

# Multicultural Auditor

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## INTRODUCTION

### Personal Introduction



Hello. My name is Andrew Waddell and 2020 is an anniversary year for me. It marks forty years continuously as a member of RQA and its predecessors - BARQA and the QA Group. I was a tutor on the first ever training course we ran and have acted as a tutor in - as far as I can count - something over 300 other RQA courses.

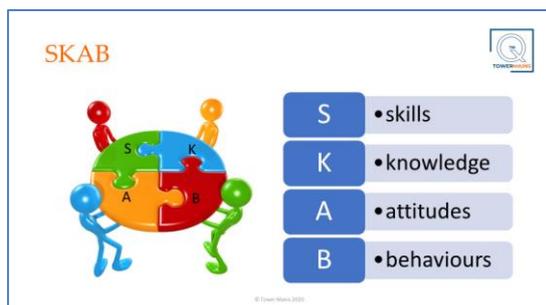
The highlight was serving as Chair and I am delighted to continue to support this vibrant, forward looking organisation. The fact that I am addressing you as part of a virtual, international conference is proof on the innovative initiatives that have been implemented in response to these strange times.

### 6th Global



From my very first week as a QA Manager I was exposed to the global nature of Quality Assurance as I hosted a team of eight American auditors. This has continued and this slide was taken the last time I travelled outside Scotland - to the 6th Global QA Conference in Sendai, Japan, where I am pictured with my local bodyguards

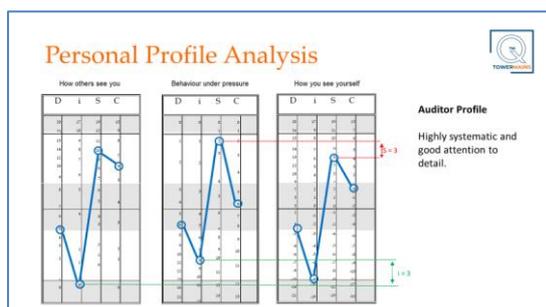
## SKAB



Whilst being the Chair of RQA during a Global Conference in my home city of Edinburgh was doubtless one of the highlights of my career, I am perhaps proudest of SKAB - a rather unpleasant-sounding acronym that sums up my philosophy of personal development for Quality professionals.

S and K stand for SKILLS and KNOWLEDGE. These are the characteristics we use to select people. We review their cvs to see what qualifications they have, past roles they have performed and other aspects of their training and experience. However, these tell us nothing about A and B - their ATTITUDES and BEHAVIOURS. SKILLS and KNOWLEDGE may get people the job but it is their ATTITUDES and BEHAVIOURS that get them fired.

## Interest in PPA



This led to an interest in PERSONAL PROFILING. Perhaps one of the reasons that we do not pay enough attention to attitudes and behaviours is that they are difficult to measure. Skills and knowledge can be demonstrated and tested relatively easily and attitudes and behaviours can be assessed at a qualitative level (helpful, argumentative, team player) but quantitative measurement of attitudes and behaviours is more difficult.

## No such thing as a typical

Personality profiling is often used to develop a "typical" profile for jobs and roles. One of the things I learned early was that there was no such "typical" profile for Quality Assurance. Some audit situations required the auditor to have patience and others required drive. A systematic, logical approach is common but flexibility is also needed to examine different ways of meeting the same requirements. Influencing skills can be important to overcome suspicion or opposition and if you have the luxury of being able to assemble an audit team a mixture of different personal styles can be highly effective allowing deployment of different styles for different aspects of the the audit. This is a luxury that is not always afforded to us and the consequence is that Quality Assurance professionals often have to modify their styles and approaches for different situations.

## Preparation v Failure

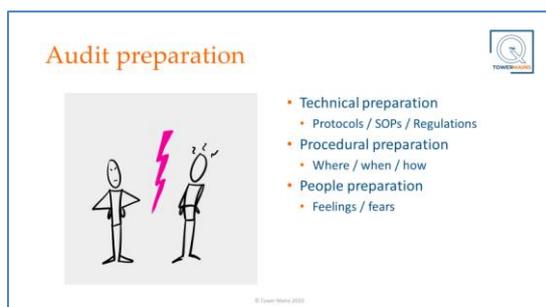


We all recognise the benefits of risk-based approaches but my experience is that this is not always applied to our preparation for audits.

We will prepare carefully for the audit content - review contracts, agreements, SOPs, regulations, reports. We will also spend time planning the audit process - where, when, how, what and who (occasionally why, but not often enough) but seldom pay much attention to the people involved.

Yet, if you look at the risk factors, they are exactly the inverse.

## Feelings are important



There is seldom debate about the hard facts of the content of the audit. People may debate whether or not there is a finding or its significance but (generally) they cannot argue that it is not the appropriate protocol or regulation.

Failure to plan the process can carry greater risk. You may be in the wrong place at the wrong time (not common, but it has happened to me - I didn't realise there is more than one Newark in the USA) More common is that the appropriate people or documents may not be available or, as we perform more remote audits, the document management system does not allow easy, independent review.

However, the biggest risk to satisfactory conduct of audits is how people **FEEL** about the audit. We all know that the best audits occur when everyone feels positive and open but suspicious, defensive behaviours are a more natural reaction to audits.

## PEOPLE AND CULTURES

### People Preparation



Which leads to the obvious question - "How do I prepare for dealing with people before I meet them?"

Unlike preparations for the content and process of the audit, you have no idea how people will react until you meet them. People and personalities are an unpredictable variable but consideration of their culture may provide a degree of insight.

What does "CULTURE" mean?



We naturally assume that CULTURE equates to nationality and background. I am British, which means that you will immediately make some assumptions about me based on my nationality.

Nationality - what we will concentrate on



In fact, I am Scottish and immediately you will assume that I drink whisky, have red hair, dress up in a kilt and live in semi-darkness caused by continuous rain. All of these are true, but not all of the time (and, yes, my hair was red before nature took its course).

As soon as we hear someone is from America or Japan, we start to make assumptions. This is not to deny that there is a wide range of personalities within each culture but there is also no denying that

an audit in Austria will have a different feel from an National cultures allow us to prepare for the personal approach but there are other cultures which we should consider.

## Organisations



ORGANISATIONS may have cultures that cross boundaries. In the 80's I recall being able to identify senior members of one international company by their appearance (dark blue suit, white shirt, blue tie) wherever we were in the world. I have never been totally convinced that the superimposition of organisational culture over national culture will always work. My experience is that harmonisation across countries within an organisation may be desirable but often the side effects of globalisation can negate the benefits.

## Professions



Other cultures that we should consider when planning for the people aspect of Quality Assurance are INDUSTRIES and PROFESSIONS.

It is easy to recognise the differences between a small Contract Research Organisation and a big Pharma company; out of necessity they have different cultures and operating models to meet their business objectives.

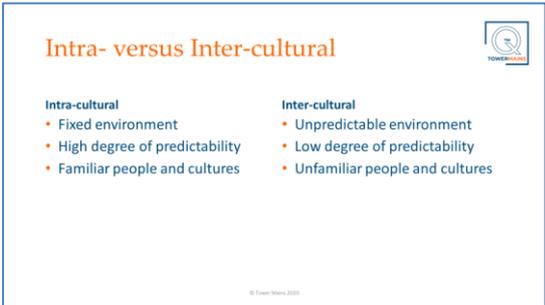
## INTRA-cultural v INTER-cultural



Auditors may find that their roles are INTRA-cultural or INTER-cultural.

An INTRA-cultural auditor operates in a static compliance environment with fixed standards and behaviours. This is most typically found in an in-house auditor and can be referred to as a "first party" auditor. An INTER-cultural auditor is typically a second or third party auditor, that is one who is auditing other organisations on behalf of their own organisation or is providing independent audits separate from both the audit client and auditee.

## INTRA-cultural



**Intra- versus Inter-cultural**

Intra-cultural	Inter-cultural
<ul style="list-style-type: none"> <li>• Fixed environment</li> <li>• High degree of predictability</li> <li>• Familiar people and cultures</li> </ul>	<ul style="list-style-type: none"> <li>• Unpredictable environment</li> <li>• Low degree of predictability</li> <li>• Unfamiliar people and cultures</li> </ul>

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The INTRA-cultural auditor is operating in a fixed environment with fixed expectations. There will still be variations in the personality of those who are being audited but these should be within a fairly well-understood range. It is also likely that the auditee will have a degree of familiarity with the personalities of those involved, if not by direct experience then certainly by reputation.

The challenges facing the INTER-cultural auditor are rather different and the skill set is more demanding.

He or she will be operating in environments and cultures that could be very different from normal experience and may be strange. This is not just the situations in which the audit is being conducted but also the understanding of the audit criteria and regulatory expectations.

## INTER-cultural



**Inter-Cultural Variation**

ICH  
harmonisation for better health

Should  
Must

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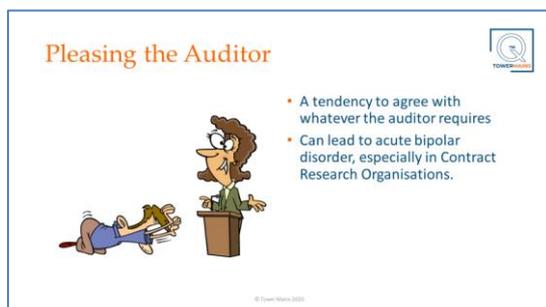
### ICH

The International Conference (now Council) on Harmonisation was a classic example. It managed to develop a single set of standards from three very divergent cultures - North America, Japan and Europe. Yet there remain within different cultures varying interpretations of what the words actually mean.

One good example of this is the European "Should / Must" gradient. It is my experience that criteria are much more "digital" in northern Europe. Expectations are black-and-white and there is little room for debate. In southern Europe the situation becomes more "analogue" and discussion about the degree of application of a requirement is encouraged or expected. I have also observed that the amount of flexibility is opposite to the words used. The word "should" is often used in northern Europe

to mean "Don't even think of doing anything else" whereas the word "must" in the south means "try to do it if you can".

### Pleasing the Auditor



Another example is the degree to which pleasing the auditor is expected. I remember an audit where variances were found but the auditees were only too happy to acknowledge them and provide commitments to change. Frustratingly, the next time I audited, nothing had changed. Apparently, another auditor had followed me who had different ideas about what was required and the organisation's culture was to always please the auditee.

(I have also seen the opposite where organisations want to argue every point and defend their position whilst subsequently taking the audit findings on board and making change. This has got to be seen as change because the organisation wanted to change, not because some auditor told them to.)

## CULTURAL SPECTRA

### Recognising and Dealing with Cultural Differences

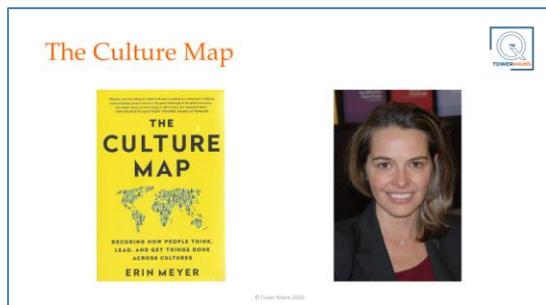


The solution is to be able to respond to different cultural expectations and adapt your approach. But, before we start, we must recognise the GOLDEN RULE

***It is the responsibility of the auditor to adapt to the auditee, not vice versa***

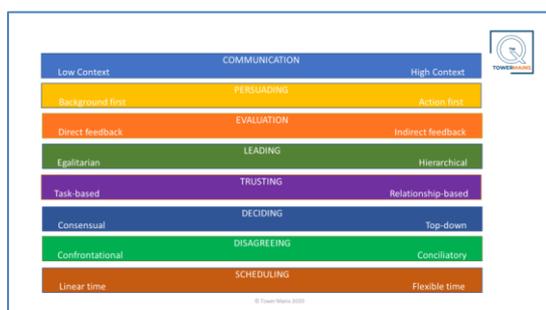
The first step in the process is to anticipate or recognise the cultural characteristics of the auditee.

## The Culture Map



For those interested in exploring this in more depth, I recommend the work of Professor Erin Myer from the world-famous business school, INSEAD in Paris, specifically, her book, "The Culture Map".

## Eight Scales



She identifies eight scales for measurement of different national characteristics. Every country can be placed on these scales but please bear in mind that these are "averages" and there can be a range within each country. For example, you may find a culture in which decision-making is generally consensual but you will still find managers and organisations within that culture that are "top-down" decision makers. It is just that they are, on average, less common. So, even when prepared to expect certain cultures you must always be flexible and prepared to adapt your approach depending on your own observation of the audit situation.

The eight scales are:

- COMMUNICATION - direct to subtle
- PERSUADING - theory or action first
- EVALUATION - direct or indirect feedback
- LEADING - egalitarian or hierarchical
- TRUSTING - task-based or relationship-based
- DECIDING - consensual or top-down
- DISAGREEING - confrontational or not
- SCHEDULING - linear time or flexible time.

## Four major topics

Of these, Communication, Evaluation, Trusting and Disagreeing are the ones most relevant to the audit situation.



## Selected Countries

For the purposes of illustrating my points, I have selected five countries - the UNITED KINGDOM, USA, NETHERLANDS, INDIA and JAPAN. I have also included additional countries where relevant to demonstrate the interactions that occur between different cultures.

As we go through these slides, you will notice that the USA and UK tend to occupy similar space in the mid to left of the scales whilst Japan is usually placed to the right. We know this instinctively - Japan is culturally very different from Europe and North America and everyone who does business across these countries is aware of this.

INDIA is usually just to the left of Japan except, interestingly, when it comes to developing a trusting relationship where India and Japan swap positions. More of this later.

## COMMUNICATION



COMMUNICATION occurs in a spectrum from LOW CONTEXT to HIGH CONTEXT.

LOW CONTEXT communication is entirely in the words. There are no nuances or hidden meanings. HIGH CONTEXT communication is much more subtle and you have to be aware that there is much more to the communication than just the words that are used.

Generally, High Context communication is found in Asian and African cultures where the listener has to interpret what is heard. Perhaps the most famous example is the Japanese for "Yes". which may be agreement of just acknowledgement of your question.

## EVALUATION



Evaluation operates on a scale from DIRECT to INDIRECT feedback.

You might expect cultures that have low-context communications to also have direct feedback but there is a marked difference. The Netherlands remains at the left (low context communication / direct feedback) and Japan at the right (high context communication / indirect feedback) but USA, UK and India move towards the middle.

The Dutch or French approach is to give and receive direct feedback - to "tell it as it is". In the UK and USA there is more of an emphasis on giving balanced feedback. How often have you been advised to start feedback with positives? In cultures on the right of the spectrum it is important to be sensitive and nuanced in giving feedback. It is certainly my experience that closing meetings in Japan have to be managed carefully to ensure that the message is received positively, even when issues have been found. On the other hand, when communicating findings to cultures on the left of the spectrum I will go straight to the bottom line. I can find that is often more uncomfortable for me than for those receiving the feedback

### Persuading

This leads me to a related area - should audit reports start with the findings?

My personal opinion is that you start with the most important content and that has to be the findings. Surely it makes sense to start with the bit that you really want people to read rather than keep it to the end where concentration may be diminished (or people might have given up reading the report). Vital messages should be on page 1, not buried on page 17.

However, many audit reports start with the background, methods, documents reviewed, people interviewed and then (eventually) the findings.

This reflects another cultural spectrum, whether to start with the process or the results. In cultures such as Italy, France and Spain it is important to provide the background before the results whilst in the US, Canada and Australia the preference is to start with the "bottom line" and then fill in the background. China and Japan don't fit neatly into the background / results spectrum since their cultures are holistic; backgrounds and outcomes are closely interlinked and separating them feels uncomfortable.

## TRUSTING



The TRUSTING scale has seen the most change in the last twenty years. Up to the end of the last century, the powerhouse of world economies and the cultural models that most adopted derived from the USA. The USA is on the far left of the spectrum. Trust is based on getting the task done and as long as the team works well with the task orientation, other relationships don't matter. The BRIC (Brazil Russia, India and China) group are at the other end of the spectrum. Not only are these the emerging industrial powers, they are cultures that emphasise the importance of relationships as well as tasks.

This affects the approach of the multi-cultural auditor. It is important to invest time before and during the audit to develop an understanding and relationship with them. Task-based auditing, by which I mean a dispassionate analysis of conformance and non-conformance doesn't cut it. On the other hand, tough messages can be delivered if there is a relationship between auditor and auditee. Feedback that describes the auditor in positive terms "Professional" "Understanding", "Nice" can be linked to challenging findings to produce a positive and co-operative outcome.

## DISAGREEING



Dealing with disagreement shares a similar cultural profile with Evaluation with the UK, USA and India in a neutral position. Unsurprisingly, Japan with its innate politeness and respect adopts a conciliatory position in dealing with disagreement. It may not be surprising to see the Netherlands at the left of the spectrum given the value the Dutch attach to directness. What may be more surprising is that Israel and France are to the left of the Netherlands.

I recall being retained by an Israeli company to perform an audit of a bioanalytical facility in the Netherlands. I noted a significant deviation from the reporting standards set out in the study plan and had a predictably blunt (but respectful) exchange of views with the Dutch analyst. I noted his comments but stuck to my position that this was a major finding. This was a good example of agreeing to disagree. The Israeli Quality Director announced that she would be attending the closing meeting and I raised, with the evidence, the excursion from the study plan. I had anticipated what would happen when I raised this point. It was as if I had lit the blue touchpaper and the Dutch analyst was subjected to what I will call (for politeness) very robust and direct disagreement which reduced him

to silence. I managed to resist the temptation to pass him a note saying "Now you know how it feels" - but only just.

I have also had similar experiences with French auditees and have learned that audits of French clinical opinion leaders can be combative.

The other end of the spectrum is no easier. Delivering significant audit findings to Japanese organisations requires careful preparation of nuanced messages that convey the significance of the finding but without loss of face or insult. "Polite, but firm" is definitely the order of the day.

## PRACTICAL APPLICATIONS

So, how does this translate into practical applications for the multicultural auditor?

I have taken two examples to illustrate the point:

- UK and Netherlands
- USA and India

### UK and Netherlands



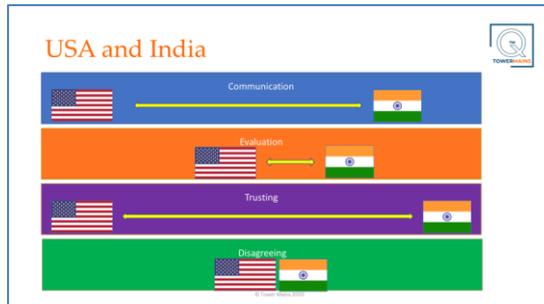
The UK and the Netherlands are to the left-hand side of the spectra, which is not unusual for Western European countries. There is a great deal of overlap in COMMUNICATION STYLES with both favouring a low-context manner of communication (the Netherlands slightly more so than the UK)

When it comes to EVALUATION there is a gap. The Netherlands is more direct in criticism and the British try to be a little gentler in feedback. This can lead to misunderstanding. When a British person says "I would like you to consider this a bit more" the meaning is that the British person is not keen on the idea. The Dutch person will interpret this as "He likes it and I should develop it further". Or, the comment "It is certainly an original approach" is meant to convey that it is not favoured by the British but the Dutch will take this as a compliment.

TRUSTING is the one spectrum where the Dutch are to the right of the British. The British multi-cultural auditor may be put off by Dutch directness but this does not reduce the Dutch need to feel that the auditor is interested in them as a person and not just in the task.

DISAGREEING is similar to evaluation and Dutch response may be more confrontational than is comfortable for the British auditor.

## USA and India



The USA and INDIA have rather more polar positions, with India always to the right of the USA on the spectra. Indeed, when it comes to COMMUNICATION and TRUSTING they could hardly be further apart. That is hardly a surprise given the spectral differences between these cultures.

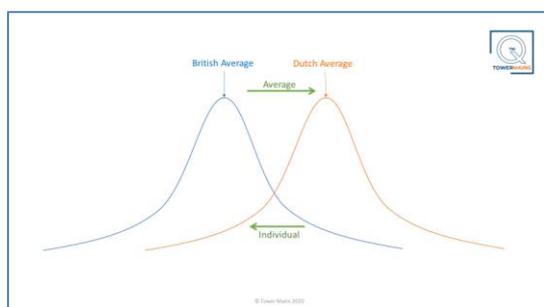
Last year, I was part of an audit team with American colleagues performing a qualification audit on a vendor in India. When it came to giving feedback and dealing with disagreements, the process was smooth and there were no issues. It was a different matter when it came to TRUSTING and COMMUNICATION.

The opening meeting was a rather protracted affair and it was obvious to me that the Indian hosts were keen to ensure that there was a positive, trusting relationship between all the parties. I could see one of the American auditors becoming impatient during this because, to her, the relationship was less important than the task and sticking to her timetable. She was persuaded that investing some time in establishing a trusting relationship would reap benefits but I could see that she was not convinced.

The differences became further obvious during the interviews. We asked direct questions and did not receive direct answers. This was, in part, because our hosts were looking for "hidden meanings" which did not exist. We wanted to know the name of the Study Director and the question, "Who is the study director" seemed appropriate. The answer was "The person who has been appointed by Management for this particular study", which is correct but did not give us the information we wanted

## HEALTH WARNING

These are statistical norms



One word of caution - the characteristics I have described are "average" or "typical" and there is a range within each culture. This may mean that, for example, on the TRUSTING scale, the Dutch are on average more relationship based and the British more task based. Within these cultures there is a



normal distribution of individual attitudes and you may find in any particular transaction that the Dutch participant is more task-focused than the British participant.

## WHY DOES IT MATTER

**Final Thoughts**

- Very rapid introduction to the effects of culture on QA and Audit
- Lots of good materials for those who want to take it further
- Remember – Two ears and one mouth – pick up the signals first

Happy to have questions to [andrew.waddell@towermains.com](mailto:andrew.waddell@towermains.com)

The content of this presentation is my personal ideas to stimulate thought and discussion. I hope I haven't upset any entire nations during this presentation but, if I have, please blame me and not RQA or Tower Mains.

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There is no way that the topic of the Multi-cultural auditor can be done justice in a 25-minute presentation but I hope that I have been able to put some science and structure to a topic which we are all aware of instinctively and that the understanding of the challenges facing the Multi-cultural auditor can assist us as to ensure the maximal benefit for Quality Assurance and audit.

Thank you for your time and I look forward to your questions either now or by contacting me at [andrew.waddell@towermains.com](mailto:andrew.waddell@towermains.com)