WHITE PAPER

ISO 13485 Standard and SmartSolve

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IQVIA SmartSolve ISO 13485 reference chart

Subpart	Section	IQVIA Solution(s)	Page
4	4.1	SmartSolve®	5
	4.2	Document Management with the Optional Repository Management Add On	5
5	5.1	SmartSolve®, Audit Management	7
	5.2	N/A	7
	5.3	Document Management, Training Management	7
	5.4	Document Management	8
	5.5	SmartSolve®	8
	5.6	SmartSolve®, Audit Management	8
6	6.1	N/A	10
	6.2	Training Management	10
	6.3	Audit Management, Document Management, CAPA Management	10
	6.4	N/A (Document Management)	10
7	7.1	N/A (Document Management)	11
	7.2	Complaint Management	11
	7.3	Design Control	12
	7.4	Supplier Quality Management	15
	7.5	N/A (Document Management)	15
	7.6	Equipment Management	16
8	8.1	SmartSolve®	17
	8.2	Complaint Management, Audit Management, CAPA Management	17
	8.3	CAPA Management	19
	8.4	SmartSolve®	20
	8.5	Document Management, CAPA Management	20

Introduction

MedTech manufacturers worldwide have the ability to produce goods that can improve the quality of life, and at times, even save them. With this capacity, however, comes the responsibility to comply with industry and government regulations, and to consistently manufacture and distribute safe and reliable products.

Around the world in the 21st century, the impact of FDA, Notified Body and other regulatory audits and inspections, and fines levied for non-compliance and high-profile product recalls, are driving a powerful reaction among Medical Device organizations. The immediate challenge lies in proactively eliminating risk.

Today, compliance with Good Manufacturing Practices (GMP) in a global environment means understanding the increasingly complex industry regulations and standards. Failing to adhere to these regulations can erode shareholder confidence and damage brand equity. As a result, regulated companies seek to implement enterprise-wide compliance and quality management solutions that can quickly address customer and regulatory issues consistent with worldwide requirements, while simultaneously being leveraged to enhance business processes.

ISO 13485, Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes is an international standard designed to improve quality management systems applicable to manufacturers of medical devices and organizations providing services related to these devices. It provides a uniform model for quality management system requirements in the international market since different countries might have different standards. ISO 13485:2016 replaced ISO 13485: 2003.

In this White Paper, brought to you by IQVIA's SmartSolve team, we describe how the different modules of the IQVIA SmartSolve eQMS software can be utilized to support compliance with the clauses of the ISO 13485 standard.

***Note:** for copyright reasons we have redacted the text of the standard and replaced redacted text with … Please refer to the ISO 13485:2016 standard for the full text.*

SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
4	**Quality management system**	
4.1	**General requirements**	IQVIA's SmartSolve® platform manages the various elements of a quality system. See the remainder of Section 4 for details.
4.1.1	The organization shall document a quality management system and maintain its effectiveness in accordance	
4.1.2	The organization shall: a. ... b. ... c. ...	
4.1.3	The organization shall: a. ... b. ... c. ... d. ... e. ...	
4.1.4	The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a. ... b. ... c. ...	
4.1.5	When the organization chooses to outsource any process that affects product conformity with requirements, it shall monitor and ensure control over such processes ...	
4.1.6	The organization shall document procedures for the validation of the application of computer software ...	

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
4.2	Documentation requirements	
4.2.1	**General** The quality management system documentation (see 4.2.4) shall include: a. ... b. ... c. ... d. ... e. ... Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented ...	The IQVIA SmartSolve Document Management application manages all quality system documentation from quality policies to product specifications. Document Management allows for different owners, workflows, approval sequences, security, numbering, etc. for different document types.
4.2.2	**Quality manual** The organization shall establish and maintain a quality manual that includes: a. ... b. ... c. ... The quality manual shall outline the structure ...	The quality manual may be stored in Document Management. Documentation structure is also defined within Document Management. Users create document types to organize document structures within the system.
4.2.3	**Medical device file** For each medical device type or medical device family, the organization shall establish and maintain one or more files ... The content of the file(s) shall include, but is not limited to: a. ... b. ... c. ... d. ... e. ... f. ...	IQVIA SmartSolve Repository Management, an add-on component of Document Management provides users with a secured Medical Device File Repository that allows users to organize the required documents for a Medical Device File (MDF) in its appropriate section based on the MDF structure. Repository Management provides users with OOB multi-level MDF templates for the EU MDR and the FDA CDRH; users can also create their own templates for other regulatory body formats. The user will be able to create both global and country-specific medical device file packets for each product with a system-generated table of contents for the packet based on the MDF structure for distribution, inspection, audit or registration.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
4.2.4	**Control of documents** Documents required by the quality management system shall be controlled. Records are a special type of document ... A documented procedure shall define the controls needed to: a. ... b. ... c. ... d. ... e. ... f. ... g. ... h. ... The organization shall ensure that changes to documents are reviewed and approved ... The organization shall define the period for which at least one copy of obsolete documents shall be retained ...	Document Management manages the document workflow from document creation to approval to revision and obsolescence. Policies are defined within Document Management to manage the review and approval of documents prior to their release. This includes provisions for the re-review of documents. Document revision is indicated within the document record. Changes that have affected the document are attached to the document record. Document Management is a web-based system, which allows any user to access the system with an internet browser installed on his computer. This facilitates document availability to all users. Document Management's system security ensures that end users only access the current revision of each document. Obsolete documents are stored in the system, but are unavailable to end users. Document Management provides a change management workflow for the request, approval, implementation and traceability of document changes.
4.2.5	**Control of records** Records shall be maintained to provide evidence of conformity ... The organization shall document procedures to define the controls needed ... The organization shall define and implement methods for protecting confidential health information ... Records shall remain legible, readily identifiable and retrievable. ... The organization shall retain the records for at least the lifetime of the medical device ...	Document Management is able to maintain records for an indefinite time period in a 21 CFR Part 11 compliant database. Records are retrieved using Document Management's user- friendly search and reporting features.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
5	**Management responsibility**	
5.1	**Management commitment** Top management shall provide evidence of its commitment to the development and implementation ... a. ... b. ... c. ... d. ... e. ...	Quality reports or data necessary for management review are easily retrievable. This includes reports on audits, corrective action, customer complaints, document control, employee training, equipment management and supplier quality. These reports are customizable to meet organization-specific needs. The IQVIA SmartSolve Audit Management application is frequently used to schedule and document management review activities. This includes attaching any reports or evidence to the management review record and documenting follow-up activities.
5.2	**Customer focus**	N/A
5.3	**Quality policy** Top management shall ensure that the quality policy a. ... b. ... c. ... d. ... e. ...	Document Management facilitates the review and implementation of the quality policy. Document Management provides a formal approval workflow to ensure that the quality policy is reviewed prior to release. Document Management also provides a discussion capability so managers can communicate and collaborate on the quality policy's content prior to the formal approval. Document Management's electronic document release notifications and web-based access facilitate the communication of the quality policy to end users. Assessments are available through integration with SmartSolve Training Management application to ensure that each employee understands the organization's quality policy. Document Management provides reminder notifications for document reviews to allow authorized personnel to review the document for continuing suitability. This review is maintained within the document record. The features described above are applicable to the quality policy or any document maintained within Document Management.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
5.4	**Planning**	
5.4.1	**Quality objectives**	N/A
5.4.2	**Quality management system planning** Top management shall ensure that: a. ... b. ...	Document Management manages changes to the quality system and its documentation through a closed-loop change management process. This includes the identification of the change, proposed change approval, change implementation, implemented change approval and new document release. The change management process includes the obsolescence or expiration of invalid documents due to new document release. The integrity of the quality system is maintained by ensuring that users have access to only the up-to-date document revision and that obsolete documents are removed from user access.
5.5	**Responsibility, authority and communication**	
5.5.1	**Responsibility and authority** Top management shall ensure that responsibilities and authorities are ... Top management shall document the interrelation of all personnel ...	Responsibilities and authorities are documented using SmartSolve's role-based security features. Once defined, the system security ensures that responsible personnel have the "independence and authority" needed to perform their tasks. Role-based security also limits un-authorized personnel from accessing or signing off on tasks.
5.5.2	**Management representative**	N/A
5.5.3	**Internal communication** Top management shall ensure that appropriate communication processes are established ...	SmartSolve facilitates communication throughout the various areas of the quality system. Automatic e-mail notifications, escalations and discussion threads and reporting ensure that relevant personnel are aware of the effectiveness of the quality system as well as the effectiveness of other quality related activities.
5.6	**Management review**	
5.6.1	**General** The organization shall document procedures for management review. Top management shall review ...	The IQVIA SmartSolve Audit Management application is frequently used to schedule and document management review activities. This includes attaching reports or evidence and documenting follow-up activities. Audit Management retains records of the management review for an indefinite time period in its 21 CFR Part 11 compliant database. These records are easily retrievable using Audit Management's user-friendly search and reporting tools.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
5.6.2	**Review input** The input to management review shall include, but is not limited to, information arising from: a. ... b. ... c. ... d. ... e. ... f. ... g. ... h. ... i. ... j. ... k. ... l. ...	Quality reports or data necessary for management review are easily retrievable. This includes reports on audits, corrective action, customer complaints/ feedback, document control, employee training, equipment management and supplier quality. These reports are customizable to meet organization-specific review needs.
5.6.3	**Review output** The output from management review shall be recorded (see 4.2.5) and include the input reviewed and ... a. ... b. ... c. ... d. ...	Actions are documented within the Audit Management application. Audit Management provides an attachment feature so that any relevant reports or documents may be linked to the review record as evidence of decisions and actions taken.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
6	**Resource Management**	
6.1	**Provision of resources**	N/A
6.2	**Human resources** Personnel performing work affecting product quality shall be competent ... The organization shall document the process(es) ... The organization shall: a. ... b. ... c. ... d. ... e. ... NOTE: The methodology used to check effectiveness ...	The IQVIA SmartSolve Training Management application documents personnel training and competence requirements. The application provides reports and notifications to keep managers informed of both employee competencies and employee training needs. When training is required, Training Management supports training sessions, web-based training, computer-based training, self-training and on the job training. Electronic employee training reviews are provided to evaluate training effectiveness. Training Management maintains training records as well as detailed employee training requirements and employee training history.
6.3	**Infrastructure** The organization shall document the requirements for the infrastructure needed ... a. ... b. ... c. ... The organization shall document the requirements for the maintenance activities, ... Records of such maintenance ...	Document Management electronically manages the document workflow for maintenance activities. Audit Management is used to ensure that internal standards are created to maintain the infrastructure needed to achieve conformity to product requirements. Auditors document the infrastructure's conformance or nonconformance on a regular basis and follow-up on any deficiencies through either Audit Management or CAPA Management.
6.4	**Work environment and contamination control**	N/A However, Document Management electronically manages the document workflow for any documents created based on this requirement.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7	**Product realization**	
7.1	**Planning of product realization**	N/A However, Document Management electronically manages the document workflow for any documents created based on this requirement.
7.2	**Customer-related processes**	
7.2.1	**Determination of requirements related to product**	N/A
7.2.2	**Review of requirements related to product**	N/A
7.2.3	**Communication** The organization shall plan and document arrangements for communicating with customers in relation to: a. ... b. ... c. ... d. ...	The IQVIA SmartSolve Complaint Management application allows customers to document complaints and feedback, and to manage the workflow needed to resolve customer complaints. Complaint Management provides customer e-mail notifications throughout the complaint resolution workflow. This includes the communication of advisory notices.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7.3	**Design and development**	To aid in the management of the design and development process SmartSolve provides our users with Design Control.
7.3.1	**General** The organization shall document procedures for design and development.	Two SmartSolve solutions contribute to our customers' compliance to general Design and development requirements. The first is Document Management which stores controlled procedures. The second is Design Control which integrates with Document Management.
7.3.2	**Design and development planning** The organization shall plan and control the design and development ... During the design and development planning, the organization shall document: a. ... b. ... c. ... d. ... e. ... f. ...	Preparing the Design Plan is a key component of the Design Control workflow. This phase of the workflow will allow for the gathering of all design evidence including but not limited to project plans, quality plans and risk management plans. Other phases that exist in Design Control include Design Input, Design Output, Verification, Validation and Design Transfer. Each phase of Design Control will be assigned to appropriate team members for the design project. Each phase of the design process includes a review, meeting notes and approval. The final phase includes final evaluation. All objective evidence is associated with the design project this includes reference to the traceability of outputs to inputs. Resources are assigned to the team and their credentials and certifications are available in to Design from Training Management. Everything is stored in the project and documentation is stored and referenced in Document Management also.
7.3.3	**Design and development inputs** Inputs relating to product requirements shall be determined ... a. ... b. ... c. ... d. ... e. ... These inputs shall be reviewed ... Requirements shall be complete, ... NOTE: Further information can be found in IEC 62366-1.	This is a standard phase in Design Control, see 7.3.2 above. This phase integrates with Document Management and Risk Management outputs also. Appropriate tasks defined to the left are assigned to the appropriate team members. The Design input process includes a review, meeting notes and approval. Everything is stored in the project and documentation is stored and referenced in Document Management also.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7.3.4	**Design and development outputs** Design and development outputs shall: a. ... b. ... c. ... d. ... The outputs of design and development shall be ... Records of the design and development outputs ...	This is a standard phase in Design Control, see 7.3.2 above. This phase integrates with Document Management and Risk Management outputs also. Appropriate tasks defined to the left are assigned to the appropriate team members. The Design output process includes a review, meeting notes and approval. Everything is stored in the project and documentation is stored and referenced in Document Management also.
7.3.5	**Design and development review** At suitable stages, systematic review of design and development ... a. ... b. ... Participants in such reviews shall include representatives ... Records of the results of the reviews and any necessary actions shall be ...	Design Phase (for all stages of Design) Review is standard.
7.3.6	**Design and development verification** Design and development verification shall be performed ... The organization shall document verification plans ... If the intended use requires that the medical device be connected to... Records of the results and conclusions of the verification ...	Design Verification Phase is standard. Documentation of the verification will be stored with the project, referenced in Document Management.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7.3.7	**Design and development validation** Design and development validation shall be performed ... The organization shall document validation plans ... Design validation shall be conducted on representative product... As part of design and development validation... A medical device used for clinical evaluation or performance evaluation ... If the intended use requires that the medical device be connected to ... Validation shall be completed prior to ... Records of the results and conclusion of validation ...	Design Validation Phase is standard. Documentation of the validation will be stored with the project, referenced in Document Management.
7.3.8	**Design and development transfer** The organization shall document procedures ... Results and conclusions of the transfer ...	Design Transfer Phase is standard. Documentation of the Design Transfer will be stored with the project, referenced in Document Management. Results and conclusions of the transfer will be recorded in the meeting information section of the Design Transfer Task.
7.3.9	**Control of design and development changes** The organization shall document procedures to control ... Design and development changes shall be identified ... a. ... b. ... c. ... d. ... The review of design and development changes shall include ... Records of changes ...	To aid in this process SmartSolve offers Change Management that will allow for the development of a change plan which could initiate the decision to open up a subsequent design project.
7.3.10	**Design and development files** The organization shall maintain a design and development file ...	These records and documents, along with their cross references to other references and documents are stored in Design Control and Document Management.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7.4	**Purchasing**	
7.4.1	**Purchasing process** The organization shall document procedures (see 4.2.4) to ensure that ... The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a. ... b. ... c. ... d. ... The organization shall plan the monitoring and re-evaluation of suppliers. ... Non-fulfilment of purchasing requirements shall be addressed ... Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability ...	The IQVIA SmartSolve Supplier Quality Management application provides inspection procedures to document incoming quality requirements. Audit Management provides tools for supplier audits. The audits may be performed prior to purchasing form a supplier or as an effort to ensure ongoing supplier quality. Audit Management maintains audit records along with any follow-up records for as long a time period as necessary to meet corporate and regulatory requirements. Supplier Quality Management manages additional tools for supplier rating and evaluation based on on-going product quality data.
7.4.2	**Purchasing information**	N/A However, Document Management electronically manages the document workflow for any documents created based on this requirement.
7.4.3	**Verification of purchased product** The organization shall establish and implement the inspection or other activities necessary ... When the organization becomes aware of any changes to the purchased product, ... When the organization or its customer intends to perform verification ... Records of the verification ...	Supplier Quality Management documents incoming inspection procedures and records. This includes the documentation of inspection requirements and inspection data. Inspection records are maintained for as long a time period as necessary in Supplier Quality Management's 21 CFR Part 11 compliant database. They are easily retrieved using the system's search and reporting features.
7.5	**Production and Service Provision**	
7.5.1	**Control of production and service provision**	N/A
7.5.2	**Cleanliness of product**	N/A
7.5.3	**Installation activities**	N/A
7.5.4	**Servicing activities**	N/A
7.5.5	**Particular requirements for sterile medical devices**	N/A
7.5.6	**Validation of processes for production and service provision**	N/A

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
7.5.7	**Particular requirements for validation of processes for sterilization and sterile barrier systems**	N/A
7.5.8	**Identification**	N/A
7.5.9	**Traceability**	N/A
	7.5.9.1 General **7.5.9.2 Particular requirements for implantable medical devices**	N/A
7.5.10	**Customer property**	N/A
7.5.11	**Preservation of product**	N/A However, Document Management electronically manages the document workflow for any documents created based on this requirement.
7.6	**Control of monitoring and measuring equipment** The organization shall determine the monitoring and measurement ... The organization shall document procedures ... As necessary to ensure valid results, measuring equipment shall: a. ... b. ... c. ... d. ... e. ... The organization shall perform calibration or verification ... In addition, the organization shall assess and record ... Records of the results of calibration and verification ... The organization shall document procedures for the validation of the application of computer ... When used in the monitoring and measurement of specified requirements, ... Records of the results and conclusion of validation ... NOTE: Further information can be found in ISO 10012.	The IQVIA SmartSolve Equipment Management application provides the tools needed to manage an effective electronic calibration program. Calibration intervals, measurement standards and instrument traceability are defined for each piece of equipment. Equipment Management allows users to document the adjustment or re-adjustment of equipment. Adjustment is documented either as a result of a calibration record or independently of a calibration record. The system can require that the equipment be recalibrated after an adjustment to ensure that the equipment is "safeguarded from adjustments that would invalidate the measurement result". Equipment and calibration records are maintained for as long a time period as necessary to meet corporate and regulatory requirements. These records are easily accessible using Equipment Management's search and reporting tools.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
8	**Measurement Analysis and Improvement**	
8.1	**General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a. ... b. ... c. ... This shall include determination of appropriate methods...	Within its various applications, SmartSolve® captures data on customer complaints / feedback, product nonconformances, product and process failure trends, supplier quality performance, corrective and preventive action, employee training, documentation and more. SmartSolve provides numerous standard reports to analyze this data and to present management with meaningful information on the effectiveness of the quality management system. In addition, SmartSolve reports are customizable to meet organization-specific quality reporting requirements. This includes the creation of new reports based on any data captured by the system.
8.2	**Monitoring and measurement**	
8.2.1	**Feedback** As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor ... The organization shall document procedures ... The information gathered in the feedback process shall serve as ... If applicable regulatory requirements require the organization ...	Complaint Management captures customer feedback and complaints to provide early warning of quality problems. If warranted, complaints and feedback become drivers for the corrective and preventive action process. This includes the ability to document, prioritize, investigate, approve, implement, escalate, verify and close the corrective and preventive action in the system.
8.2.2	**Complaint handling** The organization shall document procedures for timely complaint handling ... These procedures shall include ... a. ... b. ... c. ... d. ... e. ... f. ... If any complaint is not investigated, justification shall be documented. ... If an investigation determines activities outside the organization ... Complaint handling records shall be maintained ...	See 8.2.1 above

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
8.2.3	**Reporting to regulatory authorities** If applicable regulatory requirements require notification of complaints ... Records of reporting to regulatory authorities shall be maintained (see 4.2.5).	See 8.2.1 above
8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals ... a. ... b. ... The organization shall document a procedure ... An audit program shall be planned, taking into consideration the ... Records of the audits and their results, including identification of ... The management responsible for the area being audited shall ensure ... NOTE: Further information can be found in ISO 19011.	Audit Management supports the establishment of an internal audit program, and maintains an audit schedule, audit criteria and all related audit data and reports. This includes audit findings for follow-up. Auditor roles are definable to ensure that auditors do not audit their own work. Audit procedures are documented directly into Audit Management by defining audit and escalation policies, audit schedules and audit criteria. Audit Management notifies auditors and other involved personnel of their tasks via e-mail. Follow-up audits and/or audit nonconformance records address any negative audit findings. Audit related corrective actions and investigations are managed through built-in integration with CAPA Management. Audit Management's standard reporting and search capabilities ensure that audit records are easily retrievable and that audits and actions are easily verified. The system provides audit reports for follow-up and verification.
8.2.5	**Monitoring and measurement of processes** The organization shall apply suitable methods for monitoring ...	Quality reports or data necessary for monitoring are easily retrievable. This includes reports on audits, corrective action, customer complaints / feedback, document control, employee training, equipment management and supplier quality. These reports are customizable to meet organization-specific review needs. CAPA Management maintains corrective action processes and records when "planned results are not achieved". CAPA Management manages action identification as well as the corrective action workflow necessary to resolve the issue. (See Section 8.5)
8.2.6	**Monitoring and measurement of product**	N/A

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
8.3	**Control of nonconforming product**	
8.3.1	**General** The organization shall ensure that product which does not conform to product requirements ... The evaluation of nonconformity shall include a determination ... Records of the nature of the nonconformities and any subsequent action taken...	The IQVIA SmartSolve CAPA Management application manages the identification and resolution workflow for any type of nonconformance. Nonconformance coordinators document the steps taken to correct the nonconformity; including materials review board (MRB), disposition, and follow-up corrective actions. Rework, or any disposition, may have a controlled work instruction attached from Document Management. This ensures consistency with the approved work instruction. Reworks and other dispositions are subject to approval workflows prior to their implementation. Additional features, including checklists, help to ensure that the work to be carried out is valid and will not have adverse effect on the product. CAPA Management maintains records of nonconformance and their related corrective actions in a 21 CFR Part 11 compliant database. Records are easily retrievable using CAPA Management's user-friendly search and reporting features.
8.3.2	**Actions in response to nonconforming product detected before delivery** The organization shall deal with nonconforming product by ... a. ... b. ... c. ... The organization shall ensure that nonconforming product is accepted by concession only if ...	See Section 8.3.1 above.
8.3.3	**Actions in response to nonconforming product detected after delivery** When nonconforming product is detected after delivery or use has started, the organization shall ... The organization shall document procedures for issuing advisory notes in accordance with ...	See Section 8.3.1 above.
8.3.4	The organization shall perform rework in accordance with documented procedures ... After completion of rework, product shall be verified ... Records of rework shall ...	See Section 8.3.1 above.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
8.4	**Analysis of Data** The organization shall document procedures to determine, collect and analyse ... The analysis of data shall include data generated as a result ... a. ... b. ... c. ... d. ... e. ... f. ... If the analysis of data shows that the quality management system is not suitable, ... Records of the results of the analyses ...	SmartSolve® captures data on customer complaints / feedback, product nonconformances, product and process failure trends, supplier quality performance, corrective and preventive action, and more. SmartSolve provides numerous standard reports to analyze this data and present management with meaningful information on the effectiveness of the quality management system. In addition, any SmartSolve report may be customized to meet organization specific quality reporting requirements. This includes the creation of new reports based on any system data.
8.5	**Improvement**	
8.5.1	**General** The organization shall identify and implement any changes necessary ...	Change management is integral to many SmartSolve® features. Document Management provides a change management workflow to identify and implement changes to documents, such as SOPs and quality policies. Other changes are managed and implemented within CAPA Management's corrective and preventive action workflow. CAPA records track changes and their implementation. These changes may be the result of management review, audit results, data analysis or any type of product or process deviation. The Complaint Management application manages the identification, resolution and reporting of customer complaints and feedback. This includes electronically reporting adverse events to regulatory bodies such as the FDA in the appropriate format. Standard decision trees help users to determine whether a complaint is a reportable event. Complaint records are maintained in a 21 CFR Part 11 database and are easily accessible using Complaint Management search and reporting features. Complaint workflows include the ability to document a thorough investigation or to document why an investigation is not necessary.

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SECTION	ISO STANDARD TEXT	IQVIA SMARTSOLVE SOLUTION
8.5.2	**Corrective Action** The organization shall take action to eliminate the cause of nonconformities in order to ... The organization shall document a procedure to define requirements for: a. ... b. ... c. ... d. ... e. ... f. ... Records of the results of any investigation and of action taken ...	CAPA Management provides tools to document corrective action procedures. These procedures enforce consistency in corrective action resolution activities and ensure that authorized personnel are involved in the corrective action workflow. Corrective action activities include all the activities required in section 8.5.2, including corrective action review, cause determination, evaluating the need for action, action implementation, recording results and reviewing the record for effectiveness.
8.5.3	**Preventive Action** The organization shall determine action to eliminate ... The organization shall document a procedure ... a. , b. ... c. ... d. ... e. ... Records of the results of any investigations and of action taken ...	CAPA Management provides tools to document preventive action procedures. These procedures enforce consistency in preventive action resolution activities and ensure that authorized personnel are involved in the preventive action workflow. Preventive action activities include all the activities required in section 8.5.2, including preventive action review, cause determination, evaluating the need for action, action implementation, recording results and reviewing the record for effectiveness.

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The scope of today's Life Science companies is becoming increasingly global, both in the demand for, and the sale of life- enhancing products. These organizations must be able to support manufacturing and distribution throughout the world while addressing the potential operational risks, as well as overcoming the quality, safety and revenue pressures inherent in the industry.

The world's leading enterprise compliance and quality management companies, like IQVIA, are lowering those risks and strengthening the profitability of organizations, through enterprise-wide, automated solutions. Manufacturers then are able to dedicate their resources to designing higher quality products that will directly benefit patients' quality of life.

IQVIA is committed to helping organizations produce the highest quality products, and we believe that quality management should have a positive impact on your bottom line. We've pioneered quality management software solutions for more than 20 years. We brought industry best practices to the life sciences sector, and we've partnered with the world's leading companies to enhance their quality processes, positively impact their financial performance, and achieve regulatory success.

For more information, visit us at www.IQVIA.com

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As QMS Regulatory and Product Management Leader for IQVIA, Kari Miller is responsible for driving the strategic product roadmap, and delivery of industry best practices and regulatory compliance solutions for quality management. Kari has more than 25 years of experience delivering software solutions for life sciences. She brings that knowledge to her current team as they focus specifically on translating market and industry requirements into industry-leading enterprise quality management solutions that meet the needs of the heavily regulated life sciences QMS market. Kari earned a Bachelor of Science in Business Administration and a Bachelor of Science in Psychology from Marian College of Fond-du-lac, Wisconsin.