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CQI and IRCA Certified Courses

The **CQI** is the only chartered professional body dedicated entirely to quality. **IRCA** is its specialist division dedicated to management system auditors.

The CQI are now launching a new portfolio of **CQI and IRCA Certified** courses, beginning with Foundation level courses. These courses will be followed by courses at Practitioner and Professional level. Topics include Problem Solving, Risk Management, Change Management and Process Design.

Course Level	Duration	Description	Who should study these courses	Release date
Foundation	8–16 hours	These courses will provide students with a basic awareness and understanding of the relevant topics and knowledge. Students will gain an understanding of the skills relevant to the competency.	Those who are new to quality or currently work in a different function or business area.	Released
Practitioner	16–24 hours	These courses will provide students with a full understanding of the relevant topics and knowledge, and enable them to apply this knowledge. Students will gain the skills to execute relevant activities under supervision.	Those who are currently practising in quality and are aspiring to middle management.	<i>Release in June 2016</i>
Professional	24–40 hours	These courses will provide students with a full understanding of the relevant topics and knowledge, and enable them to apply this knowledge. Students will gain the skills to execute relevant activities unsupervised, and to develop or manage these activities.	Those who are currently practising quality at a mid to senior level and are aspiring to leadership or senior management.	<i>Release in September 2016</i>

Further details can be found on www.qmt.co.uk and if you are interested in any of the courses, please contact help@qmt.co.uk

Standards Update

Most people will now beware of the revisions to the ISO 9001 and ISO 14001 management system standards and have started their transition process. In addition to these updates there are on-going revisions to various associated standards to catch up with these changes.

ISO 9004 *Managing for the sustained success of an organization -- A quality management approach* has just begun a major revision to take into account not only the revised requirements of ISO 9001:2015, but also the increasingly complex and changing environments businesses operate in.

ISO 14004:2016 *Environmental Management systems - General Guidelines on Implementation* has recently been released and this standard provides detailed guidance to help organisations navigate their way through creating an Environmental Management System (EMS), specifically helping with the new requirements set out by ISO 14001:2015

ISO 13485 the latest edition of the internationally recognized quality management system standard for the medical device industry has now been published, ISO 13485:2016, *Medical devices - Quality management systems –Requirements for regulatory purposes*. ISO 13485 sets out the requirements for a quality management system specific to the medical devices industry. The recent revision responds to the latest developments in quality management, technology and regulatory requirements that relate to the industry.

Improvements in the new version of the standard include broadening its applicability to include all organizations involved in the life cycle of the product, from concept to end of life, greater alignment with regulatory requirements and a greater focus on post-market surveillance including complaint handling. There is also a greater emphasis on having the appropriate infrastructure, particularly for the production of sterile medical devices, and more focus on risk management.

ISO 27000:2016, *Information technology – Security techniques – Information security management systems – Overview and vocabulary* gives a comprehensive view of information security management systems covered by the ISMS family of standards, and defines related terms and definitions. Elzbieta Andrukiewicz, the editor of ISO 27000, said, “ISO 27000 provides a very brief introduction to the information security area and information security management systems, describing how to implement, operate, maintain and improve the ISMS”. The standard lays down the key factors of a successful implementation and the numerous benefits of using the ISMS family of standards. It provides an understanding of how the ISO/IEC 27001 family fits together through its multi-faceted approach, clarifying the standards’ scopes, roles, functions and relationship to each other.

ISO 19770-1 - the ISO Software Asset Management process standard, is being revised. Some features of the revision are:

- Integrated use with other standards
- The use of the new high-level structure for Management Systems Standards (Annexe SL) in line with the revised ISO 9001 and ISO/IEC 27001
- Leveraging on physical asset management
- The use as its basis of a new standard for generic asset management (ISO 55001)
- Adds requirements to meet the special or more demanding characteristics of Software Asset Management (SAM) and IT asset management (ITAM)

ISO 19011 *Guidelines for auditing management systems*, is a key document in helping those who audit management standards. The current version has a ‘quality’ perspective but now that so many other sectors use the same common structure and core requirements ISO has announced that it will be revising **ISO 19011** to be more relevant to all the management standards. The revision will begin this year and should be published in 2018. Should you wish to get involved with

the UK position on this please email BSUKOperations-Admin@bsigroup.com.

For further information on the changes to any of these standards, please visit www.iso.org

Risk Management

The new ISO 9001:2015 standard has an increased focus on the need to demonstrate that risks and opportunities have been identified and are being managed. This can be difficult for small and medium-sized enterprises (SMEs) who often don't carry out any formal risk management. A new handbook has been published recently that aims to help SMEs manage risks and protect their business. **ISO 31000** – *Risk management – A practical guide for SMEs* gives guidance on how to use the ISO 31000:2009 standard to integrate good practices in their strategic decisions and their operations.

John Lark, the author of the handbook said, "Whilst most SMEs manage risk to a large extent, a number of SME leaders don't consider implementing formal risk management processes, believing they aren't big enough to warrant a proper risk management system or because they feel they are too busy running the company. However, there is significant opportunity for SMEs that do engage in a more structured risk management practice. SMEs that do implement risk management in a way that is aligned with the principles and processes found in ISO 31000 can become more successful and be in a position to evolve into big companies."

The handbook is structured as a checklist with a series of questions and related actions that guide users through the development of a risk management system.

The handbook can be purchased through the ISO Store www.iso.org.

Certification for LEAN and Six Sigma

For some time there has been a need for a form of Certification for LEAN and Six-Sigma as there has been no internationally

recognised standards or approaches. There are many organisations in the market unilaterally certifying or accrediting Sigma & Lean practitioners and courses all to no agreed standard. Finally a standard has been released by ISO. **ISO 18404** *Quantitative methods in process improvement - Six Sigma - competencies for key personnel and their organizations in relation to Six Sigma and Lean implementation* ensures best practises within an organization and avoids questionable interpretations of Six Sigma and Lean.

Organizations will now be able to have an accredited ISO 18404 certificate for their Lean or Six Sigma implementation alongside their other ISO certifications such as ISO 9001 or ISO 14001. In addition, individuals can be certified under ISO 18404 as Six Sigma Green, Black & Master Black Belts and as Lean Practitioners, Leaders or Experts.

ISO 18404 sets out the separate competency requirements for Six Sigma and Lean implementation. It also provides a combined competency framework for Lean and Six Sigma.

The standard aims to help you:

- Showcase the organization's competence in Six Sigma and Lean
- Identify and interpret the requirements for deployment
- Build a system to manage applications of the Lean and Six sigma approaches
- Structure a defensible implementation of personnel and techniques
- Plan and deploy effective training to deliver required benefits

For further information please visit www.iso.org

Opportunities for Poke Yoke devices

Have you heard about the Raspberry Pi? It is a very low cost computer and you can find information on the Pi at <https://www.raspberrypi.org/> . The Pi has a wide range of sensors to integrate with it and these can record and report on almost

anything; movement, shock, knock, temperature, humidity, tilt, interruption, microphone, gas, and lots more all for a very reasonable cost.

This opens up many opportunities to use the Pi and sensors to develop Poka Yoke solutions that previously were too expensive to contemplate.

Addressing or avoiding many defect causes; omitted operations, faulty processing, wrong location, etc. can be achieved by a Poka Yoke device such as; Location, Alarms, Limit Switches, Counters, etc. This is where the Raspberry Pi and its associated sensors comes in as it can identify these potential errors and either prevent or detect a defect being made.

Like to know more about Poka Yoke?

See:

- <http://www.poka-yoke.org.uk/>
- <http://www.qmt.co.uk/books/book-d3>
- <http://www.qmt.co.uk/training/quality/poka-yoke>

If you completed any Poka Yoke assignments or projects - we'd love to hear about them, please email Geoff Vorley at help@qmt.co.uk