American Chemical Society AMA: I develop Analytical Methods in for Pharma labs, I'm Shib Mookherjea, Ask Me Anything!

AmerChemSocietyAMA [1] and r/Science AMAs[1]

[1]Affiliation not available

April 17, 2023

Abstract

Hi Reddit! I am Shib Mookherjea, Principal of Val Qual International, a Consulting/Training company offering various advisory and Management Training services to the Pharma, Biotech, and Medical Device industries both in the US and abroad. I have diversified expertise and experience in Analytical Development, R&D, QA/QC, and Laboratory Management, having held supervisory and leadership positions in several companies spanning over 25 years. I have proven track record of initiating and implementing GLP/GMP in several laboratories in addition to leading Analytical, R&D and QC teams and have offered targeted training courses in more than 20 countries. I have had also extensive experience in the areas of Pharmaceutical Development, Methods Transfer, Analytical Problem Solving, PAT applications, and Team Development and Regulatory submissions. I have held management and supervisory positions for Colgate-Palmolive, Johnson & Johnson, Troy Corporation, Allergan and CRO/CMO organizations. I have been on the faculty of Continuing Education Division of American Chemical Society, CFPA, Sindusfarma (Brazil) and several other international organizations. The aim of these training initiatives is to foster professional development while bridging the gap between academic training and industry-required knowledge base for Chemists and Scientists holding positions in various industries. Ask me questions on and about the topics of Analytical Methods Development, Validation of Methods, Qualification (IQ, OQ, PQ) of lab equipment and systems, FDA GLP Regulations, and QA/QC in Pharma labs. I'll be back at noon EDT/9:00am PDT to answer your questions! EDIT: I am ready to answer your questions. As a thank you for participating in this AMA, we'd like to extend a discount to you for any of my courses offered through the American Chemical Society. Register between now and August 1, 2016 using the code ACSREDDIT20OFF to receive 20% off of your registration fee.

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AMERCHEMSOCIETYAMA R/SCIENCE

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Hi and thank you for doing this. What are some courses or programs that an individual working for a pharmaceutical company can take to move up in QA or QC if they can't pursue a PhD and have a BS in chemistry ?

ShrimpFeces

Having a Ph.D plays a major role, however, depending on your career path, I believe that subscribing to some of the Short Courses that ACS offers is a good place to start. Most of these courses are taught by senior level professional with a depth of knowledge in their fields.

Hey Shib, I am a PhD student studying biomaterials, preparing to defend next Friday. I currently don't have a job lined up, and I know several other recent PhD students who were in similar situations. I've been doing a lot of reading on the subject, and it seems like the PhD market is super saturated. Industry jobs either don't want PhDs because of the higher salary they command,or have hundreds of

The Winnower
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PhDs to choose from for a single position.

Being in industry for over 25 years, what is your thought about the current PhD glut. Namely, how can we ameliorate this situation, and what advice would you give for PhDs who find it hard to differentiate themselves in a market that's now flooded with post-graduate degrees?

Srozbun

This is something I'm rather passionate about as stated above. I would like to see more collaboration with industry and academia. We are out of balance when it comes to that. We need the degree, yet the experience is what sets us apart. I am trying to devise programs that would bridge that gap even if it was offered as an elective of some time. I think ACS is thinking along these lines and you can share your interest and comments.

Thank you for doing this AMA! What's your educational background and how did it prepare you for your career? Do you think graduate programs can do better at teaching management and other professional skills to students? What is your primary method of networking with others in the industry and how can graduate students do a better job of connecting outside of just academia?

shiruken

Starting the path to where I am today was not an easy one. First of all I had a Masters and experience when I came to this country. Working for years in industry while getting my Ph.D was grueling, but, in one way it was a blessing because as I was being educated I was getting such a depth of practical experience. So, I am a proponent of combining practical with theory. This is what we need when we show up in our positions and how we become better leaders. With social media today its' a bit easier to network, however, never discount the power of presence. Personal connection has been a true asset and is very much missing in our careers, so, we need to be utilize tools and more education combined with hands on real world experience. That it crucial in our world today.

How are analytical methods adjusting to the increasing trend toward biologicals, such as antibodies or enzyme replacement therapies?

I assume you can't just run a protein on a GC-MS. How do you prove the product is pure?

borrax

This has developed into a totally new stream called Analytical Methods for Biologics. Often the proteins and antibodies are transformed into entities that can respond to different chromatographic techniques and related separation science. I currently cover this in collaboration in various forums like ACS, EAS and Pittcon.

My wife has a PhD in Chemistry, specifically in leveraging Cesium for low-energy magnetic resonance. She wants to get back into research, but not necessarily academia because of grant process and the difficulty getting decent funding, and we've talked about getting into pharmaceutical or cosmetic labs. Do you have any advice for her crossing into that realm?

voilsb

With a Ph.D she should be able to find a role within those fields. I am teaching a Short Corse for the ACS in August in Philadelphia, where I will provide some basic highlight of the regulatory standards like GMP etc.

Do you think that portable bio- and chemosensors for monitoring the pollutant levels or concetration of hazardous chemicals in workplaces can become as popular as blood glucose sensors in a reasonable time frame? As a person doing PhD in this area I am curious if we could expect a growing demand for this type of devices from industry and environmental institutions or perhaps most of the analysis will forever follow the most common scheme of taking the sample to the lab and doing chromatography and mass spectrometry analysis (which I assume is most popular one at the moment).

ProblemY

The good news is this scenario is changing due to the more recent emphasis on on-line and at-line testing within the framework of PAT. More recently FDA has published directives for such framework and encouraging the industries to switch to more PAT type applications. I teach a Short Course in several forums both in the US and abroad. You may contact me directly if you are interested in learning more.

Hello Mr. Mookherjea,

It may be a bit off topic, but I am curious, basing on which parameters do you hire new employees and promote older ones?

You see, I am currently studying Pharmaceutical Engineering at University of Applied Science in Germany (Bachelor of Engineering) while being employed as Research Assistant. After my Bachelor Graduation I plan to enroll for Pharmaceutical Management in Austria (Master of Science and Master of Business Administration). Maybe graduating to a PhD. I would like to work in middle to high management in the pharmaceutic industry. Since the courses untill now are a bit too easy for me and regarding my ambitions, some of my Professors advised me to switch to a more theoretical University studying Pharmacy and doing a PhD.

What do you think are my chances and what would you recommend?

dersterz

I think Germany has access to very high standards in Academia and I think you have quite a bit of options. I personally would like to see more emphasis on bridging the gap between industry and academia. The criteria in advancement in the industry is a combination of good knowledge of the science, interpersonal skills and team participation. Creating mentorship and training programs are quite useful.

What would it take to increase the amount of chemistry teachers in high schools. There is a huge shortage.

jimmyolsenblues

We have to encourage young people to take interest in science and math at a young age. Perhaps we need more social media and practical expertise merged with theory.

Hello and thank you.

I actually have two questions. The first one is what would be your suggestion for a start-up lab with limited to ressource as to which certification to go first. We are aiming at 17025 but we are quite

strugling as where to start and we always have the impression that everything is blurry and the guidance are not as clear as they should be, especially since we are doing custom analysis (often one shot) and semi-quantitative analysis.

My second questions is that we are trying to implement the article from Hubert et al. (Part1, 2, 3, 4) as a method validation system, are they offering a good system or are they complexifying thing for no reason?

Thank you.

BlindAngel

First question, I encourage you and congratulate you in the effort. ISO 17025 is a good standard, however, there needs to a Robust Quality System developed and maintained. This is an area where I support many small startups to provide guidance as a consultant. I do have collaboration with many of the accreditation organization such as A2LA, PJLA and also International Bodies like Metro in Brazil. I not in a position to comment on the 2nd question at this time.

What steps do you take to optimize your HPLC methods?

What are the best ways to improve linearity in quantitation?

What's your take on organ-on-chip devices for in-vitro testing?http://wyss.harvard.edu/viewpage/461/

MyRedditAccount001

For HPLC quantitation Linearity plays a major role as a Validation parameter that needs to be investigated and established to suit the purpose of the method. Linearity also has an impact on quantitation of the drug substance or analyses and if not properly controlled it will contribute to systematic and random errors. The specification of the method needs to be adequate to suit the purpose of the application. For the other question you can have more information through Pharmaceutical Technology, AAPS etc.

When will HPLC finally be replaced by higher pressure systems (UPLC). High Pressure LC has been on the market for more than a decade now. However, pharma companies cannot develop new methods for them as the large majority of CMOs do not have UPLCs in their QC labs (a shocking number of them have HPLCs that still say HP on them). When do you think regulatory authorities will finally start saying HPLC is no longer state of the art, NDAs have to have state of the art high pressure UPLC methods. (I know UPLC is a trademark, I am referring to both waters or Agilent system that can use < 3 um particle size stationary phase columns.) T

dtagliaferri

I understand your point. This industry in is a change mode at the current time. Most Regulatory agencies stay away from endorsing or dictating any particular set of instrumentation. They want management to understand the science and use proper tools as needed to maintain the safety, efficacy and Quality of drug substances and products.

I will be making the transition from an analyst to manager over the next few months. I'm not sure if you started in the lab and worked your way up, but, what challenges have you found most difficult to deal with as far as lab management goes? (Exipient/api producer QC lab)

muhli660

Congratulations. I have followed a similar path starting as bench Analyst to Group Leader and onwards to Sr. level management onto Director and now as a Consultant to many industries in the USA and abroad. The biggest challenges are having a through knowledge of the science, understanding people and having the support of leadership. It's a tough path, and many of the power courses that ACS and other organizations provide can be helpful especially when being taught by industry experts.

On the lighter side of things, how is your name pronounced?

sorryforthebullshit

My name is pronounced Shib with b being pronounced. Last name MookerG h is silent.

Regarding ACS the organization, why do I keep getting invitations to join it saying I've been nominated by two professionals in the field?

I was a math major in college, went into another (non-science) industry afterward, and have actually never taken a chemistry class in my life. It always seemed fishy to me...

Just_For_Da_Lulz

I think you should direct this questions directly to ACS, I do not have those details. I am a Faculty member and enjoy the collaboration with them.

Hello Shib,

As someone who works in the Analytical Equipment industry, I am curious which OEM equipment you have worked with and which you prefer for separation and mass spectrometry? Thanks! I look forward to hopefully hearing back :)

The_LJ462

I have been in labs that have worked with most of the leading equipment manufacturers, (Agilent, Waters, Shimadzu, Thermos etc an many OEM's) However, this is a scenario constantly changing and it depends on a multitude of things and I would be unable to elaborate in a short time without details.

As someone whose primary job function is Analytical Methods Development, what kind of tasks do you carry out in your day-to-day? Is this normal for this line of work? What do you enjoy most about your job and methods dev. specifically? And finally... What kind of entry/mid level positions does a person work in before they are qualified to take this type of job?

I am asking these questions because I currently conduct academic research, and designing the research methodology is my favorite aspect of the whole process.

justsomegraphemes

Many of the Academic routes can find a pathway to solving analytical problems in industry. However because of the regulated norms in many sectors, all such methodology must go through a process of Pre Qualification and Validation. Sometimes papers are published in various journals with less emphasis on the validation rigors of the methods. However, recently the picture is getting better and

there appears to be more collaboration. I have been asked to provide guidance at times in Academic settings and I believe there is room to grow there. I had enjoyed Methods Development and Validation as both a Scientist and Leader of teams and I am a preacher and teacher in the aspect and I enjoy such collaboration. Typically as a technician or bench level chemist would be the beginning role.

Seeing your experience both in the USA and abroad, what advantages do you find in each country (eg, Brazil team-oriented, USA well resourced)?

Gaviero

Brazil particularly has a very well organized forum called Sindusfarma, which acts as a bridge between the Pharma industry,ANVISA (their version of FDA), Academia and Global Subject Matter experts. I have been invited many times over the last 20 years to present and collaborate. USA is certainly well resourced, but, we do not yet have an exact forum to bridge the gap. This is something that ACS can play a role in as well.

What type of degree would one need for work like this

BloatedKitty

Masters in Chemistry with specialization in Analytical Chemistry/Pharmaceutical Sciences. However, this industry is very much in favor of hiring Ph.D level scientists for most roles inside the organizations.

Hi Shib,

Sorry if this is outside your area of expertise. I've wondered how the pharmaceutical industry approaches testing the metabolites of the drugs they produce. I ask because of the possibility that a metabolite is actually producing the useful effect of the drug and maybe it should be administered directly, or perhaps the mechanism of the drug's effect is misunderstood because it's assumed that the drug itself is effective instead of the metabolite. I'm also curious if there are any intellectual property problems, ie whether metabolites can't be patented because of of "naturally occurring" limitations.

rcglinsk

The Pharma industry addresses this issue at the Pre-clinical stages through serious PKPD studies conducted on animals with the experimental drug and proper assessment of metabolic pathways. However, your angle for patenting a metabolite for pharmacological effectiveness may be explored if someone prefers, but, that calls for a different study.

For managing a small analytical lab, there are a lot of moving parts. What is a good system/ software for managing the lab and ensuring nothing is dropped.

smells_like_hotdogs

You need to look into various LIMS systems that are available and the instrument manufactures such as Agilent, Waters etc. If you need any guidance and support you can contact me directly.

Hey Shib! I was wondering what methods are respectable for instrument calibration and how to retain great QA/QC for a lab that audits other chem labs for the EPA. We make sure the labs use X amount

of known standards and produce a calibration curve from data. Do QA/QC policies vastly differ for different fields of work?

akru3000

Accessibility of adequate and appropriate CRM's and other standard materials is very critical in QC in both drug development as well as Quality Control measures. Through the influence of International harmonization efforts like ICH, USP, JP, EP etc. the area is improving in bringing more harmony and QA/QC measures. I have been involved with EPA on the water analysis side for which standard methods are available.

Hi Shib Mookherjea,

I am currently a rising senior at Johns Hopkins studying biomedical engineering. From my studies I have developed an interest in systems biology, specifically with a focus on pharmacology. My dream profession would be advising pharmaceutical companies on which drugs to invest in. I'd like to be involved on both the science and business aspects of drug production. I personally see this profession as developing models for a variety of drugs which target a specific disease, from which the effectiveness of each drug can be compared. I would in theory couple this with a optimization program weighing out the price costs. What I am ultimately asking you is if a job such as this, or one close to this, actually exists. If not, how feasible would a consulting firm which provides these services be. Finally, I would like to ask you if pursuing a biomedical engineering graduate degree would hinder my pursuit of a career in pharmaceuticals. Thank you for your time.

SoundLightRedBlue

I am currently consulting with a couple of clients who came from Biomedical Engineering Training and are following a path of targeted therapeutic models and I encourage you to follow your path. But one thing, remember in order to be respected on the science side the education and understanding and experience play a major role. However, one thing that is sometimes missing is understanding of the regulations and their interpretations GMP/GLP etc. and the cost involved in drug development, so the business side has to always remember that. Good luck on your path!!

Some general statistics questions:

Are Frequentist methods on the way out and Bayesian on the way in?

Do you use equivalence testing rather than regular hypothesis tests?

Do use advanced SPC tools like EWMA and EWMA for autocorrelated data?

true_unbeliever

I have used various SQC techniques including Variance, ANNOVA, Fisher test, Dixon test, Control Charts in support of laboratory QA/QC initiatives.

Hi Shib,

I'd genuinely love to know how much document peer-review you're engaged with, and if it's as much of a headache as I'm lead to believe.

Is there really that much of it in regulatory? Who has to put up with the most?

hellhasnofury

From the QA side I am involved with a ton of documentation for many clients and of course sometimes related to Regulatory Submissions, FDA Enforcement Actions, etc. The entire world of GLP/GMP largely depends on a robust quality systems comprising of various levels of documentation (policies, protocols, masterplans, product review, SOPs, batch records etc.