AsphaAssure
by Asphalion MedTech

Electronic QMS & Process Management System: One Tool, All Regulations, Effortless Quality.

In a MedTech environment that is becoming increasingly demanding, many organizations face the growing challenge of ensuring quality and regulatory compliance in order to launch their Medical Devices and In vitro Diagnostic Medical Devices. At Asphalion, we believe not only in meeting compliance, but in fostering a culture of quality management.

Introducing our eQMS, a comprehensive **Process Quality Management Software** tailored for **startups and SMEs** in the MedTech sector. Our eQMS enhances **operational efficiency**, ensures **compliance** with the most stringent regulations, and helps businesses **stay competitive** in the market.

With Asphalion, you can transform quality and compliance challenges into opportunities to commercialize in the market.

Why AsphaAssure?

Consolidated Compliance Framework: AsphAssure supports a range of compliance frameworks, including ISO 13485, ISO 9001, EU Regulations, FDA QSR & MDSAP. This ensures your organization is always up to date and compliant with the latest standards and regulations.

Tailored compliance: AsphAssure is as customizable as your needs require. It grants the client control and underscores the software's ability to meet their specific needs.
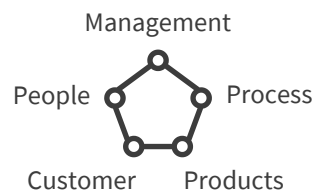
No-Code System: AsphAssure is a 'Do it yourself' solution by being a No-Code system, facilitating its implementation and use without needing extensive technical knowledge.

Expertise & Simplicity: Developed by MedTech industry experts who understand the unique challenges, its user-friendly interface is designed for an effortless navigation and implementation.

How it Works:

1) Normalized Requirements under 5 pillars

Management

People   Process

Customer   Products

2) Organization setup and remote services

- Changeable filters criteria
- Customizable organization structure
- Applicability and exclusion of process
- SW platform validation divided by fields of groups
- Disclaimers

3) Document Control

Visual editor for regulatory field documents, including DHF, DHR, DHD, MDF and TD

For more information about our eQMS services, please visit our website www.asphalion.com or contact us for a demo and get ready to elevate your Quality Management System!