TWENTY TIPS IN LIFE SCIENCE MANAGEMENT

TO ACHIEVE BETTER PROFESSIONAL AND COMPANY PERFORMANCE

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ABOUT THE AUTHOR

Nancy Parenteau was recruited to the biotech industry out of her postdoc. She figured she could risk exploreing the intriguing opportunity on offer "for two years" without losing her ability to switch paths... Fifteen years later she became instrumental in establishing the field of tissue engineering, bringing an academic concept out of MIT to reality and delivering the first FDA-approved living combination product.* Now twenty years later, Apligraf® (Organogenesis Inc.) remains unmatched as a scientific and technical as well as medical achievement; having helped over a million patients with non-healing wounds.

She has been helping others translate biology into application since 2005 as a co-founder of Parenteau BioConsultants and is still actively pursuing cutting-edge research with her cancer immunotherapy company Verik Bio.

* Skin: The First Tissue-Engineered Products," by Nancy Parenteau and Gail Naughton (Scientific American, April 1999)

ORIGIN OF THE TIPS

Many years ago, a wall-street analysist asked me how we could achieve what we were claiming to to have done (pre-FDA approval) when others couldn't. It seemed too bold, even outrageous, still does for some still in denial. I reallu didn't know how to answer. I didn't know. We just worked hard and things came together. After Organogenesis, I spent years analyzing what was different. We certainly weren't perfect but it wasn't all dumb luck either. This twenty tips come from our own experiences in bioscience reinforced by the wisdom of the late great Peter Drucker, the insightful Gary Pisano, the brave Brené Brown, and other management and behavioral experts. The content first appeared as part of our 2009 series *Highlights in Applied Science and Strategy* and our *Best of Bioscience Newsletter*. Ten years later, the challenges remain much the same, and the principles to deal with them are still highly relevant.

WE'RE PASSIONATE ABOUT HELPING YOU ACHIEVE

The tips provide a taste of some of what goes into being great at managing bioscience. Of course, there's alot more to it. If we've sparked an interest to learn more, consider joining one of our workshops on Mastering the Bio in Bioscience™. You'll find more information at www.mbb-workshop.com.

Also, you can use AdvisoryCloud as an easy online portal to book a confidential meeting with Nancy.

Questions? You can reach us at (617) 848-0973 or info@parenteaubc.com.

To your success!

THNIGS NOT MOVING FAST ENOUGH? DELEGATE!

You were hired for your skills, talent, and experience. You like things done a certain way. No one knows more than you about an issue. All are feelings that we have when deciding whether or not to delegate a critical task to someone else. But one of the most valuable skills you can have as a senior level executive or manager is knowing how to effectively delegate.

No one can do everything and in life sciences in particular, no one person can know everything. Delegation is a necessity and it frees you to tackle things that really do need your skills, talent and experience.

The key to effective delegation in a knowledge environment is to be sure that you delegate the responsibility along with the task. If you ask someone to handle something, he or she must manage it, take responsibility for it, and be held accountable for it. Micromanaging defeats the purpose and in that case, you are better off doing it yourself. Also, handing something off to someone ill-equipped to manage. it is not only bad for the company but unfair to them. So how can you handle delegating responsibilities comfortably? Start small and gradually increase responsibilities in staff that are up to the task. Don't hand something over and close your office door! Let people know that while the job is their responsibility, you are always available for advice and review, as any good boss should be. Soon your delegation skills will help develop potential in your team that you didn't even know was there.

Develop your ability to effectively delegate. It not only empowers and develops your team, but gets the best out of you too!

MANAGEMENT BY CRISIS

There is crisis management and then there is management by crisis.

The occasional crisis is part of life and certainly part of the life science business, but have you ever noticed that some people need a crisis to really feel the urge to act on something? As consultants we see it all the time. Maybe we should be glad, since solving crises cost more than avoiding them but we'd much rather work with companies that appreciate the value of action, even on a good day!

It is inevitable that things pile up on everyone's plate. What becomes critical is the thing with the most urgent deadline, or what can be accomplished that day. But is that where your effort really needs to go that day? Often, management by deadlines takes over prioritization leaving the issues that seem far off, far off. That is until the day of reckoning and yikes, we now have a crisis and the issue gets pulled to the top of the stack.

What is the danger? Well there is a distinct possibility that the quality of how you deal with the issue will suffer, that time will play a factor in what you can do, and that compromises are made. Instead of managing the situation, the issues are now managing you.

Critical issues deserve attention when the focus can add the most value.When options are the most open, there is time to deal with them effectively, and prevent a crisis! Foster a passion for pro-active effort.

Take action when it can generate the most value or find yourself being managed by "the situation."

"WE ALL KNOW THAT IT SAVES A TREMENDOUS AMOUNT OF TIME AND MENTAL CAPACITY TO … FACE [THINGS] HEAD-ON…IT'S ACTUALLY MUCH LESS SCARY TO APPRAISE THE SITUATION FROM A FACE-FIRST POSITION, RATHER THAN LOOKING BACK OVER OUR SHOULDER RUNNING." **BRENÉ BROWN IN: DARE TO LEAD, RANDOM HOUSE, 2018, P.110:**

RESEARCH FOR DEVELOPMENT

R&D implies that the two are distinct and separate; activities that when added together results in a product. However, research and development in complex life science are not really two distinct entities but rather effective R&D is a cooperative continuum. It's like constructing a building from the foundation up, rather than building out. It is progress rather than expansion of effort.

Research generates the opportunities for development and should stay aware of how their findings could impact future development. Likewise, Development must be willing to accept a reasonable challenge while not losing site of the valluable insight resesarch can and should continue to contribute. From Research to Product Development, Product to Process, Process to Clinical Research – each is intimately linked, and the better they communicate and cooperate, the stronger and more efficient the road to product approval is likely to be–maintaining momentum while continually stabilizing the base.

Watch for "us versus them" attitudes and stop the silos and fences from forming. Manage R for D as a cooperative continuum that respects all aspects needed to reach the common goal.

BUILDING YOUR YOUNG ORGANIZATION UP RATHER THAN OUT

Raise money, make some progress, meet milestones, advance your product and invariably the company grows. That is a good thing, but growth can do some damage if the organization doesn't grow in the right way.

We often hear the word "expansion" to describe company growth, which implies a growing out. Growing out puts the burden of holding everything together on management, and we all know management isn't perfect. And that isn't all. Interaction of key players is lost as soon as someone is no longer down the hall.

Pharma is struggling with how to reorganize R&D. For most of the recent past, pharmaceutical R&D growth has been outward. It didn't work well. Now, projects are being pulled in, concentrated and held together based on objectives to gain efficiency and greater effectiveness.

Although small companies may not think they have similar problems, growing out can still occur. In can happen in the placement of offices as your space expands, for example. You can unwittingly foster reduced interaction by cordoning off sections, which pigeonholes personnel. I once visited some beautiful biotech offices where the scientists' cubicles were cordoned off from the rest of the company behind thick doors. Even the decor was different. The labs were on a different floor entirely so the scientists could come and go without ever having to enter the main area. There was no reason for them to say hello to the receptionist, walk down a hall past their CSO's office, the alliance management group, or the regulatory affairs group. Process work was being done in another facility entirely. Management would now have to work overtime to maintain a common sense of purpose and a unified effort. The company had expanded out even before they had produced their first successful product. They might make it work, but it would now be harder.

Keep the whole project in mind when you decide how to situate your personnel. Don't create reasons for them not to interact in person if you can avoid it.

Growing up requires building up through mutual awareness and the continual interaction of all the critical players. The more you can preserve that interaction the better.

THE FAST FAIL APPROACH TO SUCCESS

Nothing is probably more painful for a company than failing late. When a candidate fails a Phase III trial it is after many years and many millions of dollars. Ironically, a company may persist in advancing a project because they fear the repercussions of not continuing. Yet often it only prolongs the inevitable and cuts the chance of ever producing something of real value. Facing a failure early, while painful in the immediate term, is far better than propgating a failure. How do you know when to pull the plug?

Pharma industry maven John Northrup suggests that companies today must use a fast fail approach and drive to achieve a "higher biological understanding" as early as possible. * This is great advice but there are plenty of examples of where it's not followed. Once a decision is made to pursue a certain "product", its damn the topedoes full speed ahead. Often, that commitment comes early, too early. Lingering questions go unanswered and the additional research to substantiate the hypothesis, get pushed aside. Better not to know? Nope, it's better to know, and the sooner the better!

Be your program's harshest critic. Dig deep to test the premise of your therapeutic to find answers as soon as possible. That way, if it isn't what you had hoped, less harm is done and there is time and money to pursue something better.

*Northrup, J., The Pharmaceutical Sector in: The Business of Healthcare Innovation, LR Burns, ed. 2005, Cambridge Univ. Press.

"...ARTICULATE CLEARLY THE DIFFERENCE BETWEEN PRODUCTIVE AND UNPRODUCTIVE FAILURES: PRODUCTIVE FAILURES YIELD VALUABLE INFORMATION RELATIVE TO THEIR COST. A FAILURE SHOULD BE CELEBRATED ONLY IF IT RESULTS IN LEARNING." GARY PISANO, THE HARD TRUTH ABOUT INNOVATIVE CULTURES, HBR, JAN-FEB, 2019.

THE MOST PRESSING RISK IN LIFE SCIENCE

Ten years ago, Earnst and Young's Carolyn Buck Luce, offered that life science companies were 'looking with renewed vigor in how they manage ther risks at the very core of their business.' In their 2009 report* Ernst and Young listed the ten 'most pressing' risks facing the life science sector. Access to capital only made it to number two and one could argue that access is capital is not as hard as it once was.

What was the number one risk? Demonstrating the value of their innovation–a risk still number one today.

So how can you be certain that your team and technology are capableof generating a product that will make the grade, i.e., be benedicial enough to be reimbursed and adopted by the physician customer?

There is increasing pressure for pay-for-performance deals between government and pharma, and a push to examine the comparative benefit of therapeutic options. Gone are the days of charging what you will for statistical significance without scrutiny. Physicians and patients don't measure value based on statistics.

How can you show that you're serous about creating commercial and medical value?

Demonstrate that you have a realistic grasp of the medical need and understand the level of efficacy required to the patient needs – not regulatory approval.

LETTING THE BANDWAGON PASS ON BY

Analysis by Dr. John Ioannidis* has revealed that erroneous conclusions permeate most published scientific and clinical studies – victims of grantsmanship, self-fulfilling prophecy and of course, the bandwagon. Getting opposing views published has been a problem for a long time and it is much easier to be on a bandwagon than down on the ground. In academics, the wrong path eventually rights itself and views gradually change. But in industry, you're asked to use science to make some pretty important decisions right now, and a lot is riding on your being correct. Almost doesn't count!

How do you protect your company from erroneous conclusions or specious reasoning that will lead to off-target decisions?

Communicate to your R&D team that:

- **RESULTS ARE NOT PERSONAL**
- **BEING OFF-TARGET LEADS TO INCREASED RISK AND FUTURE PROBLEMS FOR THE COMPANY**
- **BEING CORRECT IS THE GOAL, REGARDLESS OF WHAT CHALLENGES THE TRUTH MAY BRING**
- **FINDING A MONKEY WRENCH IN YOUR PROGRAM OR DEVELOPMENT STRATEGY EARLY CAN SAVE THE** DAY!

*PLoS Med. 2005 August; 2(8): e124

NO WINE BEFORE ITS TIME

Years ago, Gallo had an advertising slogan "We will sell no wine before its time." It conveyed the idea that they understood what made a good wine and would never prematurely rush to sell something that wasn't yet in its prime.

Innovation is often viewed as disruptive to the status quo and innovators as risk takers. But the late Peter Drucker, father of modern management, argued that in fact, successful innovators reduce risk. How? By taking on a development effort at the right time, when there is a critical mass of information to make things happen in a timely way. No matter how flowing or tight the money is to develop new prospects, there is always a strong push toward application of the latest discovery; to start new companies or get a jump on the latest opportunity. But the question is, will it fizz or fizzle? How can you tell whether the science is ripe for development or still too green to be worth the risk?

Take in the available information and see if you can arrive at even a sketchy sense of what the road to commercialization would look like. Are there major gaps in understanding? Do you have little or no clue how those gaps might be bridged? Then it probably means the science is not yet ready for development. Do you have a sense of what would be needed? Can you define the hurdles clearly? Then the new technology may be ripe for innovation and investment!

„THE ABILITYTO MAKE EFFECTIVE DECISIONS INCREASINGLY DETERMINES THE ABILITY OF EVERY KNOWLEGDE WORKER...IN RESPONSIBLE POSITIONS, TO BE EFFECTIVE ALTOGETHER. " PETER DRUCKER, IN: THE ESSENTIAL DRUCKER, 2001, HARPERCOLLINS NY, P. 260.

EVALUATING CORE COMPETENCIES

Lay people (read investors) often have the notion that science is science and technology is technology. If an approach has potential then just about any group can pull it off with enough money.

Truth is, decisions and execution are 90% of success. Those with strong core competence in key areas will leap hurdles others can't and their decisions will be wiser, their options greater. You might like to think, "if we can't do it, nobody can." However, that isn't always the case.

Ideally, every company tries to acquire competencies that will give their effort its best shot. They hire "experience." But performance is what counts. How can you evaluate the performance of your core competencies to be sure you'll leap those hurdles and forge the best path?

Don't accept "We can't" at face value. Track your own and your competitor's performance. Assess your innovative performance compared to the entire field. Have you recently missed something? Botched something? Missed an opportunity?

A yes to any of those questions points to a weakness that should be remedied.

THE MARRIAGE OF EFFICIENCY AND EFFECTIVENESS

At first, efficiency and effectiveness enjoy wedded bliss. There is a honeymoon of exciting, passionate effort to advance the most effective product that technology and talent will allow. Every effort and everyone is in step. As programs advance in development, the tasks needed to meet requirements for clinical trials, production, regulation, contract milestones and investor expectations mount – creating pressures that can cause efficiency and effectiveness to separate.

An organization can be very efficient. It can broker great deals, advance a product to IND, Phase II, even Phase III, and yet ultimately advance something that isn't worth the effort. Decision-making overly focused on tasks and the short-term can compromise the marriage and a company's future. Effectiveness is what ensures that the product will be worth the effort. Efficiency and effectiveness must remain happily married despite the pressure.

Save the marriage between efficiency and effectiveness with focus on the ultimate commercial objective. Communicate that objective and measure all labors against that objective. Your teams will then be more apt to make decisions that don't compromise effectiveness for the sake of efficiency – no matter what the team's role is, or how much is on their plate.

PIVOTAL NONCLINICAL DATA

You've heard about pivotal clinical trial data but nonclinical pivotal data? Although it's not talked about as such, it is still a critical and often crucial component of a regulatory submission and product approval. To get a sense of how important nonclinical data are, go to some of the product sites for some of the newest, most promising biologics and under mechanism of action you'll usually find reference to preclinical data, not clinical. Clinical support of mechanism of action is often years in coming, often through trials designed and done post-approval. Even then, nonclinical data help makes sense of it. This makes the value of your nonclinical data pivotal, not only for an IND submission to begin clinical testing, but for your BLA or NDA for product approval as well.

The challenge in nonclinical data comes in making it relevant and valuable. Some regulatory consultants claim that while companies may have reams of data, tthey leave the the FDA wanting more, or should we say something different. Quality has to trump quantity. Burying the FDA with data just burns time if it doesn't make your case. It also gives the impression that you are unfocused and uninformed about your technology and its clinical application. However, a good nonclinical package can do wonders for the impression of your company creates, the quality of your submission, including the clinical data, and can support interpretation oc clinical findings. Lack of it can raise concerns and lead to a level of discomfort that can translate into difficult questions and delays, even with positive clinical data. This is particularly true for novel technologies. Being proactive with strong, innovative and thoughtful nonclinical data can smooth your regulatory path and could be pivotal to product approval.

The nonclinical data package is one of your best friends in a regulatory submission. Done well, your preclinical data support, defend and shine a positive light on your clinical data and your company. Done poorly, it raises more questions than it answers.

DO YOU HAVE A PRECLINICAL PLAN?

You may have a pipeline strategy, project plan, and perhaps even a publication strategy but what about a nonclinical data plan? Some might think that the activities listed are the preclinical plan but the preclinical plan is more. Ideally, it should be focused on answering development questions, illuminating mechanism of action, justifying targets, product strategy, process and clinical indications, i.e., focused on providing a level of understanding about your technology as a product and a therapeutic.

The preclinical plan builds a foundation that reduces risk, supports good decision making, helps validate the process including future changes and improvements, and more. Many efforts have failed because of insufficient preclinical research.

The nonclinical effort is also something that doesn't end with IND approval or even product approval; it continues to support postmarking efforts, competitive comparison of technology and the clinical safety of your product for years.

Non- or pre-clinical research is vital to reducing risk, making the best product and supporting that product from concept to market. Don't leave it to chance–have a preclinical plan.

"SPECIAL ATTENTION NEEDS TO BE PAID TO PLANNING KNOWLEDGE WORK, WHICH DEMANDS MORE ANALYSIS, MORE DIRECTION, AND A MORE SHARPLY FOCUSED PLAN OF ACTION THAN ANY OTHER WORK." PETER DRUCKER IN: MANAGING FOR RESULTS,HARPER. 2006 P.218.

INSTILLING RIGOR WITHOUT RIGA MORTIS

First let me admit a little secret, I was that kid in the back of the science lab laughing and joking around. In college, I once had a TA separate me from my lab partner because we were having too much fun – he was just jealous. As a postdoc, the lab down the hall remarked that the noise level went up significantly when I and a young work-study student (now a brilliant ER doctor) joined the lab. So I have a long, albeit dubious history of having fun doing laboratory research. I have always missed my lab rat days of loud music, spirited conversation, plenty of laughs, good friends and…exciting data. Yes, they do mix.

Many young biotech companies flush with their first round of financing or a new IPO will provide free snacks in the lunch room or have pizza and beer on a regular basis to keep the people happy and engaged with the company and its people. While that may be great for company interaction, the engagement must follow them back to the lab -- to the 50th gel they are loading or the 100 culture plates they are tending to.

If you've managed 2, 20, 200 or 2,000 R&D scientists you know that there is an elusive quality that makes someone "good at the bench." While we assume academic research needs people like this, it may be even more important in industrial R&D. The data must be reliable enough to make decisions, the timeline must move forward and upper management must be satisfied that the company is closer to a product this month than it was last month. You need to trust the data and you are far from the days when you could do it all yourself.

When at the bench, we all desire to see smooth curves, minute standard errors, repeatable numbers. But in biological experiments, it is often not that easy to determine what results are real and what results are victims of a reduced level of rigor. The pereception that biological experiments are "touchy feely" sends shivers down the spine of many scientists but it does not mean that rigor goes out the window. It just means that lack of rigor has more places to hide.

Rigor comes from precise measurements to be sure, but an important part of instilling rigor in experimentation is by helping your staff develop a comfort, an ease and a flow in what they do and, as importantly, a genuine interest in the results. You can be very focused on obtaining the result and still have hustle and bustle going on around you and a smile on your face. Look to hire staff that truly love science and you are likely to find a technical star.

If you are finding increasingly erratic results from your R&D, look at the mood in the laboratory. Are your associates fully engaged in what they are doing? Are they tense or concentrating too hard? Do they appear to just be going through the motions? Are they more interested in what is happening out in the hall? Visit the labs and talk to your staff to get a sense of the mood, do what you can to lighten the mood if need be. Everyone needs to relax!

Institute additional training sessions if needed, and where possible, lead by example. Show an interest and appreciation of data that really tell you something whether it is positive or negative. Be sure your associates understand where their experiments will fit in adding value to the company or product goals.

If a person gets a sense that their data are valued, then they will also feel valued. Setting a standard of values is different than setting expectations. In setting expectations, you are focusing the pressure on the individual, but by communicating how much you value, and are counting on obtaining accurate information, you allow the person to do their best to deliver it without it being personal. Small points perhaps but I cannot remember a day when I did not enjoy walking into the laboratory – no matter what tasks were at hand. The more your staff can have that feeling, the better your data returns will be.

"IF YOU THINK YOU CAN DO A THING OR THINK YOU CAN'T DO A THING, YOUR'RE RIGHT." HENRY FORD

THE ZEN OF BEING AN EMPLOYED PROFESSIONAL

Keeping your job is a vital necessity for most of us, and unfortunately a source of anxiety for too many. What used to be a stable job in pharma can be out with the next change in command. You have to produce. Consequently, we have to be careful that the focus on being or remaining employed doesn't squelch talent, motivation and potential.

There was a saying I used to use, "We're not here to be employed!" It meant the responsibility of a knowledge worker went well beyond the perfunctory.

It was both a rallying cry as well as a reminder to the professional staff that, as professional knowledge workers, we appreciated that there were also careers at stake. Performance was important on a personal level as well as for the company.

Top-tier professionals don't slog through the advanced training merely to "be employed." They want to do something great with their skills and intellect and have something to show for it. Take that zen away and you will gain much less than you could or need to from that individual! Don't think that just because you're less likely to lose a person by them quitting that you can't lose them in other ways. Watch it in yourself as well!

Be sure now, more than ever, you rally your professional troops and find a way to maintain job satisfaction by respecting career ambitions/motivations, yours included. When corporate objectives and career ambitions meet, they can make for a personally satisfying and productive environment no matter how challenging the situation. Ohmmm.

Don't treat your professional staff as head count. Be sure to maintain motivation by showing them you respect their career within the framework of your corporate objectives to maintain personal satisfaction and productivity.

WAITING FOR GOD NOT...

A common mistake when looking to the outside for help is timing. For example, early input on regulatory, technology, and commercial strategy can create a clarity that is enabling for years to come; yet bioscience companies rarely seek advice for the long-term when it can have the greatest positive impact. Persistent gaps in expertise can limit innovation and the ability to overcome hurdles in a timely way, yet most companies wait for problems to mount before picking up the phone or justifying the "added" expense. Outsourcing is reactionary rather than strategic. The question is, "How much time and money is lost struggling?"

Trying to be a 'jack of all trades' through hiring can be slow, costly and risky. Asking your inside experts to wear too many hats can render a company 'master of none' by diluting and overburdening key talent with work that could be handled more efficiently and expertly with outside help. Ideally, outside expertise is used to avoid problems rather than solve them!

Outsourcing should be strategic rather than reactionary. It should support core competencies and fill in gaps in expertise to enable progress and avoid problems altogether. It is the surest way for a company to be good at everything!

"EVERYTHING REQUIRES TIME. IT IS THE ONLY TRULY UNIVERSAL CONDITION. ALL WORK TAKES PLACE IN TIME AND USES UP TIME...NOTHING ELSE, PERHAPS, DISTINGUISHES EFFECTIVE EXECUTIVES AS MUCH AS THEIR TENDER LOVING CARE OF TIME." PETER DRUCKER, IN: THE ESSENTIAL DRUCKER, PETER F. DRUCKER, HARPERCOLLINS NY, 2001,P.226.

IS SCIENCE A LOST ART?

Ten years ago the then CEO of Glaxo SmithKline (GSK), Sir Andrew Witty offered an interesting take on R&D in Reuters: '"We've really thrown into reverse much of the trend of research organization that had developed over the last 15 years," Witty said.

Over that time, the drugs industry was a big commercial success but it took a "wrong turn" by deciding that drug discovery was an industrial process based on large-scale application of technologies like genomics, proteomics and combinatorial chemistry.

"These were all supposed to transform productivity yet none of them did. It turns out, in my view, that research is much more of an art than a science," Witty said.' It looks like Witty never did figure it out before he retired in 2017. The current CEO Emma Walmsley is hoping the new CSO and President Hal Baron will help reignite GSK's R&D. Time will tell. Attention is paid to what new areas they can get into but there is something more fundamental to be fixed, something Witty tried to get his arms around.

We've all heard stories of great breakthroughs made when a person recognized something others repeatedly missed. A part of that ability comes from being close to the results and open to innovation – possessing a certain passion, curiosity and confidence. The art of science comes from human input and insight.

The definition of breakthrough is "productive insight" and it appears technology alone is unable to generate it. Once heralded as fountains of potentially insightful information, what many 'omics technologies have been successful at doing is creating methods where the human is now one or more steps removed from the generation of data - with scientists waiting for the computer read out to alert them to what is interesting, important, or significant. Most are still waiting, left with a mountain of data (some based on methodology of dubious applied relevance) to sift through, ironically less sure of the value it contains than ever.

Can we "reverse" the trend? How do we get back to circumstances that will lead to breakthroughs and foster innovation without turning our backs on what technology can truly offer? We offer a few suggestions to start:

-Avoid experimental work that doesn't have at its root, a well-thought-out hypothesis or, at least a big, fundamental question driving it.

-Be open to discovering things in big data so you want to maintain an open

mind (big questions help) but, fishing expeditions are for the weekend with real fish.

- Artificial Intelligence has its place but it's not your place. Stay intellectually close to the process and the data. Your insight is important. If, in attempting to answer a question, something different does jump out, you'll be more apt to recognize it for the breakthrough it might well be!

Technology and AI have their value but they won't deliver your value. The art of science still comes through human insight. Innovation and breakthroughs come when the scientist asks the astute questions, uses technology to acquire the information, recognizes the answers within that information and then acts.

"'THE BIOMEDICAL RESEARCH COMMUNITY BELIEVES THAT IF YOU PUBLISH A PAPER ON A BIOMARKER, THEN IT'S REAL.AND MOST OF THEM ARE WRONG...THERE HAVE BEEN LIKE TEN THOUSAND PAPERS PUBLISHED ON OSTEOARTHRITIS BIOMARKERS WITH NO RIGOROUS CORRELATIVE SCIENCE GOING ON.'", **JANET WOODCOCK IN: RIGOR MORTIS BY RICHARD HARRIS, BASIC BOOKS NY, 2017 P.211.**

REIGNING IN TECHNOLOGY

Technology is a fabulous thing as long as it is used wisely. How are you using technology? Is it helping you advance your pipeline programs in less time with less money or do you feel frustrated like Sir Witty (above) at the rising cost, the persistent, if not increasing, risk and R&D efforts that are just as long and, in some ways, more arduous than ever before? Chances are you understand where Witty's frustration is coming from.

It seems we can do more and more but that is all it is, more and more. What we are looking for is a way to use new technology to achieve more with less; to yield better information, and better insight that supports better decisions. But the average R&D organization isn't getting better in its R&D.

In the last twenty years, the new era of research involved screening the complex, automation, high-throughput screening, and computer analysis to help process it all, yet the only businesses appearing to benefit from this trend were the technology providers. Now it's all about AI. So how do we get "back to basics" while still tapping into the potentially important information technology can provide? In an attempt to derive some answers, we pose a few questions...

What are you using high throughput screening for? What is the quality of the event when it occurs? What is the relevance of the event? How will you act upon it? Could a change in approach or use of the technology make for better answers?

Remember the old (and worn) addage garbage in garbage out? But honestly, can you improve what is going into the technology? Are the cell lines a convenience? Are the samples you are using the most relevant ones you could use? Could a little more up-front effort make the technology output more relevant and actionable?

Could your hypotheses be stronger, more thoughtful; your questions more astute?

The more thoughtful your work, the more directed your use of technology will be. The result may be research that rekindles the "art" of a good R&D program while gaining the most from the latest technology and AI capabilities.

Be sure you are the master of the technology. Look for ways you can improve the input, both materially and intellectually to ensure you'll get the most valuable output.

EFFORT THAT IS NEITHER FISH NOR FOWL

The idiom "neither fish nor fowl" refers to something that is no one recognizable thing. Are some of your efforts neither fish nor fowl? Could outsiders review your activities and easily recognize your objectives? Or would they be left scratching their heads or worse yet shaking them in confusion?

The idiom often comes to mind when we encounter a project that seems stalled in research, never quite making it to bonified product development. Mid-stage programs usually have a higher risk of becoming neither fish nor fowl through drift, lack of a cohesive, "earnest" effort, or loss of perspective. Prompting one to ask, "Just what are you hoping to accomplish from this?"

It can happen when new questions develop based on the ongoing line of investigation, new information or opportunities suggest greener grass, or the tasks needed to advance the program to the next step mount. There is a fear of committing (or lack of urge to commit) too firmly to one path. After all, what if you're wrong?!

Of course the problem is not unique to R&D and can develop just as much in business development and general management. What do you (the company) really want to be when you grow up? Could we tell based on a review of your deals and activities? How well do the deals and activities connect with your ultimate objective? Is there a fear to commit fully to a single strategy?

The lack of a firm commitment to clear, strategic objectives leaves the door open for inefficiencies and worse yet, disarray. It is OK to change paths when you discover a good reason to, but not committing in earnest to a path, well, leads to be becoming neither fish nor fowl; neither a failure nor a success. Eeuw!

Don't let fear of committing to a specific path or objective turn your efforts or company into the unrecognizable! It is okay to change paths, but not committing to one leads to nowhere.

COMFORTABLE INNOVATION

Do you need innovation? Sometimes? All the time? Only in times of crisis? Not at all? Your answer may have a lot to do with how you define innovation and what you think of it.

Many managers find innovation threatening, a disruptive influence. If it's not broken, why fix it, right? But guarding the status quo isn't always sufficient for a life science company to maintain their competitive edge. Others view themselves as always being innovative thinkers but truth is innovation has an inspirational component that you just don't have every day, nor do you need it every day. So really, innovation first, should come at the right time, and second, an innovative culture should be fostered so that it will be there when you really need it, and will be embraced when you really need it while allowing the nuts and bolts of the system to continue to work smoothly, predictably and reliably.

Life science companies lose their capacity for innovation when they adhere too closely to dogma, the mechanics of a process over the reason for the process, adhere too fervently to the "tried and true" and are uncomfortable being the company doing something new, differntly or for the first time. They are, what a fellow postdoc of mine once termed a "plugger". A term that he used to describe someone that worked very hard but lacked that certain something that would allow him or her to work smart, make a difference.

Pluggers may get a job done, eventually, but the time and cost, both financially and competitively, may be enormous. Do you know any life science companies that you'd categorize as pluggers? What about innovators?

The innovative culture appreciates and sets an expectation of thinking outside the box, looks beyond the scope of their work for perspective and inspiration and is willing to stick their necks out to try something, that, if it works will be of far greater value or solve a problem in a much better way.

The question is, will your team be the pluggers or the fearless innovators next time your faced with a hurdle, challenge or problem to solve? The answer could save you or cost you millions.

Your management and company culture can create an environment that fosters diligent plugging away at the expensive of innovation or one that

fosters the brilliant ideas but with a reluctance or lack of appreciation of the hard work that has to come with it. Ideally, you want innovation and diligent effort hand in hand, both used in the right way, in the right places, at the right times.

Reward diligent effort but set the expectation that, where needed, everyone should look outside the box for answers. Brilliant performance is one that gets the job done in the best way possible.

WEIGHING FIT OVER FASHION

A pipeline challenge new technology companies face is determining the right commercial strategy and opportunity for the technology. It comes down to a matter of finding a match between what you believe your technology can do with what needs to happen in the patient to meet a medical need. A key component of that is the strength of the biological fit of your therapeutic with the medical problem you hope to address.

The temptation is to choose a therapeutic target based on the market and then push development of the technology to try to meet the need. A technology may have potential for multiple indications, yet it is unlikely that it will address each equally well. Ideally, your pipeline capitalizes on your technology's core strengths. The objective is a successful commercial product. It doesn't have to cure heart disease, cancer *and* diabetes, but it will have to do at least one thing very well.

When developing your pipeline, favor biological fit over the lure of an *in vogue* market. If both come together like couture then great! If not, tailor the strategy to capitalize on the strongest features of your technology. Investors might like to see your technology tackle certain "opportunities" because of a perceived financial potential, but it doesn't serve anyone to dress an "emperor with new clothes".