Finally, what are the key tools and techniques that you personally find the most effective in your work?

**R Baj:** In terms of the statistics tools we use a lot of control charts and host capability type tools and indices, and in terms of the non-stats tools, things like process flow diagrams and Ishikawa fishbone diagrams work really well. We're big fans of fast jump and mini tab as well in terms of statistical software packages and we use them quite a lot in everyday activities.

**Pharma IQ:** And just to round us off, you're going to be delivering a presentation at the PAT and QbD conference. What is going to be the key learning lesson that you'll be offering at the event?

**R Baj:** I hope the people will get an appreciation of what we do at a diagnostic plant, and the kinds of challenges that we're facing in terms of using these quality control charts and quality control process capability type tools and things like that, and how we've implemented them into the culture of the organisation. So I hope they get away with a sense of appreciation of what we're trying to achieve on the site.

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