ISO 13485

The proposed changes and what they mean for you

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Why ISO 13485?

The Quality Management System (QMS) for the manufacturers of medical devices must meet certain requirements to support the safety and effectiveness objectives of the products they sell. In order to successfully obtain approval for those devices for sale in the European Economic Area (EEA), manufacturers must demonstrate conformity to the European Medical Devices Directive (MDD), In Vitro Diagnostic Directive (IVDD) or Active Implantable Medical Device Directive (AIMDD), referred to later in this document as the 'Directive' or 'European Directives'. The result of this approval is the authorization to use the 'CE Mark' that may or may not include the notified body identifier on these devices. Control over the entire QMS is one way to demonstrate conformity to the Directives. As it relates to medical devices, that system is best managed through meeting the requirements of ISO 13485 as adopted in the EEA by the European Committee for Standardization (CEN) as EN ISO 13485 (harmonized European version). The normative (requirements) parts are identical and therefore throughout this document we will simply refer to it as ISO 13485.

Officially titled *Medical devices – Quality management systems – Requirements for regulatory purposes*, ISO 13485 is the QMS complement to the product specific European Directives and other country and regional regulatory requirements. As is the case in many jurisdictions, this is the standard for the development, implementation and maintenance of a QMS. This standard is recognized as describing the minimum requirements of an adequate, suitable and effective QMS to consistently produce safe and effective medical devices.

The last revision (2nd edition) of this international standard was published in 2003. The ISO technical committee (TC 210) responsible for the maintenance of this standard has been working on a significant revision. As part of this revision process, a survey of the users of the standard was completed and a new design specification was developed and unanimously approved by the technical committee voting members. The working group (WG) used this design specification throughout the process to drive the draft changes to the standard. The current status is as a second Draft International Standard (DIS2) and the changes outlined in this paper are not final, as additional changes are likely before the final version is published. The particular items covered are likely to remain as outlined, however until the final text is published, the content is subject to change. This 3rd revision is designed to harmonize the QMS requirements with the product specific requirements as outlined in the corresponding device directives. As the directives have evolved over the last several years, the QMS standard, ISO 13485, has lagged behind and a revision is well overdue.

As a side note, the technical committee responsible for ISO 9001 has also been working on revising the 4th edition of ISO 9001 with an estimated release of the 5th edition in September 2015. Significantly, this 5th edition has been revised with a new high level numbering structure as outlined in the revision to the ISO Directive in Annex SL, resulting in the standard now having 10 clauses, where previously there were 8. The 3rd edition of ISO 13485 will keep the current clause structure and a new Annex is proposed for ISO 13485 to provide a clause by clause correlation between the new revisions of ISO 9001 and ISO 13485. The new revisions of both ISO 9001 and ISO 13485 have an increased focus on a risk-based thinking approach to compliance.

Historical development and current timeline

The work item was approved by the ISO Technical Management Board and ISO/TC 210, Working Group 1 (WG1) began work in April 2012 to start to revise ISO 13485. The WG has met several times over the three-year period to draft, address comments and resolve disagreements on the content of the revised standard.

February 2015 – The 2nd enquiry release or DIS2 ISO 13485 was published for balloting, review and comment by ISO TC 210 members and for a separate European ballot.

May 2015 – The comment and review period closed on DIS2 ISO 13485. The ballot results approved moving forward the draft to the final draft stage.

June 2015 – The WG met in Denver, Colorado, USA to address comments received on the DIS2 document. Although all the comments were addressed, the WG felt a final review was necessary after completion of the editing before moving forward to publication of the Final Draft International Standard (FDIS) version.

August 2015 – The WG met in London, UK, to review the final version to be published as the FDIS and to determine if any additional publications should be completed by the WG (e.g. transition plan position paper, verification documentation, guidance documents).

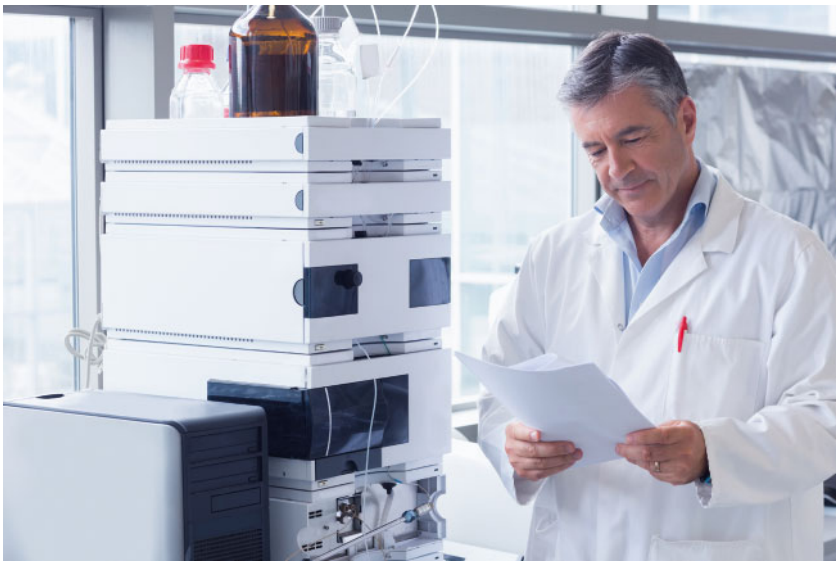
September 2015 – Following the completion of the review and translation, the FDIS will be published and the FDIS will be subjected to an 'up-or-down' vote of the voting members of ISO/TC 210. No technical edits will be allowed at this stage. Any technical comments received will be held to this 3rd revision of the standard.

NOTE This revision of ISO 13485 is being executed under the provisions of the Vienna Agreement in order to permit parallel voting within Europe and as such allows for the issuance of both the FDIS and prEN versions and so allowing a simultaneous vote so that both versions, assuming a positive vote, can be published together. For this to occur the text needs to be translated into French and German as these along with English are the official languages of the EU. Harmonization of the final EN version will occur at a later date.

Fourth quarter of 2015 or First quarter of 2016 – The WG will meet, if necessary as determined by the ballot and accompanying comments received on the FDIS document. Publication of the approved ISO 13485:2015(6) and recommendation as to the transition period will be determined by ISO/TC 210 at its meeting in Seattle, Washington, USA during the week of 16th November 2015.

Outline of proposed changes and what they might mean for you

The following is a brief summary of the proposed changes to ISO 13485:2003 as they are written and understood at the time of authoring this paper in August 2015. Since there is one more meeting planned with more opportunities for revision, this summary is subject to change. However, it is highly likely that the technical content of these changes will be carried through as written into ISO 13485, 3rd edition.



Introduction, Scope and Normative references (Clauses 0, 1 and 2)

These clauses do not specify requirements, however they do add clarification of the use of the standard. The revision to the introduction includes:

- the explicit inclusion of the storage and distribution of the product within the QMS;
- a new statement that this standard may be used by 'suppliers or other external parties' that provide a product or service to medical device manufacturers;
- the inclusion of 'associated activities' (e.g. service of product at customer requirement);
- a need to identify the organization's role (e.g. distributor, supplier, manufacturer); and
- further clarification that the standard does not include other management systems (e.g. environmental).

In addition, there is clarification of the relationship with both the current version of ISO 9001 (2008) and the new version (2015).

The scope adds wording to define the use of the QMS throughout the product life-cycle, the idea that an organization should identify those processes that are outsourced, the ability to declare non-applicable clauses of the standard for the organization's QMS (from Clauses 6, 7, or 8) and some clarification of terminology and phrases used in the standard.

There is further clarification of the kinds of risk that need to be addressed by the QMS. The risk-based approach is intended to minimize harm as specified in ISO 14971, specifically the harm associated with the safety and performance (quality) of the medical device and the safety and performance (effectiveness) of the QMS. Managing the organization's business and financial risks are specifically excluded.

Terms and definitions (Clause 3)

Several new definitions have been added and some definitions have been slightly modified. The supply chain definition in the prior version has been removed. While there is little impact from this clause on compliance issues, the new and revised definitions for complaint, importer, manufacturer, distributor, medical device, life-cycle, risk/risk management and sterile barrier systems provide clarifications to ensure proper understanding of applicability of the standard and its requirements. Additionally, the definitions have been harmonized with Global Harmonization Task Force (GHTF) definitions for consistency with current industry practices.

Quality management system (Clause 4)

4.1 – General requirements

QMS processes will be required to be developed using a risk-based approach. It is essential that the manufacturer specifies how the risk is managed, and how the risk of one process affects other risk aspects of the QMS. When creating process flow diagrams, an associated risk analysis needs to be completed in order to assess the risk associated with a particular process if there is a resulting risk that will impact another process.

As outlined in the new introduction, the organization's role shall be defined. Are you the legal manufacturer? Are you responsible for regulatory requirements, notifications, post-market surveillance (PMS), and vigilance? Are these requirements properly defined and documented? The proposed changes to this clause will require that this type of information be documented and justified accordingly.

4.1.3 – 4.1.5 (currently no title)

This is a proposed new series of subclauses that clarify the requirements that were contained in the 2003 version of the standard. These new subclauses include specifying the need for documentation to meet regulatory requirements.

Also, these subclauses cover the QMS requirements related to the organization's responsibility to control outsourced processes and the risk associated with those outsourced processes. Is there enough knowledge to control the processes, determine their level of compliance, and determine the risk as needed? These questions should be considered when developing outsourced process controls.

4.1.6 (currently no title)

This is a new subclause that is likely to be added to the standard. This will require that all software utilized in the support of the QMS be properly validated and documented. It is important to note that this is a separate requirement from any product specific software validation requirements outlined in the Directive or as a technology specific requirement.

4.2 – Documentation requirements

In an effort to bring the QMS standard into alignment with the requirements of the European Directives and other regulatory expectations, the requirement to maintain appropriate technical design documentation is likely to be added to this standard (including a list of applicable topics to be included). This listing is new, and will hopefully assist in aligning the standard with regulatory requirements. The addition of this subclause pushes down the subclauses by one on Documents (tentatively now 4.2.4) and Records (tentatively 4.2.5).

Since the revised standard explains in the introduction that wherever the term 'documented' is used in the standard, it carries with it the obligation to establish, implement and maintain the documented requirement, organizations will need to ensure this is carried out through the processes established under this subclause. The revised standard requires that documentation control procedures prevent the deterioration or loss of documents in addition to maintaining the requirements related to the retention of documentation. Additionally, the revised standard provides guidance which indicates the extent of the QMS guidance can be influenced by product and process risks. Also included in the control of records, the organization needs to specify the methods to protect confidential health information.

Management responsibility (Clause 5)

In an effort to bring the QMS standard into alignment with the requirements of various country and regional regulatory requirements, the 'regulatory requirement' wording will likely be added throughout the clause.

The requirements for a quality policy, quality objectives and a management representative are substantially the same with some minor clarifications.

5.6 – Management review

This subclause has been updated and aligned with the subclause on Improvement (Clause 8). In addition, there are several other clarifications to improve management involvement.

Resource management (Clause 6)

6.2 – Human resources

It is expected that the revision will include not only a requirement to ensure personnel with the appropriate competence, awareness, and training but the organization needs to also document a procedure or mechanism to identify how the personnel at the facility maintain and update their competence and expertise. Continued training and maintenance of expertise are critical to the organization.

6.3 – Infrastructure

It is anticipated that this subclause regarding 'infrastructure' will now require documentation of the infrastructure requirements and general record keeping to ensure against product mix-up and to ensure orderly handling of the product. This may be required to support all procedures to demonstrate compliance, not just maintenance records (as an example). Also included is a requirement for planning of maintenance intervals.

6.4 – Work environment

Much of this subclause was reorganized for clarity with some specific additions to understand the requirements for health, cleanliness and clothing of workers and arrangements to prevent potential cross-contamination of product.

6.4.2 – Contamination control

It is expected that this new subclause will be included in this revision of the standard and may include a clarification to document the requirements for microbial control, validation of sterile control and control of sterile device manufacturing requirements.

Product realization (Clause 7)

7.1 – Planning of product realization

While the requirements remain unchanged, some clarification is provided in this subclause. It is likely that additional wording under the requirements for required planning activities will be added to the list of processes that shall be part of planning for product realization. The processes are revalidation, measurement, handling, storage, distribution and traceability. Along with these clarifications to the requirements, an emphasis to utilize risk management and risk-based thinking throughout the design and development planning steps referenced is provided. This includes ensuring updates of the planned activities with the appropriate documentation as design and development progresses.

7.2.1 and 7.2.2 – Determination of requirements related to the product and Review of requirements related to the product

There is a clarification added to ensure that the organization documents the regulatory requirements as part of the product requirements (the regulatory bodies are considered a customer). It is likely that if additional training is required for the end user so that misuse due to lack of clarity or misunderstanding is minimized (risk management), it will need to be documented accordingly.

7.2.3 – Communication

The previous version of subclause 7.2.3 stated that communication with customers or internally was required. Going forward, a paragraph will likely be added to include requirements for the notification of regulatory authorities (external communication). This is consistent with PMS and vigilance requirements of the European Directives and other regulatory requirements.

7.3.1 – General

This subclause was added to specifically state that organizations shall document procedures for design and development.

7.3.2 – Design and development planning

For design and development planning, the organization is required to maintain and update the documentation as the design and development progresses. Also, a list is provided to clarify what the organization should document during design and development planning. This includes methods to ensure traceability of design and development outputs to design and development inputs and the resources needed including competence of personnel.

7.3.3 to 7.3.5

The requirements of 7.3.3 Design and development inputs, 7.3.4 Design and development outputs, and 7.3.5 Design and development review, remain virtually unchanged. However, much discussion in the WG was around the reference to 'specialist personnel' in 7.3.5. The intent of this phrase is to meet the regulatory requirements of several jurisdictions to include an independent reviewer in the review process.

7.3.6 and 7.3.7 – Design and development verification and Design and development validation

It is possible that these subclauses will now include requirements to document the verification and validation (V/V) plan, the methods of V/V, criteria for acceptance or failure, justification for sample sizes and the risk associated with those sample sizes, V/V of device interfaces, e.g. user instructions, failure modes. Finally, any validation activity shall be conducted on final production units or documented equivalent devices.

7.3.8 – Design and development transfer (new subclause)

This is likely to be a new subclause added to this revision of the standard. This subclause, in the 2003 version, is currently called Control of Design and Development changes; the original content of this subclause will be moved to 7.3.9. It is expected that this new subclause will focus on the organization's transfer plans with regard to suppliers (contract manufacturers, for example) including manufacturing and its environments, personnel (competency), and installation of equipment as applicable.

7.3.9 – Control of design and development changes

This subclause will likely be revised to require established processes to control design and development changes. The process should include means to determine the significance of changes to the product function, performance, safety, and applicable regulatory requirements for the intended use and what actions should be taken.

7.3.10 – Design and development records (new subclause)

This is likely to be a new subclause added to this revision of the standard. It is anticipated that this subclause will require that all design and development records be properly maintained and identified (processes, product type, manufacturing, etc.) for each device or family of devices.

NOTE Certain subclauses including 7.3 and 7.5 have been restructured/renumbered with no change to the normative content to enable the classification system proposed by the International Medical Device Regulators Forum (IMDRF) for the Medical Device Single Audit Program (MDSAP) and the classification of manufacturers audit non-conformances. The IMDRF working proposal uses the GHTF Study Group 3 N19:2012 document as a basis for these classifications.

7.4.1 – Purchasing process

It is likely that this subclause will have clarified requirements for a documented procedure which defines the process of supplier approval, how they will be monitored for continued compliance to established requirements, a requirement to document the rationale and justifications for supplier use, what criteria is used to evaluate those suppliers, and what/when re-evaluation is required.

7.4.2 – Purchasing information

The proposed revision to this subclause may include an additional requirement to include where applicable the supplier's agreement to notify the manufacturer of any changes to the agreed upon contract or requirements as appropriate.

7.4.3 – Verification of purchased product

It is expected that this requirement will be added to the existing subclause in order to outline the utilization of a risk-based approach to the process.

7.5.1 – Control of production and service provisions

This subclause will require that production and service provisions be monitored and controlled in addition to being planned and carried out to ensure products conform to their specifications.

7.5.2 – Cleanliness of product and contamination control (2nd edition 7.5.1.2.1)

A new requirement to document cleanliness of products or contamination control of products was added for products which cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use.

7.5.4 – Servicing activities (2nd edition 7.5.1.2.3)

This subclause now distinguishes that service activity records should be analysed to determine if the information is to be handled as a complaint and should feed into the improvement process where appropriate.

The requirements of 7.5.3 – Installation activities (2nd edition 7.5.1.2.2) and 7.5.5 – Particular requirements for sterile medical devices (2nd edition 7.5.1.3) remain the same.

7.5.6 – Validation of processes for production and service provision (2nd edition 7.5.2)

It appears at this time that new wording may be added to this subclause. The words 'IS NOT' will likely be added to this subclause to be a part of this provision. If a process cannot, or IS NOT, verified, then validation is required.

7.5.7 – Particular requirements for validation of processes for sterilization and sterile barrier systems (new subclause)

This new subclause is divided from the other validation requirements, from the 2nd edition. In addition, even though protocols have been an existing requirement, the standard may require procedures for validation of sterilization and sterile barrier (packaging) processes. In particular, the validation of sterile barrier packaging processes has been identified.

7.5.8 and 7.5.9 – Identification and Traceability (2nd edition 7.5.3)

The Identification and Traceability requirements in the 2nd edition, subclause 7.5.3, are likely to be divided into separate subclauses (7.5.8 and 7.5.9) and may include new requirements.. Based on the work done by the IMDRF, where an area of the world requires it, a unique device identification needs to be applied to the device and documented accordingly. The WG extensively discussed the differences between traceability and tracking, but did not add any requirements or clarifications to the standard. Also, the standard currently requires that the returned product be identifiable, however the new revision clarifies the need to distinguish the returned product from the conforming product.

7.5.10 – Customer property (2nd edition 7.5.4)

While not included directly here in the FDIS, a paragraph was added to the subclause on records regarding protection of confidential health information. This could come to an organization as part of customer property and so an organization would need to have processes to address this in addition to intellectual property.

7.5.11 – Preservation of product (2nd edition 7.5.5)

The current version of the standard does not include shipping conditions and their impact on product and packaging integrity as a consideration. In addition, the current version of the standard does not specifically reference sterile device packaging considerations (sterile barrier testing, expiry dating). It appears that if the revision is confirmed as currently proposed, these items will be required under the standard, just as they currently are under the device directives. This is another area of harmonization between the product and quality system requirements.

Measurement, analysis, and improvement (Clause 8)

8.2 – Monitoring and measurement

If the proposed revision successfully becomes incorporated into this version, this subclause will state that procedures detailing feedback processes shall also now specify the requirements of inputs and outputs from feedback sources and be incorporated into the risk management program. That feedback shall then be statistically analysed for proper entry in the Corrective Action or Preventive Action (CAPA) system. This will allow the risk to be assessed with solid data in an effort to create better corrective and preventive actions.

8.2.2 and 8.2.3 – Complaint handling and Reporting to regulatory authorities

Both of these subclauses are new. The 2nd edition of the standard discusses these subjects as part of 8.5.1, General. In this revision, additional details have been provided relating to the content requirements of complaint handling procedures.

In subclause 8.2.4 Internal audits (2nd edition 8.2.2) and 8.2.5 Monitoring and measurement of processes (2nd edition 8.2.3) contents have been reworded, but the requirements remain unchanged.

8.2.6 – Monitoring and measurement of product (2nd edition, 8.2.4)

This subclause will now likely require the manufacturer to not only document the measurement and approval of product specifications, but now the organization needs to also identify and document the measurement equipment used and the individuals conducting the measurements. This links directly to training (including competence and awareness) and supports the appropriate levels of calibration and preventive maintenance.

8.3 – Control of nonconforming product

If this proposed addition is accepted, the manufacturer will be required to determine and document the need for the investigation (or lack thereof) regarding the root cause of non-conforming product and document the actions taken with regard to corrective actions.

8.3.1, 8.3.2, 8.3.3, 8.3.4 (new subclauses)

Subclause 8.3 was divided into further subclauses for clarity as follows: 8.3.1 – General, 8.3.2 – Actions in response to nonconforming product detected before delivery, 8.3.3 – Actions in response to nonconforming product detected after delivery and 8.3.4 – Rework.

If the addition of these items are confirmed, each of these new subclauses is intended to identify and clarify the requirements and documentation necessary for the control of nonconforming product while under the control of the manufacturer in the post-delivery arena as it affects an end user or after any reworks to nonconforming products is conducted.

8.5.2 and 8.5.3 – Corrective action and Preventive action

It appears likely that there will be a requirement to review product and process data as a part of the CAPA process (historical non-conformances, trends, process changes, product problems such as complaints, failures, PMS and vigilance reports). In addition, if accepted as written, there will be a requirement for the CAPA process to link to product risk management to ensure the corrective actions taken are proportional to the risk associated with any effects.

Final summary

Overall, the proposed revisions to the current version of ISO 13485 can be summarized as follows:

- Harmonization of regulatory requirements.
- Inclusion of risk management throughout the QMS.
- Additional clarity with regard to validation, verification, and design activities.
- Strengthening of supplier control processes.
- Increased focus regarding feedback mechanisms.

As the Directives are under revision as well, the harmonization of quality management requirements with product conformity requirements is essential to creating a complete and consistent approach to global certification.

In all likelihood, some upgrades will be required to your systems. Some of the items outlined earlier may already be in practice, some might be need to be formalized, and as we have seen some of these requirements are new. The increased focus on risk analysis and risk management as it relates to the quality system may be a challenge, as this approach is quite different from the current process approach. A thorough gap analysis is recommended to provide the user with a baseline of significant changes to be addressed. Although there is likely to be a transition period of 36 months, many of the items above are current industry common practices and can be immediately addressed, hopefully resulting in a much easier transition when the final version is ultimately published.

BSI is grateful for the help of the following people in the development of the white paper series.

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Bill has been with BSI for more than 10 years. His responsibilities include auditing quality systems and review of technical files and other certification activities related to sterile medical devices (environmental controls, sterilization validation and release, biocompatibility, devices containing tissues of animal origin, accelerated ageing, package validations, etc.). Before joining BSI, Bill was vice president for technical sales and business development at Microtest Laboratories, where he was involved with all aspects of medical device and pharmaceutical testing and manufacturing. Bill was with Microtest for 11 years and held several positions, including laboratory technician, laboratory manager, and director of quality systems, ultimately leaving after the vice president position. Bill is a published author, BSI tutor and trainer, auditor, and technical specialist. Bill received his Bachelor of Science degree in microbiology in 1993 from Western New England University.

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Mark Swanson (ASQ CMQ/OE, CQE, CBA) is the President and Lead Consultant of H&M Consulting Group; a group focused on helping small- to mid-sized companies have the same regulatory and quality systems knowledge as the large medical device companies. In addition to this, Mark is also the Director of the Medical Technology Quality Graduate program at St Cloud State University.

Mark has spent the last three years as an active member of ISO Technical Committee 210 (TC 210), Working Group 1 (WG1) working on the revision of ISO 13485:2003 and has also participated with ISO TC 176, WG24 on the next version of ISO 9001. This work includes discussions regarding the impact of changes in the ISO quality management system standards, the integration of various standards and how to effectively integrate the different management system standards and other regulations into a single quality management system.

Expert reviewers

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Paul has worked in the healthcare industry for over 30 years and is currently project managing BSI's implementation of EU Commission Recommendation 2013/473/EU dealing with Unannounced Audits. Previously he held senior RAQA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical, and Ohmeda (formerly BOC Group healthcare business). His experience spans a broad range of medical devices including anaesthesia systems, patient monitors, ventilators, single use sterile disposables and devices for re-use, incubators, infusion pumps and surgical instruments. Paul is a member of the Association of British Healthcare Industries (ABHI) Technical Policy Group and Convenor of the ABHI ISO TC 210 Mirror Group. He is Convenor of the BSI Committee which monitors all of the work undertaken by ISO TC 210, and Convenor of the BSI Sub-committee dealing with Quality Systems. As UK Delegation Leader to ISO TC 210, he is also actively involved in the work of national, European and international standards' committees. Paul has published articles in medical device industry journals, presents at conferences, and is a Module Advisor at Cranfield University on a Master's program dealing with Regulatory Affairs for Medical devices.

Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market, Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

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The Growing Role of Usability and Human Factors Engineering for Medical Devices: What is Required in the New Regulatory Landscape? Robert North

Negotiating the Innovation and Regulatory Conundrum, Mike Schmidt and Jon Sherman

Forthcoming paper

An Update to the Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market, Erik Vollebregt and Gert Bos (September, 2015)

About BSI Group

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