

Data from February 2026 FDA QMSR Inspections

Inspection ID	FEI Number	Legal Name	Inspection End Date	Program Area	Act/CFR Number	Short Description	Long Description
1303142	3008363932	Seacole-CRC, LLC	02/13/2026	Devices	ISO 13485:2016 Clause 4.1.1	QMS not documented and maintained adequately	The quality management system was not documented in accordance with applicable regulatory requirements.
1303142	3008363932	Seacole-CRC, LLC	02/13/2026	Devices	ISO 13485:2016 Clause 7.5.6	Procedures for validation of processes not documented	Procedures for validation of processes were not documented.
1302698	3010539401	Gobiquity, Inc	02/12/2026	Devices	ISO 13485:2016 Clause 4.1.2	Risk-based approach not applied to QMS processes	A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.
1302698	3010539401	Gobiquity, Inc	02/12/2026	Devices	ISO 13485:2016 Clause 7.3.9	Requirements for design and development changes not met before implementation	Design and development changes were not adequately reviewed, verified, validated, and approved before implementation.
1301914	3010331770	BioSensics LLC	02/09/2026	Devices	ISO 13485:2016 Clause 7.3.1	Design and development procedures not documented	Design and development procedures were not adequately documented.
1301914	3010331770	BioSensics LLC	02/09/2026	Devices	ISO 13485:2016 Clause 8.3.1	Nonconforming product not identified and controlled	Product which does not conform to product requirements was not adequately identified and controlled to prevent its unintended use or delivery.
1301914	3010331770	BioSensics LLC	02/09/2026	Devices	ISO 13485:2016 Clause 8.5.2	Corrective action not taken	Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.
1303546	3007532396	EUSA Global, LLC	02/06/2026	Devices	ISO 13485:2016 Clause 4.2.1	QMS documentation does not include required documents	The quality management system documentation does not adequately include documents and records to ensure effective planning, operation, and control of processes.
1303546	3007532396	EUSA Global, LLC	02/06/2026	Devices	ISO 13485:2016 Clause 7.1	Product realization risk management processes not documented	One or more processes for risk management in product realization have not been adequately documented.

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1301452	1720734	IPAX, Incorporated	02/05/2026	Devices	ISO 13485:2016 Clause 7.1	Product realization risk management processes not documented	One or more processes for risk management in product realization have not been adequately documented.
1303440	3004825240	Ecotec Manufacturing, Inc.	02/05/2026	Devices	ISO 13485:2016 Clause 8.2.2	Complaint handling records not maintained	Complaint handling records were not adequately maintained.
1303440	3004825240	Ecotec Manufacturing, Inc.	02/05/2026	Devices	ISO 13485:2016 Clause 8.3.4	Rework records not maintained	Records of rework were not adequately maintained.
1303440	3004825240	Ecotec Manufacturing, Inc.	02/05/2026	Devices	ISO 13485:2016 Clause 8.5.2	Corrective action procedures not documented	Corrective action procedures defining the requirements for determining the causes of nonconformities have not been adequately documented.
1302466	3009887475	BBS Enterprises	02/04/2026	Devices	ISO 13485:2016 Clause 4.1.2	Risk-based approach not applied to QMS processes	A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.
1302466	3009887475	BBS Enterprises	02/04/2026	Devices	ISO 13485:2016 Clause 7.1	Product realization risk management processes not documented	One or more processes for risk management in product realization have not been adequately documented.
1302466	3009887475	BBS Enterprises	02/04/2026	Devices	ISO 13485:2016 Clause 7.2.1	Requirements related to product not determined	Requirements related to product do not include requirements necessary for specified or intended use, as known.
1302466	3009887475	BBS Enterprises	02/04/2026	Devices	ISO 13485:2016 Clause 7.5.6	Process for production and service provision not validated	Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not validated.