

cognidox

CLEARED FOR TAKE-OFF

Accelerating medical device product development with Cognidox



One eQMS platform



Supports multiple clients



One license fee

Forget the way document management and eQMS software used to be sold and resold.

Expensive license fees, complex implementation, pay per module and pay per user. Charging the earth for access to clunky eQMS solutions just stops clients' medical device development projects from taking off. It stops developers bringing new products to market rapidly and on budget.

At Cognidox we do things differently.

Cognidox offers consultants a single eQMS platform that works out of the box. Inside is everything a medical device consultant needs to get all their clients started; structuring their documentation and business processes to meet the unique demands of the industry.

8 REASONS WHY EVERY MEDICAL DEVICE CONSULTANT NEEDS COGNIDOX

1) It's a business case no-brainer

This is not pay per module. It's not PAYG. It's everything all your medical device clients will need from day one with exactly the number of users you need. **All for a single, annual fee.**

"Other providers charge consultants a license fee for access to their platforms and the same again for every client they bring on board. That made no sense as a business model for us or our customers. But with Cognidox it's different. The single fee model means we can give all our clients access to an eQMS at the price that's right for them"

Fabio Cirillo
Avanti Europe AG

8 REASONS WHY EVERY MEDICAL DEVICE CONSULTANT NEEDS COGNIDOX cont.

2 'Limited Access Partners' - is a unique offering

Cognidox's 'Limited Access Partners' (LAP) feature is a unique offering in the market. It lets you set up as many developer clients as you need on a single platform. You won't be charged additional fees every time you bring a new client on board. Each client has secure, individual access to their own eQMS and you can manage each of them individually through your master account.

3 It's a complete platform from day 1

Cognidox is a DMS, QMS and BMS out of the box with LMS tools included. You won't be charged extra to access a new module or advanced functionality like e-signatures.

4 It's fast to set up

There are preloaded templates for many of your BMS and QMS needs that can be easily adapted to fit the way each of your clients' work. Don't get bogged down changing your process to fit the template.

You can migrate your way of setting up clients directly to Cognidox. It offers you the ultimate flexibility to cherry-pick the features you require to meet your client's needs and help them focus on their goals.

5 It's a secure solution

Cognidox is ISO27001 certified. All the LAP functionality keeps each client's data, documentation, and IP separate and secure. Data is encrypted both in the system and in transmission.

6 Training materials and LMS tools come as standard

The system comes with video and text guides that our clients love. They are accessible to all their workers through the platform and really easy to understand. This ensures training is consistent, effective, and always available whenever you need it, for onboarding and continual improvement. It also automates training self-certification on documentation created in the system. These are important parts of any LMS.

7 It offers an ISO 13485 framework

Cognidox offers a graphical framework that maps to ISO 13485 with preconfigured processes and forms to help you meet the standard. CAPA, change requests, OFI's, non-conformance, and complaints come as standard. But these templates can be adapted at will to reflect the unique way each client needs to build their product and operate their business.

8 It's primed for growth

Cognidox's unique business model helps consultants and their customers grow and scale rapidly. With the ability to right-size to each of your clients needs, you can set up a flexible eQMS framework that can grow and become more robust as their compliance needs ramp up. Cognidox can accelerate the time scale for product delivery and increase profitability by supporting more projects that are optimised for success.



CASE STUDY

WHY AVANTI EUROPE PARTNERS WITH COGNIDOX

Avanti Europe is a specialist consultancy for the life science industry.

They support medical device and combination product projects with flexible tailor-made solutions to help companies in every stage of the development lifecycle as they bring new products to market.

Avanti are using Cognidox and their Limited Access Partner features to give their clients bespoke, early access to the robust document management, BMS and eQMS tools that will be vital for their commercial journey.

Delivering a BMS, QMS, LMS tools & Extranet - all in one platform

Few systems can boast they give access to a BMS, QMS and LMS tools from day one. It's this approach that gives Avanti the competitive edge when supporting the fast-growing medical device and pharma companies they work with. It means they have all the tools to power their growth from the very start of their journey, with no hidden costs to ambush them along the way. It puts process and documentation at the heart of the way they work, but keeps them focused on delivery:



"Our Extranet feature allows a company to link to their eQMS from anywhere, making it an extension of the way each company 'does things' as a business. Their business management structures and processes are easily accessed by all their workers and future auditors," says Joe Byrne CEO at Cognidox

"The BMS drives good business practice and the LMS tools are available from the start", he continues "On top of this, we can demonstrate to auditors (through graphics and video) how they share knowledge internally and train their workers according to the requirements of ISO 13485. This makes product approval as smooth as possible."

Cognidox: where business and quality management meet

And Fabio Cirillo echoes these thoughts:

"It's everything you need for internal training, compliance and best commercial practice. In the graphical eQMS you can create and envisage the whole process landscape. At the top level you can see the steps in every required process visualised as flow diagrams, but you can click through for more detailed visualisations of a particular stage or drill down even further to look at the version-controlled written documentation that underpins it all."

The configurable platform transforms the way Avanti works

"But the backbone to the Cognidox system is definitely the ability to move outside of the existing templates and adopt the system to suit our customers' need," continues Fabio, "It's great to have those templates, of course, but in other systems they can be restrictive. Instead, with flexible and configurable forms our developers can build out their own unique approach to capturing CAPA, feedback and non-conformances, so they can meet the regulation in a way that fits the product and processes. We have plans to use the forms to create dynamic, interactive SOPs to further increase risk control. And the truth is we can only do this using the Cognidox platform."

50% less time and effort to set up a client's eQMS

"Cognidox gives our clients complete digital control over their design and development processes. We use interactive graphics and flow charts to help them organise the way they work. It promises them a head start with the document governance and business management that is crucial to med dev and pharma success. Cognidox paves the way to successful sharing of organisational knowledge, smoother auditing and a faster route to commercial success. Through adopting the Cognidox licensing model this has not only accelerated timescales for product development (we are able to implement an eQMS for clients with 50% less time and effort) but has given us a high return on investment that would not be possible with any other platform on the market," explains Fabio.



Avanti and Cognidox are building a client base more able and equipped to rise to the future challenges of regulation and auditing. They're giving their clients the tools they need to build the required QMS and LMS in a secure, scalable and cost effective way. They are helping them lay the early foundations for frictionless development and rapid business growth.

It's the platform that every consultant needs to accelerate their client's through the product development process.



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