Q. Already auditors are starting to interpret that organization need a Risk assessment document to verify if they have considered all risks prior to making a decision. An organization takes a number of decisions on regular basis, Expectation to record all?

A. Section A.4 of ISO 9001:2015 FDIS states “Although 6.1 specifies that the organization shall plan to address risks, there is no requirement for formal methods for risk management or documented risk management process” and organizations are required to per 4.4.1 f) address the risks and opportunities as determined in accordance with the requirements of 6.1. The word ALL is not shown. It is, however, important to note the requirement in Clause 10.2.1 to “update risks and opportunities determined during planning, if necessary” when a nonconformity occurs.

Q. Interested parties, internal and external issues are welcome new concepts. However are we expecting a formal strategic planning from organizations?

A. There is no requirement within the ISO 9001:2015 FDIS for a formal strategic planning process. Understanding the “strategic direction” is expected, starting with the Process Approach (Clause 0.3.1) through context (Clause 4.1) through leadership commitment (Clause 5.1.1, 5.2.1) and ending with management review (9.3.1).

Q. TS16949 is based on ISO9001. Will that be updated as well, and when? How would an organization that has certification to both manage 2 different standards at the same time?

A. Like QuEST Forum's TL 9000 for ICT, the automotive and aerospace industries are updating their standards to address ISO 9001:2015. For info on aerospace’s update please see QFA webinar: http://www.questforum.org/ict-initiatives/qf-academy-webinars/aerospace-and-iso-90012015/ and hopefully there will be QuEST Forum Academy webinar on automotive in the future. Also, ISO Implementation Guidance for ISO 9001:2015 available at: www.iso.org/tc176/sc02/public states “Users of specific sector schemes are recommended to refer to the organization that is responsible for that sector scheme’, e.g.:

- ISO/TS 16 949 refer to the IATF (www.iatfglobaloversight.org)
- TL 9000 refer to the QuEST Forum (www.questforum.org)
- AS9100/EN9100 refer to IAQG (www.iaqg.org"

Q. Standard has evolved into a business management standard moving from a narrow confinement (misperception) of quality standard. What is in horizon for 2020?

A. Work is beginning later in 2015 on the revision to ISO 9004 (“Managing for the sustained success of an organization — A quality management approach”) which provides guidance for organizations that wish to go beyond just meeting the requirements of ISO 9001. That revision process is expected to last for around 3 years, so the new ISO 9004 should be published in late 2018 / early 2019. To stay abreast of information regarding ISO’s Technical Committee No.176, Sub-committee No.2 (ISO/TC 176/SC 2) who are responsible for the development of the ISO 9001 and ISO 9004 International Standards as well as other International Standards and documents in the ISO 9000 Family, please visit: www.iso.org/tc176/sc02/public.

Q. Is ISO 13485 adopting the new 9001:2015?

A. See response below.
Q. Will medical device ISO 13485:2003 be adopting the new version 9001?

A. Although we are not explicitly familiar with ISO 13485, at the August USTAG TC 176 meeting, TC 210 reported that it had submitted a revised Draft (“DIS2”) for the revision of ISO 13485 to the ISO Central Secretariat at the end of January 2015. However, it is not believed that the update of ISO 13485 will align with the revised structure of ISO 9001:2015.

Q. What are the differences between 8.7 Control of nonconforming outputs and 10.2 Nonconformity and corrective action- Is this apparent repetition due to trying fit Annex SL?

A. Section 8.7 Control of nonconforming outputs of the ISO 9001:2015 FDIS is equivalent to 8.3 Control of nonconforming product within ISO 9001:2008. It relates to the way in which nonconforming process outputs (which can include intermediate stages of production or service delivery) are dealt with Section 10.2 Nonconformity and corrective action relates to any kind of process, product, service or system nonconformity and is equivalent to 8.5.2 Corrective action of ISO 9001:2008. So this does not support the comment that there is repetition due to Annex SL.

Q. Does ISO 9001:2015 provide the details needed to fully understand the QMPs or does Dr Croft recommend the use of ISO 9000:2015 to improve the organization's understanding?

A. Dr Croft definitely recommends the use of ISO 9000, not only to obtain a deeper understanding of the quality management principles, but also because ISO 9000 is cited as a “normative reference” in ISO 9001, meaning that the use of the definitions cited in ISO 9000 become an integral part of the interpretation of ISO 9001.

As stated within ISO 9001:2015 FDIS at 0.4, This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000 Quality management systems — Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this International Standard; ...

Also, the quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of [ISO 9001:2015]. These principles are not requirements in themselves, but they do form the foundation of the requirements specified by ISO 9001:2015.

Q. Adding requirements to "leadership" is a welcome change. Does this imply that internal and external auditors are interview senior leadership team on the requirements under their responsibility?

A. Definitely! But this should not be considered as something new. Senior leadership members were expected to be interviewed by internal and external auditors based upon the previous version of ISO 9001, which included requirements for “top management”. Section 5.1 – Leadership is an improvement from the previous version of ISO 9001 and still uses the term “top management”.

Question: There are many instances in the standard where QMS requirements are not supported by the requirement for "documented information" How could an organization demonstrate implementation or auditors look for objective evidence.

According to A3 of ISO 9001:2015 FDIS - Where this International Standard refers to “information” rather than “documented information” (e.g. in 4.1: “The organization shall monitor and review the information about these external and internal issues”), there is no requirement that this information is to be
documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information. QuEST Forum’s TL 9000 uses the term "method" which is defined as means by which activity is accomplished which is not necessarily documented but which is demonstrated to be consistent. During an audit, auditors may evaluate activities while they are being implemented. Additionally, the ISO 9001:2015 states A requirement to “maintain” documented information does not exclude the possibility that the organization might also need to “retain” that same documented information for a particular purpose, e.g. to retain previous versions of it. The requirements for documented information to be retained remain within ISO 9001:2015 similar to the previous version of ISO 9001 which required “records”, therefore an auditor may review the retained documented information. It is, however, important to note that organizations seeing certification are expected to provide objective evidence that they meet all the requirements of ISO 9001, and in many cases, the most convenient (though not required) way of providing evidence is likely to be in the form of records.

Q. Concerned about 3 year period explanation.... if we have to be compliant as an HQ for both ISO9001 and TS16949 it means that next year when recert happens I must comply with the new ISO, but also with the old ISO.... confusing for my organization.

A. IAF’s ID9:2015 accessible here: http://www.iaf.nu/upFiles/IAFID9Transition9001PublicationVersion.pdf states that the International Accreditation Forum (IAF) and the ISO Committee on Conformity Assessment (CASCO) have agreed to a three year transition period from the publication date of ISO 9001:2015. And ISO Implementation Guidance for ISO 9001:2015 available at: www.iso.org/tc176/sc02/public states “Users of specific sector schemes are recommended to refer to the organization that is responsible for that sector scheme’, e.g.:

- ISO/TS 16 949 refer to the IATF (www.iatfglobaloversight.org)
- TL 9000 refer to the QuEST Forum (www.questforum.org)
- AS9100/EN9100 refer to IAQG (www.iaqg.org)”

For example, at QuEST Forum, we expect to release TL 9000 R6.0 approximately 1 year after ISO 9001:2015’s publication, allowing a 2 year transition which will allow alignment with ISO 9001:2015’s 3 year transition.

Specifically regarding ISO/TS 16949, accredited certification does not come under the IAF, and is administered directly by the IATF (IAOB). Unfortunately, until the new version of TS 16949 is published, organization wishing to claim conformity to both ISO 9001:2015 and TS 16949 may need to meet both ISO 9001:2008 and ISO 9001:2015 standards. Refer to the IATF site for additional information.

Q. So we can delay recert until the TS is upgraded? Our plants will likely not transition until this happens. But the HQ must comply with TS, but is still certified to ISO. This is where the compliance with both comes in....

A. ISO Implementation Guidance for ISO 9001:2015 available at: www.iso.org/tc176/sc02/public states “Users of specific sector schemes are recommended to refer to the organization that is responsible for that sector scheme’, e.g.:

- ISO/TS 16 949 refer to the IATF (www.iatfglobaloversight.org)
- TL 9000 refer to the QuEST Forum (www.questforum.org)
Q. If the company has a QM team or department managing ISO standards, should this be dissolved since the management representative is being eliminated?

A. Not if it is working well, and helping the organization to ensure that the QMS achieves its objectives. Although ISO 9001:2015 no longer has a prescriptive requirement for “a Management representative”, top management still has to determine the responsibilities and authorities for the effective deployment of the system and reporting back to top management on the system performance. That could continue to be a single person (if that is working well), and there’s no reason why that person shouldn’t continue to be called the “Management Representative”. ISO 9001:2015 gives organizations more flexibility to decide what works best in their particular context. Note that the Correlation matrices between ISO 9001:2008 and ISO 9001:2015, accessible at: www.iso.org/tc176/sc02/public shows that the requirements of 5.5.2 Management representative of ISO 9001:2008 now correlate to 5.3 Organizational roles, responsibilities and authorities of the ISO 9001:2015 FDIS.