The ISO 9001:2015 Standard:
Quality Management Systems – New Concepts

PEER REVIEWED

The ISO 9001:2015 Standard: Quality Management Systems – New Concepts

Last September, the newly revised BS EN ISO 9001:2015 'Quality management systems – Requirements'[1] was published, along with BS EN ISO 9000:2015[2] which covers terminology and definitions to aid understanding and uniformity of interpretation. The ISO 9001 standard was first established in 1987[3], and sees accredited certifications approaching 1.5 million worldwide. It was the start of a global phenomenon which saw the range of ISO management systems standards expand to include, amongst others, the environment as well as continuity, insurance and risk (1996), through to the current business continuity management and environmental management standards (see Figure 1). So, why has the core quality management systems (QMS) standard been updated and what are the aims and aspirations of this new edition?

The ISO standards are revised every ten years or so; 2015 saw a major overhaul of ISO 9001:2008, in line with the new high-level structure of ISO Annex SL (2012) for Management Systems to better reflect modern-day organisational planning and process management. The revision is three-fold: (i) the revised clause sequence with two new clauses; (ii) seven revised quality management principles; and (iii) new concepts in quality assurance. There is a new emphasis on risk management approaches and incorporation of new business terminology to describe and capture the ways that business and technology have advanced, and are set to advance for the next decade. This should allow for integration of further development and influence on business practice from sectors such as: information technology, internet, remote electronic storage, advances in data security, protection of brand-rights and trademarks, as well as supply chain security.

Each modern-day business is required to meet not only the complexity of the various regulatory requirements to gain access to market, but also the need for compliance with multiple ISO management systems standards (MSSs) – and not only product-related ones – but standards which advocate corporate social responsibility: environment, sustainability, occupational health and workplace safety. This has culminated in a re-think to ease the need for multiple system manuals to reflect the needs of differing operating standards. The move is towards a combined portfolio of MSSs for ease of use and ease of audit, hence the transition of ISO standards to the new high-level structure to aid consistency of approach.

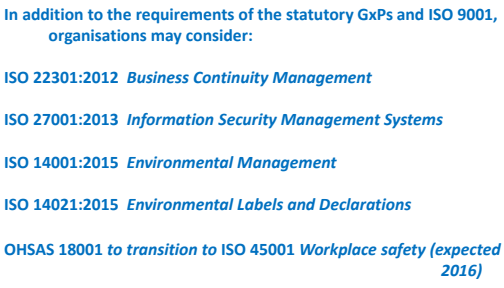

Figure 1 - A combined portfolio of management system standards

Is the ISO 9001:2015 QMS Relevant to Pharmaceutical Quality?

Well, yes it is, in that it is often a primary condition to be met as an assurance of quality, for sub-contracting service providers of temperature-mapping, cold-chain monitoring or supply logistics, for example. Depending upon your product, other ISO standards as well as regulations may apply. For example, in the relatively new pharmacovigilance regulations, EU No. 520/2012,[4], the European Medicines Agency (EMA) mandate compliance with the terminology within ISO 11615, ISO 11616, ISO 11238, ISO 11239, ISO 11240 and ISO 27953:2011, from 1st July 2016, for electronic data capture of health informatics to facilitate clinical data submissions and reporting of pharmacovigilance monitoring[5].

Are there similarities between the QMS described by ISO 9001:2015 and the EU GMP[6,7], pharmaceutical quality system (PQS)? Absolutely, since the incorporation of ICH Q9 into cGMP, quality risk management is not only of current emphasis in ISO 9001, but the PQS model and component processes draw upon the ISO 9001 process model and plan-do-check-act (PDCA) cycle. Both the process model and the PDCA cycle remain as core concepts of the ISO standard. However, the scope has been broadened from its focus upon design and manufacture of products as the single main output, to encompass products and services – thus extending its application to service-based industries, organisations which provide information and charities.

The New High-level Structure

There are now ten clauses instead of eight (Figure 2); the first three clauses cover the introduction of the scope, the normative reference (in this case, ISO 9000) and definitions. In Clause 4, the previous QMS requirements have become the 'context of the organisation', which challenges each organisation to really define external factors such as market and socio-economic conditions. Internal factors are also key: organisational culture, education and training are fundamental to organisational success and longevity (Figure 3). Resource management has become part of 'planning' and the old Clause 7: product realisation is now support (Clause 7) and operations (Clause 8). Measurement, analysis and improvement are now performance evaluation (Clause 9) and improvement (Clause 10).

	From 2008	*To ISO 9001:2015*
Clause 4	Quality Management System	Context of the Organisation
Clause 5	Management Responsibility	Leadership
Clause 6	Resource Management	Planning
Clause 7	Product Realisation	Support
Clause 8	Measurement, Analysis and Improvement	Operations
Clause 9		Performance evaluation
Clause 10		Improvement

Figure 2 - The new high-level clause structure

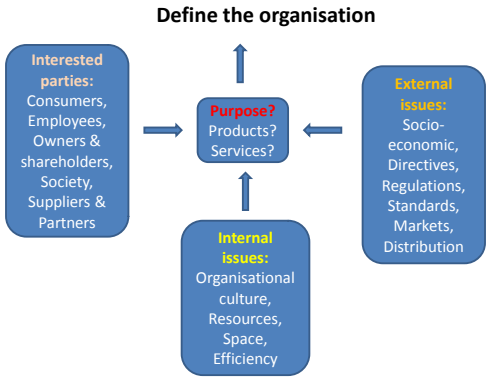

Figure 3 – The context of the organisation: New factors to consider

In summary, the new clause structure reflects up-to-the-minute business terminology for organisational planning and process management (Figure 4). However, ISO 9001 states there is no pressure or expectation for businesses to use the new clause sequence in their QMS structure. It is still acceptable for each business or organisation to use its own terminology which best describes its operations. The new wording is deliberately more generic to allow greater flexibility in how the standard is interpreted and applied. It is therefore the intention that, as technology advances, new terms and processes can be easily incorporated into the QMS.

Clause 4	Understanding the context of an organisation, its QMS and processes
Clause 5	Leadership, policy and responsibilities
Clause 6	Process for planning and consideration of risks and opportunities
Clause 7	Process for support, including resources, people and information
Clause 8	Operational processes relating to customers, products and services
Clause 9	Processes for performance evaluation
Clause 10	Processes for improvement

Figure 4 - Clauses that capture modern-day organisational planning and process management

The Seven QMS Principles

These are as follows: (i) customer focus, (ii) leadership, (iii) engagement of people, (iv) process approach, (v) improvement, (iv) evidence-based decision-making, and (vii) relationship management. Clearly, your primary consideration is to meet the customer's requirements and expectations. You want to attract and retain customers, but to stay ahead, it is important to understand future needs. Leadership: instead of management responsibility, the emphasis is on managers with ability as leaders, who do not delegate everything, forego their responsibilities and sit back and wait for it all to go wrong, or conversely, are promoted on the back of the effort of their underlings. Leaders need to create a unity of purpose, give direction and engage all employees.

A company culture which is quality-conscious, positive and forward-thinking, and values the integrity and skills of its people, is paramount. Employees need to be competent, empowered, and engaged, i.e. their input matters, their skill and knowledge matters and can be enhanced through further training, their decisions matter and everyone should be respected as individuals. The occasional reward does not go amiss or un-noticed.

A process approach, improvement, evidence-based decision-making – all things you are no doubt aware of. And lastly, relationship management – this refers to the inter-relationship with other management standards and regulations, the different regulators and licensing authorities which inspect the organisation from time to time, as well as actively managing the relationships with suppliers and other interested parties, such as stakeholders and executive and non-executive directors. The latter will have both financial and technical insight of the organisation.

New Language: Changed, Simplified, New Emphasis

Flexibility when applying ISO 9001 is the way forward. The core terminology has changed to allow this. 'Documented information' is the new ISO term for: records, protocols, standard operating procedures – all documentation in any form: all new media as well as traditional, hard copy. 'External provider' covers: suppliers, partners, vendors, co-working organisations, processors, sub-contracted manufacturers, QC test laboratories and calibration providers. There is flexibility to allow for new information sources, for example, wireless applications and devices with touch-screen or infra-red technologies such as iPads, smartphones, data readers – the list goes on. Thus the ability to record and access data from sources which permit the ability to record data on the go, whether it be from satellites, laptops, data-matrix readers, mobile phone apps or biotelemetry – anything which holds or transmits information in any format which has an impact upon delivery of output, can be included as documented information.

The 'management representative for quality' has gone, as all of top management shall demonstrate through leadership, their commitment to quality; 'preventive action' as well as 'exclusions' – exiled to the ISO 9001 archives. However, the core concept of identifying and addressing potential mistakes before they materialise stays, but how this is achieved has changed. Organisations now think in terms of 'risks and opportunities' – remember the old risk-benefit analyses? Well, this is much more integral and part of not only organisational planning, but can also be applied during other phases of the product (output) lifecycle (see Figure 5).

New – 'Risk' as a Preventive Tool

Assessing potential or actual risks and identifying opportunities to overcome them is seen as a proactive driver for adapting and improving business effectiveness, whilst delivering output of the required quality. Preventive action was intended to prevent the occurrence from happening, hence this term is redundant – replaced by risk assessment and mitigation.

Organisations must provide evidence that they have determined risks and opportunities, considered the impact of a risk being realised or the effect of an opportunity being missed, considered the effect upon customer satisfaction, taken action where necessary, and evaluated the positive and negative effect upon the ability of the QMS to deliver the intended outcome.

Risk, Opportunities and Improvement

The new Clause 10: improvement, acknowledges that incremental (continual) improvement is not the only way organisations improve. Thus, improvement may come from a variety of situations: periodic breakthrough, e.g. technological advancement; reactive change, such as to a serious complaint or product failure/recall; reorganisation; audit findings; and other unforeseen errors such as equipment not behaving or power cuts.

In practice, one often sees the QMS become unwieldy from the burden of minor incremental improvements: myriads of open CAPAs, long overdue CAPAs and repeat CAPAs, all being relentlessly implemented whilst the deeper productivity or supply issues are avoided. In reality, repeat CAPAs show a process is not operating effectively. So ask yourself: was the process/procedure validated in the first place? Have the customer requirements been met or have they changed? Have the changes filtered through? Are the channels of communication effective?

Look at the common sources of corrective actions. Categorise the types from experience, then risk-assess the best, most effective way to deal with them. For example, low risk – is any action necessary? Medium risk – fix it in the easiest way first. Whilst high risk needs urgent critical review and immediate action to maintain or regain control. It is also important to look into more effective ways to communicate and the responsibilities of who must make those communications, as well as who should respond and what is expected. Ensure the recipients acknowledge the message and understand what actions they should take and report back when completed. All this sounds obvious, but sadly, poor or ineffective communication is an obvious source of error, misunderstanding and failure to act.

There are thus opportunities in the new ISO 9001 to utilise risk-based methodologies. Assess where a risk-based approach is appropriate for your organisation and take advantage of the risk-based methodologies available[8 9, 10]. Ensure the amount of time and effort spent upon any mitigation is appropriate to the level of risk and according to its perceived impact upon the expected outcome. And, to reiterate, define the criteria whereby the risk might be acceptable and at what point or level the risk would need addressing. The benefits of risk-based quality management are four-fold: (i) it allows for more effective prioritisation, which is in my view essential; (ii) permits more effective use of available resources; (iii) lowers or reduces the occurrence of unintended outcomes; and (iv) reduces waste or poor service.

No More Preventive Action; CAPA is Dead!

Corrective action stays, in its new simplified form; the term 'corrective action, preventive action' (CAPA) has gone. Why is this so? Well, let us look at CAPA in practice. Many organisations structure their corrective action forms with space for recording the planned corrective action and a subsequent space for preventive action. (Of course it goes without saying that the proposed activity needs to be reviewed to ensure there is no unintended effect upon the product.) However, surely we have all seen the person who has been nominated to devise a CAPA, spend some considerable time – half a day, perhaps more – deciding whether they need a CA and a PA, or is their CA also PA? Should they put a line through the PA section on the form? Subsequently, they have difficulty completing the form, end up confused, and may even be seen mulling over the procedure, then the CAPA form returns to their in-tray for another few days, or weeks. The exasperated QA officer comes around to chase it up. You may be familiar with the scenario? 'Well, surely this is not how CAPA was intended to operate,' I hear you say – and you would be correct. That is aside from another example, taken from personal experience as a contractor, whereby any member of staff could raise CAPAs at will. I believe this was known locally as 'proactive quality'. They were proud of this, and defended it to the hilt. (This was not Gemba, or anything like it, but a misuse of CAPA and I'll explain why.) The resulting forms would end up in QA for a retrospective evaluation. I am not kidding. I have never seen a QA team with such a backlog of manufacturing deviations to assess, because they were spending so long on the deluge of CAPAs coming from production and other parts of the business. The QPs could not release the batches and they had warehouses full to the rafters of product they could not dispatch. Surely, this was not how CAPA was intended? Once the manufacturing process has been validated, no-one should be making any CAs! The general rule of thumb, therefore, is deviations are raised whilst CAPAs are assigned. And yes, QA review the deviations for impact upon the product, patient safety and product licence. And yes, QA assign CA to whosoever they see fit! That's their job. Stop that blubbering!

Preventive Action Replaced by Risks and Opportunities

If there is a manufacturing hiccup (a deviation), potential or actual product defect, audit finding, QC result, complaint or even a mistake (heavens above!), that requires corrective action, then record it and basically – just do it! Certainly assess the impact of the action/activity in terms of risk to product integrity and quality; human, animal and environmental safety; and check it does not contravene either the marketing or the manufacturing licence terms. Ideally you should make this judgement before the CA is implemented. Again, categorise the level of permissible corrective activity so that decision-making on implementing them is timely. It is essential that your workforce knows which things they cannot on any account do which would adversely affect the product and result in what ISO call non-conforming product (in pharmaceutical terms your batch-hold-notice/recall/failed batch), which you cannot sell, have to downgrade or even worse – send to landfill. Production deviations are just that; deviations – record them and evaluate them for their effect upon batch disposition and marketing authorisation. If CA is necessary, then ensure it is timely.

So, reflect upon how much misapplied CAPA process and resulting CAPA procrastination you may have witnessed. If the CAPA concept is properly applied, then CA is your process for making relatively quick incremental corrections or minor improvements – by someone who has the experience and knowledge to understand the probable cause(s) and how to fix them. (Any substantial changes affecting pharmaceutical manufacturing must go through change control, as you well know.) Then, through further monitoring and audit if there has been a reoccurrence of similar corrective actions, then RCA and new CA will be necessary. (As discussed, the term preventive action is really redundant in this context, as it means to prevent occurrence in the first place.) So, this 'second time around' review should be accompanied by a deeper root-cause analysis (RCA) investigation. With a bit of insight / understanding / experience / intuition and even luck, the problem is solved for good. So, it is the monitoring for re-occurrence which will tell you whether a corrective action was effective. Please avoid the temptation to add a follow-up box on each CAPA form – this is not the answer, as you really are adding to your administrative burden if you do! There are better ways and

means to implement the CA process and follow up on effectiveness, as mentioned. The key is not to spend too much time on the first few occurrences. If there is a serious issue, and by that I mean the same thing keeps happening whatever action was taken, then as soon as you can, muster everyone together, as a thorough RCA is essential. How good your team is at this could save your business money as well as its reputation. I have unfortunately witnessed a business fail because it could not correctly ascertain the root cause of customer complaints quickly enough and was totally unable to respond. When they did work out the cause, they hid it – they lost credibility and repeat business, their turnover crumbled and they ceased trading. How long did that take? Less than six months.

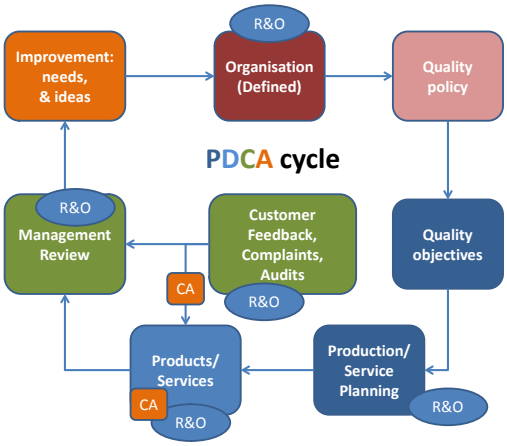

Figure 5 – The PDCA cycle superimposed upon the product/services lifecycle: including opportunities for evaluation of risks and opportunities

Key:

PDCA, plan-do-check-act (colour coded);

R&O, risk and opportunities;

CA, corrective action

In summary, it is timely for EU GMP to review the CAPA process in light of the new ISO 9001 and ask how effective it is, and how well has it been understood. Companies may tot up the wasted hours which could have been better used to run the business and QMS more efficiently, and look at a new approach for the future. After all, the goal of a QMS is to enhance the business processes whilst ensuring quality of output and customer satisfaction, not to score an own goal for poor practical application. Hence the advent of the input from ICH Q9 and now the risk management approach is further advocated by ISO 9001:2015, so get to it (for those who have yet to proceed) and make your QMS work for you and your business.

References

1. BS EN ISO 9001:2015 Quality management systems – Requirements
2. BS EN ISO 9000:2015 Quality management systems – Fundamentals and vocabulary
3. BS EN ISO 9001:1987 Quality systems – Model for quality assurance in design, development, production, installation and servicing.
4. EU Commission Regulation, No. 520/2012 ...on the performance of pharmacovigilance activities...
5. The Total IDMP Effort – an Insight into the Data Volume of an ISO IDMP Submission, p 14-16, International Pharmaceutical Industry Journal, IPI, Pharma Publications, Volume 8, Issue 1, Spring 2016
6. EudraLex Vol. 4, Good manufacturing practice (GMP) guidelines
7. Rules and Guidance for Pharmaceutical Manufacturers and Distributors, Pharmaceutical Press, 2015
8. BS EN ISO 31000:2009 Risk management – Principles and guidelines
9. BS EN ISO 31100:2011 Risk management – Code of practice
10. ICH Q9 Quality risk management, www.ich.org

Acknowledgement:
I would like to acknowledge Brian Lord, who is a longstanding BSI Committee Member and sits on the ISO Technical Committee, TC 176, SC 2, involved in the revision and content of ISO 9001:2015.

Madeleine Fairweather BSc Hons, PhD Cambridge, MRSB
Director of MSFQA Associates Limited, UK
Consultancy in: Quality Management Systems, GxPs, ISO 9001, ISO 17025 – Compliance & Training
Specialist areas: Botanicals, Biologicals, Pharmaceuticals
Subject matter expert - substances derived from botanical and biological sources: active substances, flavours and colours, recombinant DNA vaccines, anti-toxins, therapeutic antibodies, blood products. Importation testing, phytosanitary requirements, animal health requirements, maximum pesticide residue limits, purchasing specifications and quality criteria. Experience - successful acquisition of cGMP manufacturing licenses and GLP certification from scratch in R&D/D organisations and new business enterprises to meet MHRA, TGA and FDA controlled markets as Quality Manager, investigational medicinal products (10 years). Six years GDP experience: trans-global shipping of deep-frozen plasma and international audits. UKAS Quality Manager of an ISO 17025 accredited analytical chemistry test laboratory, guiding it to achieve flexible scope.
Email: madeleine@msfqa.co.uk +44(0)1264391285 Office