



Interacoustics: achieving compliance with 21 CFR 820 and the Medical Device Directives

To comply with strict FDA and European standards and regulations, including ISO 13485, 21 CFR Parts 11 and 820 and the Medical Device Directive, medical device manufacturers and suppliers must have systems in place that can help manage their compliance with legal and regulatory requirements.

Q-Pulse provides medical device manufacturer Interacoustics A/S with a fully integrated compliance management solution that helps manage system processes including Document Control, Auditing, and CAPA Management.

Part of the William Demant Group, Danish medical device manufacturer Interacoustics A/S manufactures clinical audiometers and other testing equipment for audiologists and ear-nose-and-throat specialists, hospitals and hearing aid dispensers.

Interacoustics needed a single system with which to integrate document control and CA/PA management activities. In selecting a system to support their Quality Management System (QMS), Interacoustics chose Q-Pulse, from Gael Ltd.

Q-Pulse provides medical device manufacturers with a fully integrated compliance management solution that helps manage regulated activities including Document Control, Auditing, and CA/PA Management.

'As a medical device company, we are required to comply with ISO 13485 and 21 CFR 820, together with other related standards, including the Canadian Medical Device Regulation (CMDR) and Annex II of the European Medical Device Directive,' explains Hanne Nielsen, Quality Manager at Interacoustics.



'In replacing our manual QMS, we needed a system for managing corrective and preventive actions as well as a system to manage document control. During our initial investigations, our priority was a system with which we could effectively manage our CA/PAs, as well as a system for Document Control.'

The William Demant Group – of which Interacoustics A/S is a part – develops, manufactures and markets a wide variety of technological solutions, from state-of-the art digital hearing instruments and assistive listening devices to revolutionary new diagnostic systems.

'With companies in Denmark, Germany and the US, we also had to make sure that the system we chose was capable of providing an enterprise-wide solution, which could scale to meet the needs of all three companies and allow them to share work.'

'At Interacoustics, all employees have the Q-Pulse client installed and can access different modules depending on their permissions.'

'We rely quite heavily on dynamic permissions combined with static groups: managers have one set of permissions and different functions have another. This ensures that employees see only the actions and activities that are relevant to them and for which they are responsible.'

'We currently use Q-Pulse's Document, CA/PA, Assets, Audit and Analysis modules. In terms of systems and procedures controlling processes, Q-Pulse is used to manage processes for Document Control, CA/PA, Calibration of measuring equipment and Audit planning.'

'However, more than managing processes, Q-Pulse comprises an integral part of our processes. We use Q-Pulse wherever it makes sense – and to us it makes sense to use Q-Pulse in many areas, including production, design, marketing, product management, and quality.'

'Q-Pulse tells the story of what has happened in a certain case, whether it's the control of a document or the management of an incident; by being able to track and monitor documents and incidents at each stage of their respective processes, Q-Pulse has enabled us to streamline such processes and identify opportunities for improvement. This has enabled us to be more efficient in our compliance activities.'

'We see Gael as a company with a very high focus on the needs of the customer,' concludes Hanne. 'With the release of the latest version, Q-Pulse has become a fast and reliable system for handling a great deal of our quality issues.'

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Hanne Nielsen
Quality Manager
Interacoustics

Conclusion

In the medical device market, both FDA and European regulatory bodies have significantly increased their scrutiny: in the US, for example, manufacturers and suppliers are required to ensure that the design, manufacture, packaging, labeling, storage, installation, and servicing of medical devices are all performed in a robust, quality-assured environment.

To comply with strict FDA and European standards and regulations, including ISO 13485, 21 CFR Parts 11 and 820 and the Medical Device Directive, medical device manufacturers and suppliers must have systems in place that can help manage their compliance with legal and regulatory requirements.

A compliance management solution like Q-Pulse, which fully integrates management system processes such as Auditing, Document Control and CAPA Management can help manufacturers and suppliers to maintain and improve regulatory compliance. By enabling the integration of daily compliance activities, such solutions can also streamline processes and reduce the duplication of effort.

Q-Pulse can also help medical device manufacturers identify opportunities for continual improvement, from tracking corrective and preventive actions to measuring the effectiveness of the QMS.

Contact us now at medicaldevice@gaelquality.com to find out how Q-Pulse can help you to reduce your time, effort and resource expenditure in achieving regulatory compliance.