Simplify, unlock and maintain ISO 13485 compliance with Q-Pulse® Cloud

Ideagen

A holistic, digital medical device quality management system

Patient and product safety are the core of your ISO 13485 medical device quality system. Complete control and visibility of your quality and compliance activities are crucial.

Q-Pulse Cloud is a modular, GAMP-validated electronic quality management system designed to ease the burden of compliance with ISO 13485 and to give you the tools and functionality you need to prove to your auditors that your business is compliant.

From managing key documentation to finding and eliminating non-conformances, Q-Pulse Cloud is used by dozens of regulated medical device organisations worldwide.

COMPLETE CONTROL FROM DESIGN TO POST-MARKET SURVEILLANCE

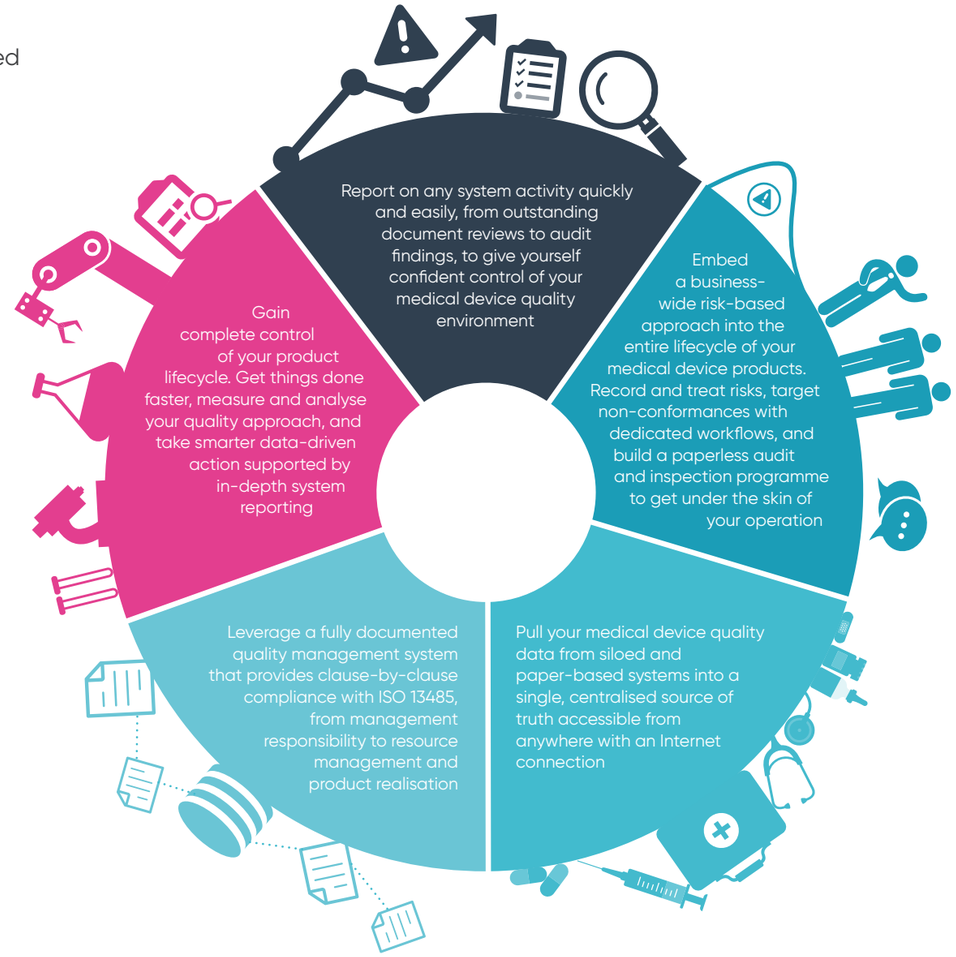
Q-Pulse Cloud gives you a single source of truth for your medical device quality management activities. Risks, documents, audits, CAPAs and more are tracked and managed in a single cloud-based system that connects your entire business.

UNSHAKEABLE COMPLIANCE

Q-Pulse Cloud is designed to embed ISO 13485 compliance automatically into your day-to-day activity. Every document is supported with robust version control functionality. Every business and quality process is traceable from beginning to end with visual workflows. And every action taken in the system is audit-trailed and time-stamped – so you can prove to your auditors you have the visibility and control you need.

A DEDICATED MEDICAL DEVICE SYSTEM

The Life Sciences Edition of Q-Pulse Cloud is designed for highly regulated GxP environments. FDA 21 CFR Part 11 e-signatures, ALCOA+ functionality, validation documentation and more are bundled as standard to give you a dedicated and appropriate industry-specific tool that will meet your regulatory demands.



ISSUES & INVESTIGATIONS

Use our visual workflow engine to map your quality and compliance processes into your digital QMS. Push actions along workflows to manage CAPA plans, out-of-specification investigations, customer feedback, and any kind of business process.

DOCUMENTS

Securely store and manage any kind of business documentation, from design history files and technical drawings to target product profiles and quality manuals, with built-in version control and approval processes.

AUDITS

Build and control a digital paperless audit programme with bespoke checklists and templates to pinpoint risks and harness opportunities. Perform targeted audits across your medical device lifecycle, from pre-clinical testing to post-market vigilance.

TRAINING

Prove your staff are appropriately trained and competent for their roles with a living training record library. Schedule, record and give feedback on training, and categorise training by departments, roles and even standard-specific requirements.

RISKS

Build a living risk register. Assess, score and manage your risks to control your risk environment and embed a risk-based approach into your medical device QMS.

INTERESTED PARTIES

Clause 7.4 of ISO 13485, like the Medical Device and In Vitro Diagnostic Regulations, places emphasis on close control of your third parties. Maintain a comprehensive record of your interested party relationships, from suppliers to customers and regulators, and associate tasks, key documentation, issues and other information to them.

ABOUT IDEAGEN

Ideagen plc is a developer of enterprise governance, risk and compliance (GRC) software for organisations operating in highly regulated industries, with operations in the UK, USA, the Middle East and Eastern Europe.
With more than 20 years' experience and success in the global regulatory environment, we have earned our customers' trust by building long-term relationships in which we work closely together to meet and exceed their quality, audit and safety management goals.

We have more than 2000 customers around the world using Q-Pulse in industries like aerospace and defence, aviation, food and drink, healthcare, life sciences and manufacturing. Our solutions have been designed and continually developed in close consultation with quality, audit and risk professionals from industries that include aviation, aerospace and defence, healthcare and life sciences, energy, manufacturing and services and engineering.

We are committed to continually improving the quality of our products, the environmental impact of our operations and the security of the information that we safeguard and this commitment is demonstrated by our certifications to ISO 9001, ISO 14001 and ISO 27001.

Ideagen

e : info@ideagen.com | w : ideagen.com