During an anxious meeting with a client the other week, the head of Quality Operations was bemoaning the fact that “management wasn’t listening.” He was desperate for additional headcount so he could do more internal audits. Fair enough, I thought. After he presented his business case to me, it was clear why his plea had fallen on deaf ears. His compliance case was strong, but his business case very weak. This highlighted a very common problem faced by ‘technical’ people – how to communicate with business colleagues and not get ignored. Fortunately, this is something one of my colleagues is very passionate about. During his 40 years in the pharma industry (research-based companies as well as generics), Frank Dollard worked his way up from raw graduate on the shop floor to the boardroom. From manufacturing multiple dosage forms to working with financial institutions on acquisitions and divestments…and everything in between.

The question I asked Frank was “How should those with a technical, operational and QA background communicate with business leaders to get things done?”

Here were his top seven recommendations:

> Get into the real world
> Understand your business and your ‘Profit & Loss’
> Ban the term ‘Zero Risk’
> Establish a strong network of contacts
> Move away from reactionary firefighting to more strategic, value adding thinking
> Focus on preparation not presentation
> Publicize your success and build your credibility

Frank: Before I get into specifics one important caveat. My views, answers and recommendations will appear to be generalizations. Some are better at this type of communication than others but overall there’s lots of room for improvement. Most QA and technical ‘middle-ranking’ people are surrounded by people in similar positions and assume that key decision makers think the same way and talk the same language. They don’t. There is an old saying that “Communication is measured by the response you get.” If you’re not getting the right response, take a different approach. Here are my recommendations!

**EMBRACE THE REAL WORLD**

The purpose of any free-market enterprise is to provide returns for investors. The enterprise makes those returns by providing goods or services that it can create for a cost less than that for which it can sell. The greater the differential between these two values, the more successful the enterprise. It is clear
that world-class companies pay meticulous attention
to four activities which support this:

- Innovating new products or services
- Growing sales value/volume
- Reducing the time taken to provide the
goods or service
- Minimizing unnecessary cost

The commercial and regulatory environment will
remain brutal and only those that excel at the above
will survive. Everyone must play their part. No one
is exempt. The quality management system must be
seen as a business management system owned by all
with just one purpose – to improve your business’s
competitive edge by:

- Reducing time to market
- Reducing manufacturing cycle time
- Reducing back-order value
- Reducing inventory (often used to hide many
  quality problems)
- Reducing product cost
- Increasing individual and team performance

Unfortunately, bureaucratic and overly complex
quality management systems do the complete
opposite which is why Quality Assurance is seen as
a cost sink in many organizations rather than an
important part of profit generation.

Martin: What would you say to companies who
view the role of QA and the QMS as compliance
enforcement?

Frank: Get in the real world, change hearts and
minds quickly because if you don’t, you won’t survive.
Compliance in some cases is a minimal position, often
imposed by external regulators, rather than a proper,
risk-based assessment of your operation by the people
who know most about it – you and your team!
However, it is an important component to staying in
business, but so is profit.

UNDERSTAND YOUR BUSINESS AND
YOUR PROFIT AND LOSS

It’s a sad fact that most view the world through one
prism…their own. To make a good business case,
you must have a sound knowledge of your business
and what sits behind the profit and loss and balance
sheet. Unless you do, you will not be able to use the
right language and you will be unable to assess the
impact of your decisions and recommendations on
the bottom line. QA’s credibility is damaged when
they add cost for no obvious return on investment.
For example; that extra check signature, the extra
approval step, the extra sample, the additional SOP.
All add cost and complexity. The credibility of QA
is further eroded when risk (fear) is used as the
primary driver. When the consequences of not doing
something fail to materialize (usually the case in my
experience), respect is lost and people stop listening.
When presenting proposals, make sure you are
numerate and quantify the benefits. The return on
investment:

- Faster or reduced testing?
- Fewer repeat deviation incidents?
- Fewer unnecessary check signatures?
- Less reworking or reprocessing?
- Less work in progress?
- Reduced cycle time?

If you just have a purely compliance-driven case, go
back to the drawing board. If what you’re proposing
is adding cost and slowing things down, why should
anyone listen?

BAN THE TERM ‘ZERO RISK’

Although linked to the above, this is worth a special
mention. The “risk card” is often played when there
is no quantifiable return on investment. You know,
the “If we don’t do this, we are at risk of regulatory
censure” type of conversation. This is often given
credence in a culture of risk aversion where zero risk
is used as an excuse for not actually thinking. We all
know zero risk doesn’t exist and is the single biggest contributing factor to increased costs, complexity and (paradoxically) increased risks!

**ESTABLISH A STRONG NETWORK OF CONTACTS ACROSS THE BUSINESS AND LEARN FROM THEM!**

In my experience, everyone wants to do the right thing and they make the best decisions available to them based on what they know. To present a good business case, you need to understand your business and its customers. It makes great sense to better understand the roles of the teams around you – starting with your true customers. In our case, these are (usually) the wholesalers, hospitals and prescribing doctors (usually accessed through a co-operative sales colleague). I cannot over-emphasize the value of understanding the sales and marketing activity and the task it has of growing sales.

Within your organization you should understand exactly how to put together a business case which is straightforward and as simple as possible – and shows benefits in real terms, i.e. NOT based on fanciful assumptions of savings! The business case should include a couple of options, one of which you will prefer for good reasons – set these out so that the risk and benefits are clear to understand.

It will help if you work closely with colleagues from:

- Sales and marketing
- Finance
- Procurement
- Human resource
- Business development
- Regulatory

This networking and inclusive approach will have the extra benefit of gaining more support from the senior leadership team.

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**MOVE AWAY FROM REACTIONARY FIREFIGHTING TO MORE STRATEGIC, VALUE-ADDONG THINKING**

I can remember my time when, as a middle-ranking manager, most of my focus was firefighting. Dealing with the here and now. This is when fear-driven decisions predominate and are usually counterproductive. My advice would be to plan and think more strategically, not reactively. Focus on proposals that provide real business benefits such as:

- Moving to a more risk-based approach to assess the robustness of your processes and devising continuous improvement activity to reduce that risk
- Educating your production and engineering colleagues (these groups have the biggest influence on quality) in how to conduct simple and focused self-inspections to drive continuous improvement
- Rewarding and celebrating success within this continuous improvement activity
- Simplifying your batch records to improve cycle time and reduce errors
- Taking a risk-based approach to environmental monitoring
- Moving from planned maintenance to reliability centered maintenance

**FOCUS ON PREPARATION, NOT PRESENTATION**

As a senior manager, I have listened to a lot of presentations and proposals for change. I never ceased to be amazed by the lack of planning and preparation. My advice is to focus more on the planning and less on the presentation.

- Make sure you consult widely with all key stakeholders (your network), creating support in advance to avoid big surprises
PUBLICIZE YOUR SUCCESS

One final point, often forgotten. Tell everyone about your successes and how your actions have improved business performance. Report the results over the following period. If those results are good, then celebrate. If they are not, demonstrate what can be done to recover the situation and identify the learning points. Use your experiences to improve your credibility so your audience is even more supportive of your proposals and ideas the next time around.

ABOUT THE AUTHOR

Martin Lush has over 30 years’ experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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