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The Quality Professional as The Business Leader

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I am here because Anne Greene kindly introduced me to Anders. Anders and I have had a couple of meetings and a couple of conversations about this. I call this an infectious dream he has about bringing the quality professional up the value chain.

I am going to start by referring back to my former colleague Lorraine Nolan, who you met earlier. I had the privilege to recruit Lorraine into the HPRA when I was there, and then I had the privilege to promote her all of four times during my tenure there. And then the privilege behind the scenes to help her become CEO when I resigned and moved on myself.

You heard her talk about her own experience and where she is coming from. So, is she the perfect model for what we are talking about today? Because clearly not every quality professional wants to be the business leader.

We have heard people talk during the day, and I think they are incredibly happy in their skin doing the jobs that they are in. So, they probably don't want to be business leaders and subject to the vagaries of the stock market and all that kind of stuff. So we need to capture that.

But I was asked to address, expecting that everybody would already address all of these other six traits during the presentations, I was just asked to finish off with the quality professional as the business leader.

Importance of Quality

Brendan Griffin [University College Cork] shared a yarn the other day at another conference, and I was planning to tell it here, so I am going to.

There were these two Irish guys heading to New York on their J-1 visa – as we do Janet [Woodcock], our students often get a J-1 for the summer to go and have a bit of fun and earn a bit of money. They had never been on a long-haul flight before. This links into the earlier conversation about airlines, so they were a little bit apprehensive.

Suddenly they heard the pilot's voice. It was very reassuring. He explained the flight pattern, the estimated time of arrival, and all that. And he talked a bit about the plane, that the plane had four top-quality engines.

So off they went, but an hour into the flight, there was this kind of shudder through the airplane. The reassuring voice came over when the pilot said, 'Nothing at all to worry about, one of our engines just shut down. It is such a unique event. It has never happened in all my career, but we have plenty of contingency within this plane. So we are going to be perfectly fine. Just we are going to be an hour late arriving in New York.'

Okay. You can guess where I am going next. An hour later, the same shudder, another engine goes. The pilot comes on and says, 'Nothing to worry about. We still have two engines. There is so much quality built into this aircraft. We are going to get there but we will be two hours late.' Get it? And you know where I am next going to go.

An hour later again, another incident, quality failure. The third engine shuts down. And the pilot says, 'We are fine. Everything is good. A lot of contingencies built in, a very resilient aircraft, just we are going to be three hours behind schedule.' We can't turn back at this stage really.

So the two guys sitting at the back of the plane, one guy says to the other, 'I hope that last engine doesn't shut down. If it does, we will be up here all night.' [Laughter.]

The moral for us in that story, as quality professionals in pharma, is: are we going to stay up there all night, are we going to land safely, or are we going to crash and burn? How does your quality system, when you implement it, get you through that conundrum?

Boeing was mentioned earlier, and a lot of people know about the Boeing story. But the piece that was not said, which I find the most illuminating, having chaired a lot of boards now – so I am kind of sensitive to what happens to board chairs – the board chair lost his job, and the CEO lost his job after that recent event.

So, if there is anything that can get a message across about quality, whatever a range of things have to be done and said, I think the senior people losing their jobs is a very salutary tale for everyone to understand.

Quality in Other Sectors

Semiconductors were mentioned during the lunchtime presentation [by FDA's Rick Friedman]. We have a massive plant, Intel, outside Dublin, and what fascinated me when I was regulating food was the semiconductor industry don't have any regulators coming to see them.

They do it themselves, and they handle it themselves. And it is 100%, 100% of the time. Nothing else is tolerated. So, it can be done.

In the health space, which is where we all live, is where I occupy. One of the things I do now is chair our Health Information and Quality Authority. We are responsible for health and social services, all of the providers…We have inspectors and we set standards and all of that stuff. And there are a number of areas there that would be lovely to talk about if we had time.

The common feature in them, which I want you to reflect upon, is the service user – or the patient, depending on whether they want to be called that because a lot of people don't like to be called patients in health and social care. They are not – they are service users, they are residents in care homes, or whatever it might be.

Making the Link with Patients

I was fascinated, always, as the head of the regulator here and in the EMA and so on, that a lot of people working in the industry don't always make the link between the job they do every day and the patients that use the medicine – not universally, of course, patients were mentioned a number of times today. But all of us have that responsibility.

That idea of the electricity that you heard earlier is the reality our patients have. [Mentioned by EMA's Brendan Cuddy in the first panel discussion]. They can't really tolerate the notion that if their loved one has some condition that needs a therapy – why isn't it there? So, yes, that is the space we are in.

The only other example I will give you, and it is very genuine, but I am stitching it into all you professionals, which you are. We have a pediatric hospital, and we have a pediatric group called Children's Health Ireland, CHI, and along with the Chairman, we are currently doing a very serious statutory investigation. I am not going to tell you anything that you don't know from the public domain, but it is to do with children with scoliosis. So extremely compromised children, really compromised conditions, and they are waiting for surgery for their scoliosis.

What the inquiry is about is, in the case of a number of children, an unapproved implant was used in surgery and put into them as a surgical correction of the curvature of their spines. The patient is at the end of this, and these are children, the more sensitive patients that we have. They are compromised children, which your products often deal with all the time as well.

But there were also a lot of professionals involved. So, there is the surgeon, who led the team. There are a number of other medically qualified people who were on the surgical team. There were the theater nurses who were involved. There was the procurement system, which managed to allow an unapproved, non-CE-marked product to get its way through the sterilization process onto the table in front of the surgeon.

Regulated Professions

But there is another one that we struggle with in Ireland. All those I have mentioned so far are regulated professions. So, they have a regulator that controls them. They have to do a qualification that allows them to apply to be regulated. And they are subject to regulation. And if there is an adverse finding against them, they will be subject to being struck off, or being sanctioned, or whatever.

What we struggle with a bit sometimes is we have a category then who are the senior managers of the hospitals, or the hospital groups, and they are not part of a regulated profession. And I am raising that because probably the last thing you want to be is part of a regulated profession, okay. Probably the last thing you want to be.

However, I think there are very interesting models around self-regulation of professions that help to drive standards of the profession, number one. But most importantly, it helps you in your interaction

with your bosses in your companies. You can say, 'Well, there is a code of practice in my profession. I can't possibly sign off on that. I wish I could. I would love to help you, and we could go for a drink afterwards. But I just can't. If I do, I won't be working here tomorrow. I will be struck off the register.'

It is something to think about as we move forward and discuss where this whole debate is taking us.

Six Traits of Quality Business Leadership

I will just come to reflect briefly, as I was asked to, on the six of these. I think they are very good. But I did see earlier drafts, so I have to take some level of ownership of them.

Figure 1: The Six Quality Business Leadership Traits

If you take the top left, the top right, and the second right, I see those kind of linked in one basket for me: *demonstrate who is responsible for quality*, *quality is owned by all*, and *engaging employees*. That again talks to patients and all of that.

And then you come down to the next one which is *making risk-informed decisions that benefit patients*. Patients are there again. How can you make a risk-informed decision when you are sometimes chasing regulatory compliance versus quality management – that particular conundrum that Janet mentioned earlier?

That brings me to the top left, *lead the path to one global quality*, which is about the regulators.

Regulatory 'Overlay' to Protect Patients

When I was at HPRA, I would meet groups of staff on a regular basis who were new or promoted to new roles or whatever, from right across the organization – so it would be the new receptionist on the front desk…to a [group] director.,

I would say, 'Have we a manufacturing site in the basement?' That was my first question. 'No, don't be silly, of course we don't. We are not a manufacturer.' 'Have we a research lab on the roof?' 'No, we

don't.' 'The industry,' I would say, 'does all that. The industry takes all the risks, financial risks, all of that piece.'

So, I would say, 'What we are is we are an overlay set up in legislation, based on thalidomide and earlier FDA issues that were talked about by Janet. We are an overlay to protect patients – to try to have the best opportunity that quality, safe, and effective products are available to them.

So, I say to them then, 'You will…say to all your friends now, 'I've just got a new job.' 'Where are you working?' 'At the HPRA.' And your friends will say, 'I've never heard of it.' So how important are you, if you are working for the regulator?

But how important you are…ICMRA [International Coalition of Medicines Regulatory Agencies] was mentioned earlier. I was one of the founders, I am pleased to say, and it has gone from strength to strength. If I were to make a qualitative comment, I suppose, we have built a reputation here in Ireland. I hope most of you will have seen it in some shape or form.

If you were building a new manufacturing site here in Ireland, you were invited to come into the HPRA, and we would spend three or four days with you. We would go through your plans and talk to you. I hope some of you have experienced that.

Some of you might not. Some of you might be afraid to come in. And that is the piece that I am worried about, if you are afraid to have a dialogue with the regulator. Because the regulators, they are not gods. They are employed by the government to have a layer of scrutiny on industry on behalf of patients.

I see industry sometimes standing back, 'Oh, we couldn't possibly challenge the regulator on that. We couldn't possibly. Because that inspector or that assessor will remember us the next time around. You know the road is long and they will catch us the next time around.'

We have got to challenge that, and some of this work that might emerge today might help us do that.

Observations from the Day's Discussions

So, I have three or four things written down from the day that I think are worth saying at this point in the afternoon.

First of all, there is the **complexity of the industry**. It is a very, very complex industry. The manufacturing processes that we have – some of them are standard. But some are very, very complex with all kinds of intermediate stages and so on. Supply chains are complicated, all of that piece you know about. The industry, generally, is very complicated and complex. We heard a very quick reference in the last panel about the branded versus generic products. I have very strong personal views about that….

The second piece is, I love **change management**, and what I always say is we have to recognize vested interests. And generally when we are in a dialogue, with people who are out there… be they regulators, or policymakers, or CEOs of companies, or whatever, who absolutely know this.

We are hearing from purist supporters, but hear me, everybody has a vested interest. At the very basic level you have Maslow's theory of needs and you are trying to provide for your family, you want a job tomorrow, so we all have vested interests.

I think, generally speaking, we don't recognize that. And if you are having a discussion or negotiation or trying to make progress, I think it is imperative to put yourself in the other person's seat or shoes to understand where they are coming from. And that was talked about earlier. If you are trying to bring change forward, you have to, as Janet said, 'talk, talk, talk.' Or I would say, 'talk, talk, talk, listen, listen, listen,' which is what you were implying of course – a dialogue.

You have to listen, and you have to navigate through people's fear of change. At one time, I had someone in my team who was old enough to be my granddad, never mind my dad. He would say, 'Change is always bad.' Oh dear…. [If you said to him], 'Your cup is three-quarters full.' He would say, 'No, it is a quarter empty.' That was his reaction to life, whereas I would be 'Oh, my cup is ten percent full, yippee, happy days!'

The next piece is **leadership**. And I was absolutely shocked one time when the leader of one of the biggest global companies at the time, about seven years ago when I was a regulator, their CEO wrote an article in the Harvard Business Review, which was extolling the virtues of bringing clinical research to India. And the whole premise was by doing it, you would save 'x.'…

As a chair and as a member of the Institute of Directors and [other experience], in Ireland anyway, if you are a leader or a chair of a board of an organization, it is no longer satisfactory, adequate, or defensible to say, 'My only interest is the economic well-being of the company and the share value.' That is no longer acceptable in Ireland.

Now we have to take in a much broader matrix – the environment and the people that you serve and all of those things.

So I think, more than likely still, most of our companies at the very, very senior level, their salary, their bonus, their future in that role, is based very much on stock market price, the profit for the year, and there is very little balance scorecard as it used to be called that is taken regard of. And I think that is a serious issue that we have to deal with.

Which kind of leads back to my point about, if we were a regulated profession, I don't know, you might not want to go there, I am just raising it as a thinking outside the box kind of thing.

The other piece that is very challenging is about **constantly trying to reduce costs**. It was mentioned a few times.

There are a number of pressures, let us say broadly, and one is to increase the profit margin for the company. But the other is to respond to health systems enforcing a reduction in the price they are paying for the medicine, particularly generics. I think we have got the balance completely wrong on that. And I am not going to give you my solution. I am going to talk about it later in relation to the shortages issue. But we are not getting on top of any of these issues. And I think that the pricing piece is not helping.

Now, we keep seeing the escalating costs of health care worldwide as a percentage of GDP. So, we are not operating in a vacuum – we know that those are real issues.

'Next Step' Challenge to Quality Leaders

I want to finish up with a challenge for everybody.

I look at all the effort that goes into quality, and I look at the progress that we are making – or not. And I look at the recurring issues – or not, depending on what company you are in. We have heard some [good] examples, but we know that that is not universal.

So, do we keep doing the same thing? And my management style is to say to somebody, it is fine if you made a mistake. It is not fine if you make the same mistake a second time, right? So if you make a mistake and learn from it, and you grow and develop and you move on, and you have matured. But if you make the same mistake again, that is not acceptable.

My sense is that the frustration of some of the work that you are all involved in is often dealing with recurring issues that are not being resolved. That is very, very frustrating, and very annoying. And it is not productive.

The final piece is – and the reason that I agreed to speak today and the reason that I agreed to have a dialogue with Anders about this initiative that he has – I think there is an opportunity for us to mandate together in some way.

Somebody said, 'Will we be having an evolution or a revolution?' And it is somewhere in between. We have been evolving for many, many decades. But the pace is too slow.

We don't want a revolution, and anyway, we couldn't bring the regulators with us if we had one. They would take too long to catch up. But it would appear there is an opportunity to try and bring them at a different pace.

The pandemic, which was a dreadful time in the world, taught us that. One of the things I am trying to push in my own local work is to let us hang on to the good things that we learned during the pandemic.

I think your sector is the same. There is an opportunity to try to have – not a massive revolution – but a step change. A step can be a one-inch step, an eight-inch step, or it can be ten steps. It takes time. I think we need to move forward.

Coalition of the Willing

So, I am very supportive of what Anders is proposing. I am hoping that a group of willing people will help. I like the term, 'the coalition of the willing.'

There was talk earlier about people who will support something and who won't support something. There were other people that were variously talked about, and 'knocking them down,' was mentioned, which is interesting – that if they are in the way, you have to maybe knock them down. But sometimes you can just go around them. You don't have to knock them down. And they see you.

So, I say, are you on the right track? 'Yes, we are on the train track between Dublin and Kerry.' Okay, next question, 'Are you going in the right direction?' You could be going to Dublin, or to Kerry. And then the issue is, 'Is the speed steady? Or is it accelerating?' And it is always going to be accelerating. We are always, always going to be catching up. That is what our lives are about, in the modern day in particular.

But the revolution of 4.0 and moving on, is that we need to move with it. And I think as a profession, which you are, the senior quality people in our organizations, I think there is a serious opportunity for those of you who want to be senior business leaders. Why should it be the accountant? Why should it

be somebody who came up through marketing or sales? Why shouldn't the quality people be represented where they want to, where they have the capacity to?

I think Anders' initiative around some type of further detailed MBA-type qualification program is to be commended, on that basis.