

APA ENGINEERING

A Class APART

Compliance Chaos to Victory

Discover How APAs' Green Check Software Transformed a
Global Electronic Company's Compliance Journey

About Our Client

Our client is a renowned manufacturer of software-controlled medical devices that enhance clinical performance, surgical safety, and cost-effectiveness.



Global



Sales 980 M€



10000+ Employees

- 1 High Quality Products**
- 2 Clinical Performance**
- 3 Surgical Safety**
- 4 Cost Effectiveness**

Clients Challenges



Challenge #1

Dynamic Regulatory Landscape

Staying up-to-date with the regulatory requirements was crucial for the manufacturer to ensure compliance. However, with the constantly evolving nature of regulations, it had become increasingly difficult to keep track of changes and integrate them into their processes. For the manufacturer to market their devices worldwide, it was essential to comply with several local and international regulations.

Challenge #2

Clinical Data Requirements

Depending on the device's risk classification, manufacturers must conduct extensive clinical trials to demonstrate the safety and effectiveness of the devices. Collecting and analysing vast volumes of clinical data became expensive and time-consuming.



Challenge #3

Supply Chain Requirements

The manufacturer relied on a complex network of suppliers. Supply chain compliance can be complex, especially with outsourcing. The manufacturer collaborated with each supplier to ensure the desired compliance quality and conducted regular performance assessments. While this was true, many suppliers were non-responsive to compliance data requests. This process was laborious and time-consuming.



Challenge #4

Documentation & Data Privacy

Documentation was an important aspect of the compliance process for proof of adherence, accountability, and traceability. The manufacturer found it increasingly burdensome to handle a multitude of documents from various suppliers and generate the final documentation required without compromising data privacy.



Bridging the Gap

APA Greencheck

- ✓ APA is a **global provider** of compliance solutions committed to delivering **high-quality solutions** that ensure customer satisfaction.
- ✓ **APA's Greencheck** was the ideal solution for the manufacturer facing several compliance challenges.
- ✓ Greencheck is a comprehensive cloud-based Compliance Management Software to **streamline and automate** the regulatory process.

Our Solution

#1 Regulatory Watch

Greencheck ensured that the manufacturer stayed up-to-date with regulatory updates by closely monitoring them and providing frequent software updates.



#3 Compliance process automation

Greencheck automated the regulatory process for multiple compliances like ROHS, REACH, PROP 65, EU MDR (EU Medical Device Regulation), ADM (Animal Derived Materials) & CMRT which were vital to achieving medical devices compliance for the manufacturer.



#2 Data Management

The software acted as a centralized hub for collecting and organizing data while safeguarding its protection through encryption and user permissions. With the latest and most accurate data made available to all users, our repository provides a reliable and single source of information for the manufacturer, stakeholders, and suppliers alike.



#4 Data Analysis

In-depth **data analysis** by the software at the product BOM level helped the manufacturer quickly identify gaps, risks, and compliance errors, reducing manual effort and time involved. With the correct data, it was easier for the manufacturer to prove the safety and effectiveness of the surgical products.



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#5 Supply Chain Collaboration, Communication, & Transparency

With Greencheck, the manufacturer could **connect** with their global network of suppliers to request product information through reminders and notifications while receiving expert guidance from APAs compliance professionals to help them reach non-responsive suppliers. The tool provided supplier intelligence data, allowing the manufacturer to evaluate and compare supplier performance and ensure transparency.



#6 Actionable Metrics & Reporting

Real-time compliance monitoring through the dashboard metrics enabled quick identification, resolution of non-compliance issues and make strategic business decisions. The manufacturers could generate compliance disclosures with a single click using built-in reports and customize the disclosures based on specific regulatory needs effortlessly. This facilitated error-free on-time submission.



#7 Document Management

The manufacturer could easily gather, organize, and audit documents with the help of a centralized repository. They were also able to map the received documentation to their respective suppliers.



Implementation

We hosted Greencheck, our cloud-based solution, on one of our servers closer to the client's preferred location. We worked intently with the compliance division's point of contact for the manufacturers' instance to set up the following:

#1 SYSTEM CONFIGURATION

- Organization information.
- Users, Roles, and Permissions.
- Enabled the compliances based on their industrial requirements.
- Notification and alerts.

#2 DATA INTEGRATION

Imported supplier and product information to minimize manual data inputs and improve efficiency.



#3 AWARENESS & TRAINING

The client received comprehensive training on the software's functionalities through webinars and online conferences. Our compliance experts were also available throughout the client's work hours to offer any handholding.

1

Centralized Repository

Centralized repository enabled easy access to parts and compliance data and view the audit trail of any modification or updates

2

End to End Automation

End to end automation allowed effective and streamlined the compliance process and eliminated errors.

3

Better Supplier Response

Through the continued use of GreenCheck Software, the manufacturer was able to request, receive, and analyze compliance data from the suppliers through the automation of survey requests, notifications, and alerts to suppliers

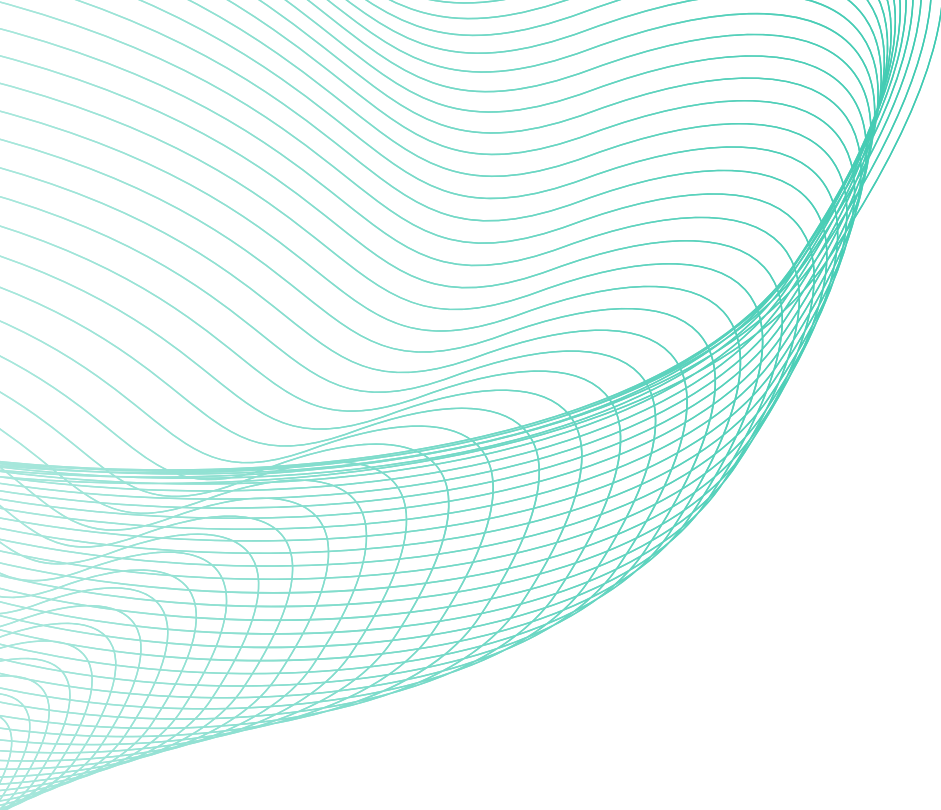
4

Quick Reports for On-time Submission

Proper data management and analysis allowed the manufacturer to easily identify errors and generate required compliance reports for on-time submission.

Keys to our Clients Success





We stand 'APA'rt

400 + Expert Team

Software tools for accurate data analysis and customizations

Global OEMs & Tier 1 customers

Offshore delivery at competitive pricing.

Comprehensive Compliance Solutions



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Contact Us

We are just a call away



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