

YOUR COMPLETE GUIDE TO CHOOSING THE RIGHT TRACK & TRACE SOLUTION



The medical device industry is growing, not only because of the rate of technological advancement, but also due to increasing regulatory pressure from authorities.

Ensuring you have the right traceability system in place means the difference between a safe working environment, and non-compliance - *which could lead to a whole host of problems, from patient safety risk, to financial losses, and reputational damage (nobody wants that!)*.

So, what can you do? You could use these tools in place to help you choose the right system for keeping track of your medical devices. The right software helps you:

- ✓ Reduce hospital-acquired infections for continued patient safety
- ✓ Reduce cancelled operations by improving availability of kit
- ✓ Minimise the cost and wastage of expired inventory
- ✓ Comply with safety and equipment tracking legislation
- ✓ Improve visibility of implants associated to patients

What are the essential criteria you need to choose your track & trace solution:

Regulatory Compliance

- Ensure the software complies with the latest EU MDR and MDOR regulations by requesting the vendor to provide documentation confirming the software's compliance. Solutions providers like Athera Healthcare not only offer such certification but also proactively inform their customers of regulatory changes, ensuring everyone stays updated.
- Your chosen provider should also have the flexibility to adapt to changing healthcare requirements - ensuring you're futureproofed for regulation changes.

Data Management and Integration

- The solution must have the capability to capture and store data from all stages of the product lifecycle, *and* be flexible enough to adapt to the variety of product lifecycles out there. It should include features that guarantee data accuracy, completeness, and security, maintaining high standards of data integrity. Additionally, seamless integration with existing systems is essential to ensure fast implementation, adaptability to changing technology, and smooth and efficient operation across the organisation.

Traceability Features

- Any traceability solution, if it is MDR/MDOR compliant, should support Unique Device Identification (UDI) assignments and management, enabling real-time tracking of medical devices from manufacturing to its end-use. Additionally, it must provide traceability at batch levels to facilitate efficient recalls. Ask your provider if they're UDI-compliant!

- The solution must be able to automate reports required by regulators, include advanced analytics for monitoring compliance, performance, and operational efficiency, and offer the ability to create custom reports tailored to your specific department/team needs.

Reporting and Analytics

- BONUS: Solutions that take a partnership approach to your provider/customer relationship could help you generate better reports. Because Athera FingerPrint experts work closely with their customers, FingerPrint helps healthcare professionals plan and implement comprehensive reports.

Security and Data Privacy

- Solution providers should ensure data is encrypted both at rest and in transit, feature user authentication, such as role-based access controls, and adhere to GDPR rules for handling personal data.

Usability and Support

- Taking time to learn new software is never an easy option for healthcare professionals, so solutions should be easy to set up and start using. There should be an intuitive interface for easy navigation and use by all staff levels, ongoing technical support, and detailed user manuals and documentation.

Scalability and Flexibility

- As your healthcare unit and team grows, your solution *should* be able to grow and accommodate you. Not only that, but with ever-evolving technology and fluctuating budgets, your traceability solution needs to flex and bend to those facets.

Cost Considerations

- Evaluate the total cost of ownership, including licensing, implementation, training, and maintenance, and ensure a clear understanding of the pricing model. Beware that some solution providers rely on upselling add-ons, making anything past basic features hard to access without additional funding from your side. Athera FingerPrint is upfront about

the financials from the start of your communication with our sales team, so there's no hidden costs to worry about.

What's next?

Now you've got your essentials down, you need to consider options.

Athera FingerPrint is already the leading solution for the HSE in Ireland, and across numerous trusts and private hospitals across the UK. We're dedicated to helping our customers stay compliant.

We recommend speaking to one of our dedicated sales team to learn more about Athera FingerPrint and how our trusted traceability solution can fit your needs 🙌

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