

ISO 19011:2018

QMS auditing skills, techniques and inspection readiness



Your speakers today



Audits are key to your competitive advantage



Kate Armitage

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Quality Assurance

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Too many organisations perceive audits as a box-ticking exercise.

But with changes to ISO 19011:2018, external pressures and a fundamental business need, you cannot afford to overlook such a crucial opportunity.

As an auditor, you are the conscience of the organisation. You need to deal with shades of grey and navigate complex company cultures and office politics. And you need to demonstrate value through improvement initiatives.

This is not easy.

Even experienced auditors struggle to identify new risks and opportunities, challenge leadership and enforce the changes required.

Today we hope we will help you to share inspiration, techniques and advice to advance your auditing skills and strategy.

We hope you enjoy the day and feel inspired.

Agenda

CQI Yorkshire event, 20th March 2019

Description

Time

Introduction & Welcome Hugh Everson, Chair, CQI Yorkshire	9.50 - 10.00
ISO 19011:2018: The good, the bad and the ugly Richard Green, MD, Kingsford Consultancy Services	10.00 - 10.45
Inspection readiness James Pink, Executive Vice President, NSF International	10.45 - 11.30
How to audit leadership Kate Armitage, Head of Quality Assurance, Qualsys	11.30 - 12.15
Lunch	12.15 - 13.00
Audits, inspections and opportunity management Chris Owen, Services Director, Qualsys	13.00 - 13.45
Suppliers and supply chain auditing Kate Krachai, MD, Instead Consulting	13.45 - 14.30
Break	14.30 - 14.45
CQI Centenary: membership options Julian Jack, Membership Manager, CQI	14.45 - 15.00
Breakout sessions	15.00 - 15.45
Round-up	15.45 - 16.00

What do you want from today?

"We are an ISO 9001:2015 accredited company. With the standard being more focused on business risk management I am particularly interested in how to audit leadership, and risk and opportunity management best practice. Our systems are quite complex and process audits have become quite involved so it would be good to learn how others operate."

"To get quantifiable information on the ISO 19011 process and the key methods used to determine a good 'leadership' and 'risk and opportunities' audit (under ISO9001, 14001 & 45001)."

"Starting to re-invigorate a slightly under-performing audit programme and up-skilling auditors around the business. Would welcome some fresh perspective. Especially keen to increase our 3rd party auditing as we simply don't do enough currently."

"I'd like a deeper understanding of ISO 19011 and perhaps an insight into auditing practices in different industries."

"I have been an ISO auditor for years but have not had any refresher training, or had the opportunity to listen to anyone else about 19011:2018. This will also be a great opportunity to network with other people in the sector and learn what's new etc."

"Meet new people and gain new experiences. Develop my knowledge of the auditing process"

"Further understanding of auditing."

"I am hoping to get some auditing tips. I perform audits and want to try and improve my technique, ensuring that I get the most out of the audits and as my ability grows my confidence will improve. I am especially looking forward to the How to audit leadership and Supplier and supply chain auditing topics. Both of these subjects are very relevant to me."

"I'm looking for advice on auditing management systems since my current task is to write an internal auditor training programme."

"Understand changes to the ISO 19011 standard and networking."

"I hope to obtain some useful and interesting tips relating to ISO 19011:2018 and general auditing skills."

"I am hoping to further develop my auditing skills"

"My main aim is to take this opportunity to learn more theory and take away principles I can apply in my current role."

"Get some ideas on best practice techniques in auditing - in particular leadership and culture. Meet some like-minded (and not) auditors and auditees :-). I would love to hear about how organisational culture impacts audit effectiveness."

"Awareness & experience of how this standard applies."

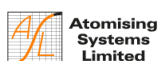
"I'm hoping to learn a bit more about the ISO 19011:2018 but also hear from more experienced auditors about their experience as auditors."

"We are struggling to maintain our audit programme and to leverage value from the process. I am really looking for ideas and a fresh injection of enthusiasm for the audit process so that we can carry out effective audits, report them on time and ensure corrective actions are understood and effectively closed out."

"I hope to improve my auditing skills and think the itinerary looks very informative and helpful. I am really looking forward to the event and very grateful for the opportunity to attend."

70 professionals signed up from across multiple industries and sectors

Some of the organisations here today:





An effective management system takes more than a single software solution or achieving a certificate for the wall. It takes time, energy, commitment and investment.

Qualsys's software and services give businesses the tools and knowledge they need to effectively plan, monitor and improve performance.

We've worked with worldwide brands such as Sodexo, BT and Diageo, as well as hundreds of SMEs, to help them make good practice natural and invisible.

Founded in 1995, Qualsys is now one of the largest privately-owned governance, risk and compliance software providers in the UK.

Our software solutions are used every day in more than 100 countries across the globe, helping all kinds of businesses meet a wide range of standards and regulations.



www.qualsys.co.uk

Get in touch

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Brands we work with



ISO 19011:2018

The good, the bad and the downright ugly

- Founder and MD of Kingsford Consultancy Services Limited
- Former Head of Technical Services CQI/IRCA
- Chair of Standards Panel & Technical Assessor



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IRCA CERTIFIED PRINCIPAL AUDITOR
QUALITY MANAGEMENT SYSTEMS



chartered quality professional



Guidelines for auditing management systems

- 'Concentrates on' 1st and 2nd party audits ('can be useful for 3rd')
- Designed to be applicable to all organisations, irrespective of size, sector or maturity of their management system
- Not based on a specific MS standard e.g. 9001/14001 – the guidance is intended to be generic

Guidelines for auditing management systems

Design specification for PC 302 - ISO 19011:2018

Be more explicit in terms of target audience

Use audit to identify risks and opportunities

Ensure audit programmes focus on adding value

Recognise the evolving role of ICT in management systems audit

Recognise increased integration of multiple management systems



Output - ISO CD 19011:2016



Delivered



Required

Structure

Clause 1 - Scope

Clause 2 - Normative references

Clause 3 - Terms and definitions

Clause 4 - Principles of auditing

Clause 5 - Managing an audit programme

Clause 6 - Conducting ~~Performing~~ an audit

Clause 7 - Competence and evaluation of auditors

~~Annex A - Guidance and illustrative examples of discipline specific~~

~~knowledge and skills of auditors~~

Annex A B - Additional guidance for planning and conducting audits

Bibliography

The principles of auditing

Integrity

Be ethical, be competent, be impartial, maintain judgement

Fair presentation

The obligation to report truthfully and accurately

Due professional care

The application of diligence and judgement in auditing

Confidentiality

Use discretion to protect information acquired

Independence

Independent of the activity 'where practicable'

Evidence based approach

Reach reliable and reproducible results in a systematic manner

Risk Based Approach

Consider risks and opportunities

The risk-based approach should substantively influence the planning, conducting and reporting of audits in order to ensure that audits are focused on matters that are significant for the auditee and for achieving the audit programme objectives

5. Managing an audit programme

- Programme to focus on areas of risk and poor performance
- Programme to be monitored on an ongoing basis
- The audit client should ensure audit programme objectives are established and that the audit programme is effectively implemented, not top management
- Changes to duties of person(s) managing the programme
- Audit team members should be 'objective and impartial'. Replaces 'need to ensure the independence' of audit team members
- Person managing the programme should evaluate the achievement of the objectives for each audit
- 'Proportionate arrangements' for SME's (scaling of audit programmes)
- Examples of audit programme opportunities are provided

6. Conducting an audit

- Information regarding the auditee's 'risk and opportunities and actions to address these' is now an input into documented information review
- Extent of documented information review now linked to auditee's context & risk
- Allocation of audit resources should be risk based
- Consideration of audit methods should be risk based
- Increased recognition of role of 'new technologies' in conducting audits, also of virtual locations and digital documents
- Objective evidence (not audit evidence) is no longer 'information that can be verified', it is now information that can be subject to some degree of verification
- Lessons learned from conducting an audit should include lessons re risks to and opportunities for the audit programme itself

7. Competence and evaluation of auditors

- Auditor competence should be regularly reviewed
- When determining whether an auditor has the competence required, a consideration is the audit methods we intend to use
- We now talk about 'desired behaviours' not 'necessary qualities'
- Auditors should pass generic training courses, not just attend them
- Auditor CPD should take into account changes in new technologies and changes in discipline and sector specific knowledge and skills
- Audit teams (not individual auditors) should have the collective discipline and sector-specific competence to carry out the audit
- Audit team leaders should have the competence to discuss strategic issues with the top management of the organisation being audited
- Auditors should understand the interactions and synergies of all management systems being audited (integrated audits)



Annexes

Old annex A – discipline specific knowledge & skills

Transportation safety management	Environmental management	Quality management
Records management	Information security management	Occupational health and safety management
Resilience, security, preparedness and continuity management		

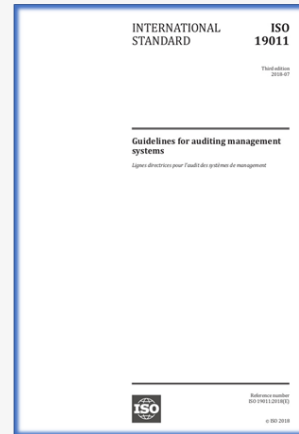


ISO FDIS 19011

Applying audit methods	Verifying information	Sampling	Preparing audit work documents
Selecting sources of information	Guidance on visiting the auditee's location	Conducting interviews	Audit findings
Professional judgement	Performance results	Auditing risks and opportunities	Life cycle
Process approach to audit	Auditing compliance within a management system	Auditing Context	Auditing Leadership and Commitment
Audit of supply chain	Auditing virtual audit activities and locations		

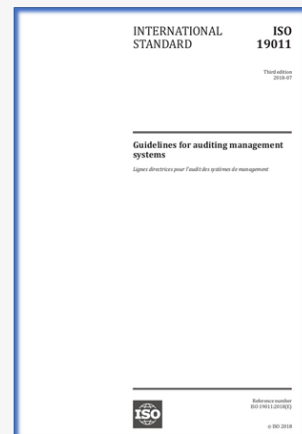
The good

- ISO 19011:2018 continues to provide the guidance auditors have come to rely on.
- It facilitates the deployment of an internal audit program by setting out recommended good practice.
- Explicitly recognises an additional 10 new areas of knowledge and skills auditors should possess, including professional judgement.
- It addresses the enhanced focus on risk.
- It provides consistency in the audit and remains **the** go-to document for anyone needing guidance on auditing.



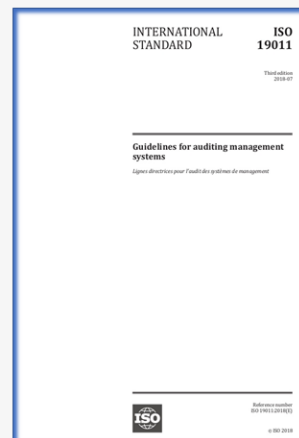
The bad

- The language used remains 'ISO speak'. This facilitates international translation but not comprehension.
- Annex A (discipline specific knowledge and skills of auditors) has been deleted even though it was considered valuable.
- Coverage of annex SL is superficial – it's only referenced once in clause A.2. Process approach.



The downright ugly

- New annex A is a 'missed opportunity'. States what should be done but gives little practical guidance as to how to do it – very limited value for those new to audit.
A.12 Audit of supply chain.
'The audit of the supply chain to specific requirements can be required. The supplier audit programme should be developed with applicable audit criteria for the type of suppliers and external providers. The scope of the supply chain audit can differ e.g. complete management system audit, single process audit, product audit, configuration audit'.
Not a 'pick it up and get on with it' document.



How to audit leadership

CQI Yorkshire

20th March

Kate Armitage at Qualsys

Agenda

- The importance of leadership
- Why you need to audit leadership
- Three lines of defence
- Tackling toxic cultures
- Example questions
- Hints and tips



Kate Armitage
Head of Quality Assurance

Importance of Leadership

"Leadership aren't engaged with quality. They do it because they have to, not because they see the cost-saving potential."

"The rules are too difficult and boring. Quality brings little empirical value to the leadership role and they feel like their time is better spent elsewhere."

"Leadership see quality as a necessary overhead, rather than a cost-saver."

"We're only consulted when something goes wrong – we're still a bolt-on at the end of a project, rather than integrated into the business processes."

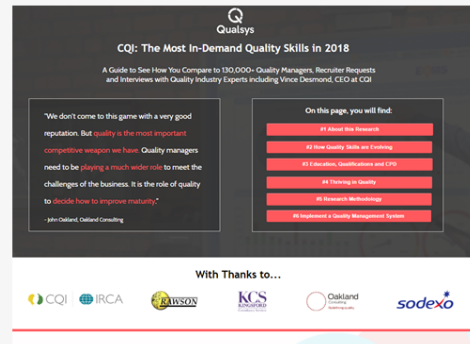
"Leadership only want a certificate on the wall."

"It's too easy for leadership to have an "over to you" attitude."

Survey feedback August 2017

Leadership vs management

- Management:
 - Processes
 - Rely on tangible, measurable capabilities
- Leadership:
 - Behaviour
 - Strongly on less tangible and less measurable



What makes a great quality leader?
<http://get.eqms.co.uk/skills-quality-career-progression/>

Role of leadership

- Leadership needs to ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation.
- Leaders need to ensure the integrity of the management system is maintained when changes are planned and implemented.
- It is management's responsibility to ensure these tasks are planned, implemented and achieved

Benefits of leadership commitment

- People will understand and be motivated towards the organisation's goals and objectives
- Activities are evaluated, aligned and implemented in a unified way
- Miscommunication between levels of an organisation will be minimised
- A clear vision of the organisation's future is established
- Challenging goals and targets are set
- Shared values, fairness and ethical role models are established at all levels of the organisation
- Trust is established and fear is eliminated
- People are provided with the required resources, training and freedom to act with responsibility and accountability
- People are inspired, encouraged and their contributions are recognised.



Five key things we need from leadership

- Clear definition of organisational structure, hierarchy, roles and performance
- SMART goals and mission
- Performance monitoring
- Time to review, every week
- Clear, collective corporate culture

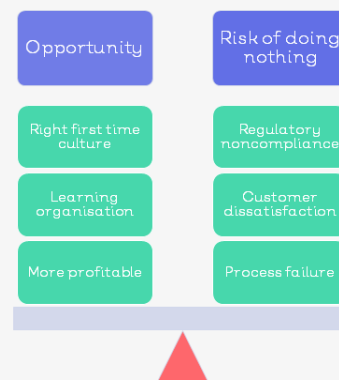


“There was no incentive to do bad things.”

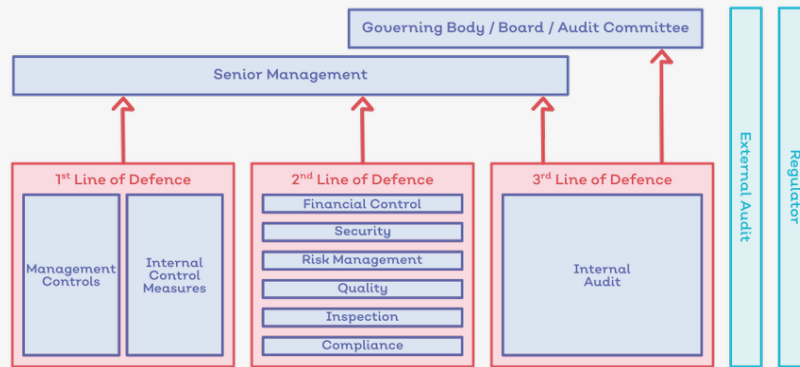
John Stumpf, Wells Fargo

Why is auditing leadership challenging?

1. HiIPPO: Highest paid person's opinion
2. Asking the right questions
3. Giving feedback



Three lines of defence



Adapted from ECIIA/FERMA Guidance on the 8th EU Company Law Directive, article 41

The expectation gap

Boards

- Understand risk
- Processes to manage risk
- Hold management accountable

Management

- Identify and manage risk
- Tone at the Top
- Identify and manage risk
- Establish processes and policies to support objectives
- Model behaviour
- Hold yourself and others accountable
- Foster an environment of top down and bottom up communications

Internal audit

- Provide assurance to management and the board that processes are functioning as designed
- Provide insights into risk and opportunities to improve mitigation strategies relating to process and controls
- Focus on root cause analysis, move beyond what and where to why
- Leverage knowledge of the business to provide insight

What drives toxic corporate culture?

Seven deadly signals of toxic culture

1. Lack of collaboration
2. Focus on self interest
3. Overly bureaucratic
4. Lack of trust
5. High staff turnover
6. Same mistakes are repeated
7. No visibility

Do you feel your leadership team is doing enough to demonstrate they are engaged with quality?

Example questions to ask leadership



- Please provide examples of how you communicate the importance of a QMS or IMS.
- How do you demonstrate commitment to your employees?
- As an organisations, how do you meet (and exceed) customer expectations?
- Do the MS objectives align with the business strategy?
- Please provide an overview of your Risk Approach
- Please provide an overview of your Interested parties and how they affect your MS
- How do you manage change?
- How do you capture and use knowledge?

Hints and Tips



- Keep your eyes open
- Keep your ears open
- Follow your nose
- Remain diplomatic
- Be open and friendly
- Remember - Management should be readily available, prepared, and 'excited' to participate in the opening and closing meetings.

Audits, inspections and reporting

Identifying risks and opportunities

20th March 2019

Chris Owen, Services Director at Qualsys

Agenda: Identifying risks and opportunities in audits

- Why audit?
- Five common auditing mistakes
- Is your auditing process broken?
- Risks and opportunity management in auditing



Chris Owen
Services Director

400+ successful implementations

Honeywell

DIAGEO

sodexo

UNIVERSITY OF LEEDS

THOMAS MILLER

IQE

smsplc

ENERGY ASSETS

+well

BT

NHS

BARR
SOFT DRINKS

Accolade Wines

HYBRID Air Vehicles

BUNZL

MarleyEternit

IOVANCE
BIOTHERAPEUTICS

RAWSON

baywater
HEALTHCARE

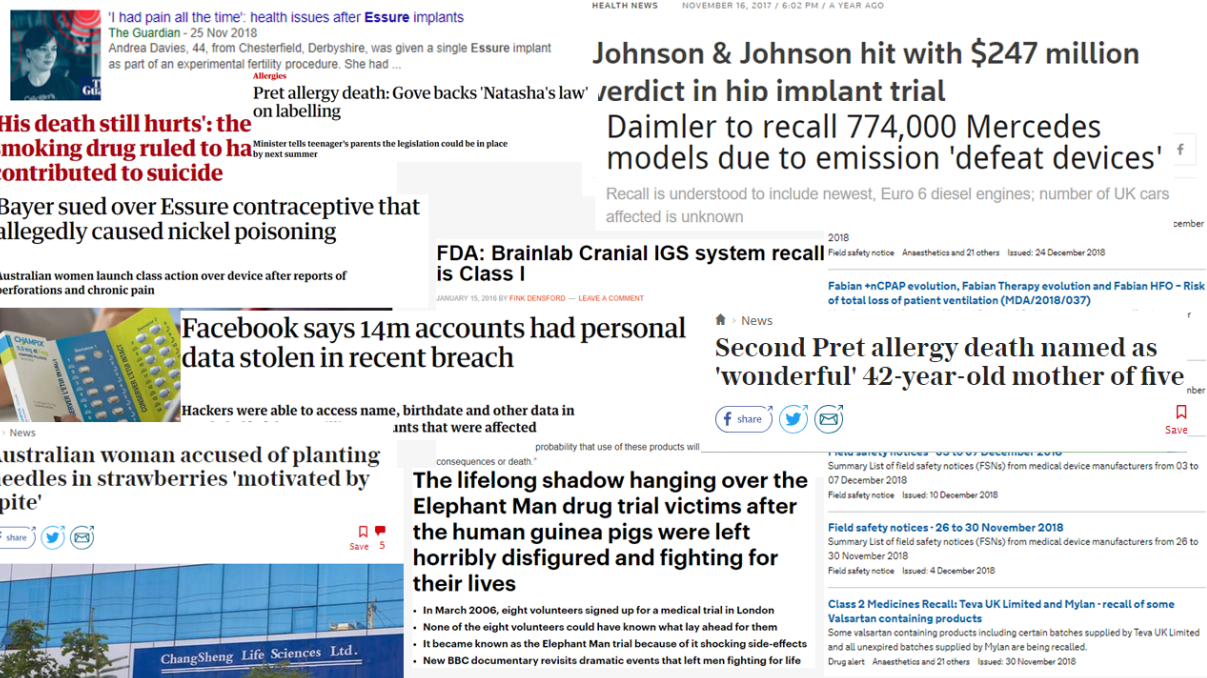
Alliance Medical
Intelligent imaging

EPC GROUPE

ofgem

BUCHER
municipal

Virgin media



A pie chart illustrating the distribution of man days across five categories of work. The largest segment, representing 'More than 20 man days', is blue and accounts for approximately 55% of the total. The next largest is '16-20 man days' in green, at about 25%. '6-10 man days' is cyan at 15%, '11-15 man days' is red at 5%, and the smallest segment, '0-5 man days', is black at 2%.

Work Type	Percentage
0-5 man days	2%
6-10 man days	15%
11-15 man days	5%
16-20 man days	25%
More than 20 man days	55%



It's all about
opportunity and
risk



Auditing



- ✓ Generates valuable insights
- ✓ Prevents waste
- ✓ Creates value
- ✓ Helps organisations to grow
- ✓ Fixes leaking buckets



Auditing has an
image problem

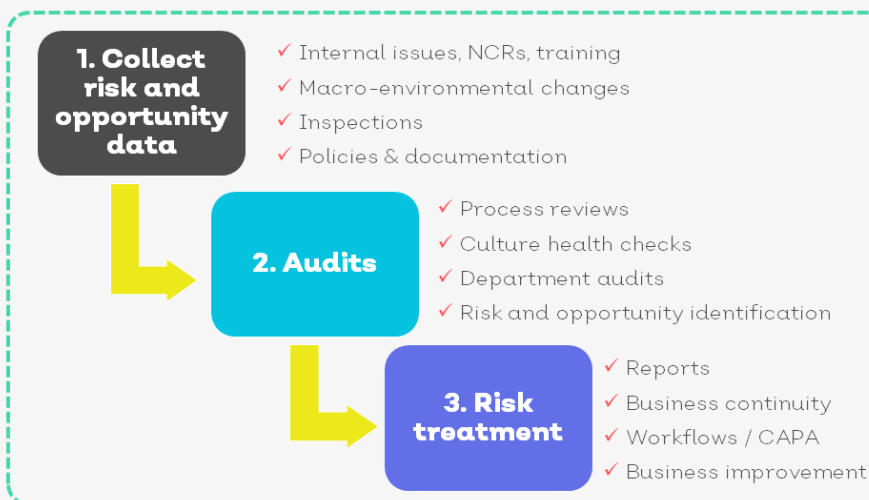


What would your organisation say about the audit function?



Internal audit survey prior to implementation of a management system

The auditing landscape



Top 5 mistakes

Mistake #1: Poor communications

Mistake #2: Lack of creativity

Mistake #3: Inconsistent approaches and experience

Mistake #4: Not investing in auditors

Mistake #5: Poor follow up activity

- The best auditors listen, learn and guide



Overly friendly

Too rigid

Good communicators

Your internal auditors are more valuable to your business than external auditors



Audits vs inspections

Audit	Inspections
Qualitative	Quantitative
Exploratory	Tick-box
Why?	What? Who? Where? When? How?
Useful for: Leadership audits, risks and opportunities, improvement initiatives, operational excellence, growth, profitability, ideas and innovation	Useful for: Exposing vulnerabilities, quality control, waste reduction, fact-checking, process management.
Complex root cause analysis and problem solving	Rapid root cause analysis

The average internal audit report contains 6-10 recommendations

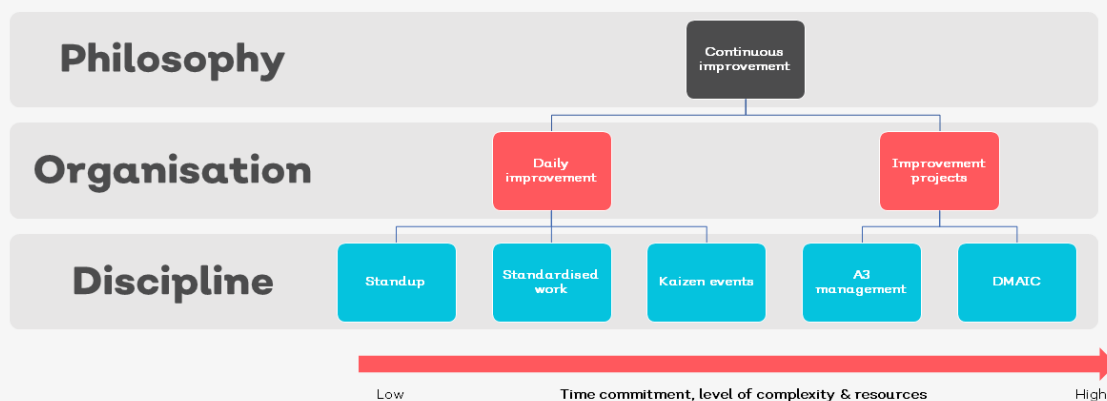


- How can we communicate risk and opportunity in a way people are going to understand?
- How can we drive action from audit reports?
- How can we change the perception of an internal audit from a tick-box exercise to one where it drives cultural change?

!Think carefully before putting a scale in the audit report

Benefits of using a scale	Disadvantages of using a scale
Simple to understand	Diversion from findings to a negotiation on a number
Provides areas of focus	Promotes competition between departments
Scale reflects risks	Repetition of recommendations against risks (no integration of activities leading to duplication of effort)
Allows committee members to assess strength of controls without reading report	Management may ignore areas of weakness or good practice
Powerful communication tool	Does not include recommendations, instead agreed management actions

Response needs context



“Quality people are the needle and the thread, stitching the whole end-to-end together. To do this you have to be a good communicator and influencer who can quickly build respect and credibility. People who can truly do this are very thin on the ground.”

Leading quality in the 21st Century – CQI & Oakland research report

Supply Chain and Supplier Auditing



Who Am I?

- ▶ Biomedical scientist.
- ▶ 20+ years experience in the pharmaceutical industry.
- ▶ Practicing QA Manager, QP, RP.
- ▶ Qualified Pharmaceutical Lead Auditor.
- ▶ Routinely plan, manage and execute supplier audit programs for small, medium and large organisations.



Why Conduct Supplier Audits?



As part of a vendor selection and on boarding process.



Periodic review of vendors as part of a company's internal control framework and prior to contracts being renewed.



Investigation into allegations of misconduct by the third-party.

Benefits of Supplier Audits

- ▶ Verify standards.
- ▶ Ensure that a functional QMS has been established.
- ▶ Identify risks.
- ▶ Active communication between customers and supplier.
- ▶ Strengthen long-term healthy business relationships.
- ▶ Development of suppliers can be documented and compared.
- ▶ Supplier risks and quality related costs can be reduced.
- ▶ Ensure quality throughout supply chain.

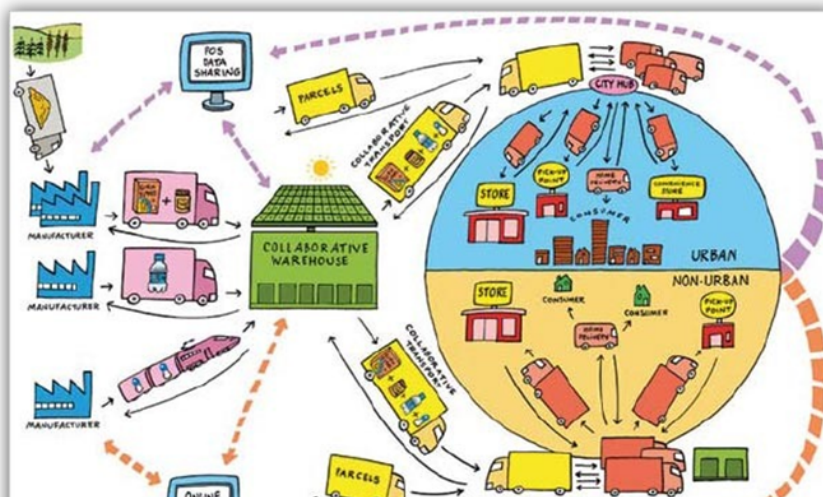
Risk Based Approach

Aim should not be to audit every vendor engaged by the organisation but to conduct a thorough audit with greater frequency for targeted, high-risk vendors.

Cost-effective.

Enhance the quality of the organisation's operation.

Complex Supply Chains



Risk Based Approach

- ▶ Operational risks.
 - ▶ Complexity of product.
 - ▶ Location of vendor.
 - ▶ Complaints, non-conformances, recalls.
 - ▶ Supplier KPIs.
 - ▶ Are they your only vendor?
- ▶ Regulatory risks.
 - ▶ Previous audit history with your company.
 - ▶ Previous inspection history.
- ▶ Reputational risks.
 - ▶ Proactivity between audits.
 - ▶ Visibility of the product.
- ▶ Financial risks.
 - ▶ Single source?
 - ▶ Cost of product.

New Supplier Onboarding

Pre-Audit

- ▶ Research.
- ▶ Prepare.
- ▶ Focus.
- ▶ Target.
- ▶ Careful selection of auditor – not all are equal.
- ▶ What's your standard?

During Audit

- ▶ Build rapport.
- ▶ Fact find with kindness.
- ▶ Open, collaborative.
- ▶ Desired vs actual.
- ▶ What's the risk?
- ▶ Do you want to work with them?

Onsite Audit

General impression of the production.

Plant equipment, machinery and manufacturing.

Internal and external communication.

Quality Management.

Testing instruments and equipment.

Inspection.

Employee qualification.

Delivery reliability.

A story...

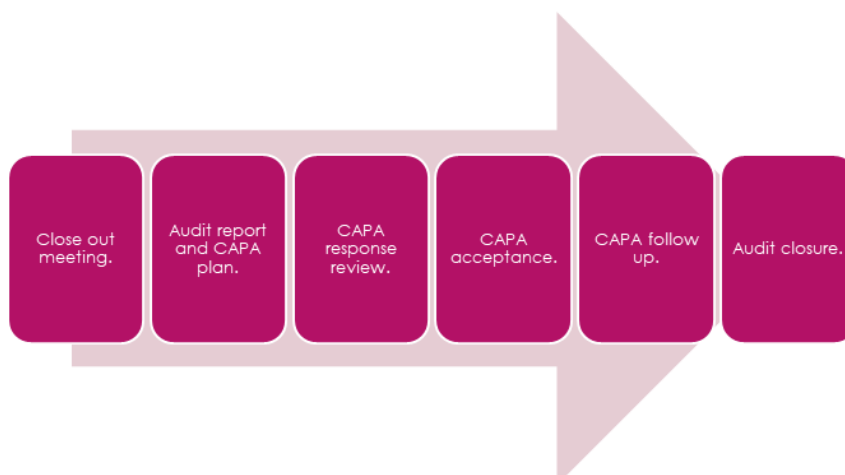


Rinse and Repeat?

Periodic evaluation

Timeliness of response
tells you a lot

Managing Follow Up Actions



Right to Audit

A right of audit clause within third party vendor contracts is a valuable asset in a company's compliance programme as it is increasingly common for customers, especially for government and large multinational customers, to mandate and exercise it in their supplier contracts.

Conclusions

- ▶ Rigorous and thorough vendor audits send strong, compelling compliance messages throughout the organisation and to the company's third party vendors demonstrating that the company values transparent and compliant behaviour.
- ▶ Taking a risk based approach focusses activity.
- ▶ Place value on the process, on the auditor, on the outcomes.
- ▶ Vendors should, in turn, be less inclined to engage intentionally in unethical conduct if they know that an audit may be conducted at any time.
- ▶ Vendor audits are, therefore, often an effective way to demonstrate and evidence a company's careful oversight of supply chain management from a compliance perspective.
- ▶ Companies should be prepared for their customers, especially government agencies and large multi-nationals, to want to exercise their right to audit clause within their contracts.

Any Questions?

Thank you





About me



- Julian Jack
- Membership Manager

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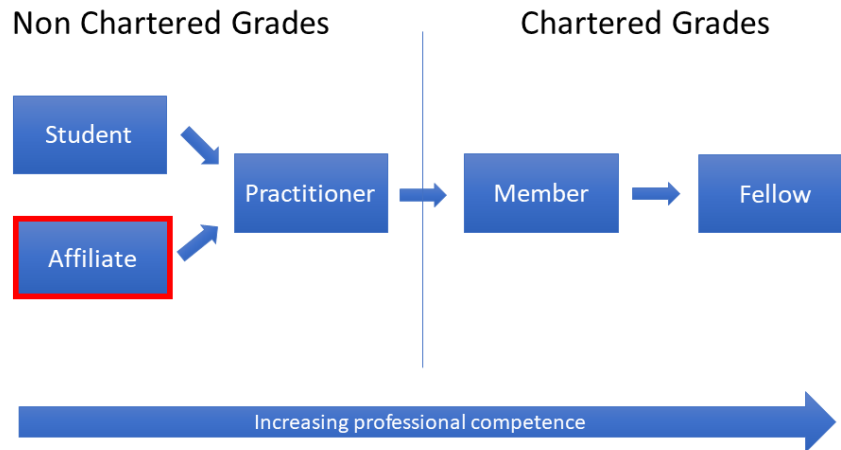
The CQI & IRCA



A **global network** of **20,000** quality and auditing professionals

- Members internationally recognised
- Assuring organisational reputation
- Eliminating unnecessary costs & waste
- Making organisations more successful
- Operate an extensive branch network
- Facilitate Special Interest Groups (SIGs) that progress quality in their respective sectors

The Member journey



Why Become a Member?

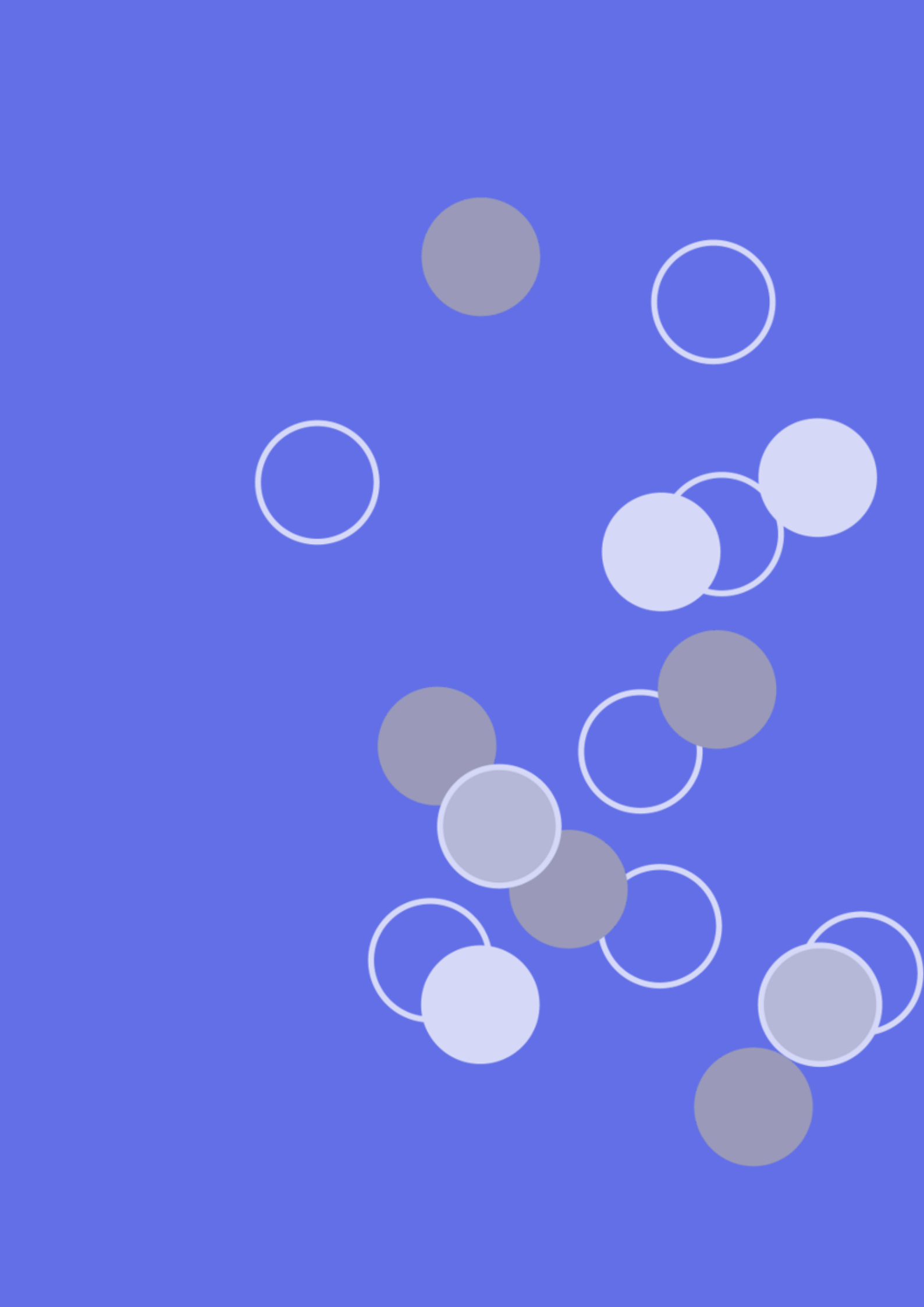


CQI Chartered Quality Professionals earn on average **14% more** than non - member quality professionals.

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audit-gap-analysis](https://quality.eqms.co.uk/audit-gap-analysis)**

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