

# An early adopter reviews Qualio's Compliance Intelligence



## About Sentec

Sentec is a Swiss-American medical device company specializing in respiratory care and non-invasive monitoring.

The company sells its medical device products across the globe, juggling simultaneous compliance with some of the toughest regulatory standards in the world, including the EU MDR and the MDSAP.

As a long-time user of Qualio's eQMS software, they were a perfect candidate to be one of the first companies to try Compliance Intelligence, Qualio's new AI-powered regulatory compliance management software product.

## The brief

We asked two members of Sentec's quality team, Site Quality Manager Christophe Dohr and Quality Specialist Simon Bitterli, to try Compliance Intelligence for 5 weeks and share their feedback.

Christophe and Simon took a deep dive into Compliance Intelligence's functionality, from its AI-automated QMS gap analysis to its remediation and continuous improvement recommendations. The tool was applied to Sentec's live quality management processes.

Industry Medical device

- Regulations
- EU MDR
  - ISO 13485
  - MDSAP

5x

Faster audit prep

2

Major improvements made to processes guided by Compliance Intelligence

100%

Audit confidence

*"Everything Compliance Intelligence does to identify gaps, and to make us more productive and speedy in resolving them, reduces our risk.*

*It's going to be part of the state-of-the-art tools we need in companies to proactively identify compliance gaps and minimize risk levels."*

— Christophe Dohr  
Site Quality Manager, Sentec



# The results

Compliance Intelligence gave Sentec the visibility and productivity they needed for total confidence

## Total top-down visibility

Like many modern life science companies, Sentec's quality management system comprises hundreds of working documents and processes. Before, Christophe and Simon relied on manual searches for compliance gaps. Spotting and fixing one didn't necessarily mean another wasn't lurking unseen.

Policing the QMS and looking for improvement opportunities took **hours of manual work each week**.

Compliance Intelligence's AI-supported gap analysis process took **just 30-40 minutes to perform an entire scan** of Sentec's QMS, from SOPs to policies and records, before delivering a detailed breakdown of every compliance gap along with recommendations to close them.

For Christophe, this 'total analysis' was invaluable, unlocking **360-degree visibility of compliance health** that simply wasn't possible when relying on quality personnel alone.

## Redirected effort for improvement

By letting Compliance Intelligence find and flag compliance gaps for them, Simon and the quality team could spend **extra time on continuous improvement which wasn't available before**.

For example, Compliance Intelligence **flagged 2 improvements** for Sentec's CAPA and non-conformance management processes, suggesting tighter step ownership and more clearly defined timelines. Christophe and Simon responded by introducing RACI metrics and more detailed event step explanations.

Both noticed that this reallocation of effort from 'spotting' to 'fixing' **boosted productivity**, allowing quality manpower to be redirected to close out events faster and cut throughput time. As Christophe puts it, "you speed up the cluster of activities you need to perform for your QMS to make it better".

*"Compliance Intelligence gives us a 360° view of our QMS and automatically surfaces the gaps.*

*We resolve issues faster, our team is more productive, and our risk is lower. With the system analyzing our documents and evidence end to end, we know we have full coverage and can walk into audits with total confidence."*

— Christophe Dohr  
Site Quality Manager, Sentec

## 1 week down to 1 day

Sentec face a lot of regulatory audits, each one taking a **full working week of preparation time**: internal audits, SOP reviews, gap assessments and more.

Simon pinpoints **dramatic time savings** in this area delivered by Compliance Intelligence.

The tool's automated gap analysis and remediation recommendations removed the bulk of this manual activity for the Sentec team, **cutting audit prep time by 80% to just a single day**.

## Risk control

Both Christophe and Simon identify the primary benefit of Compliance Intelligence as its ability to **slice audit and compliance risk to a minimum**.

Automated detection unlocked a planned 'cleaning' process for Sentec, where compliance risks could be **systematically prioritized and addressed** to cut operational risk, and gaps closed before they could ever escalate.

*"In the end, you get a stronger quality management system. You can safeguard your company against risk, and from adverse events on the market. How many critical findings did you cut from your audit, or from not being in an adverse event situation on the market by using this tool? The business case is clear."*