



E-BOOK

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# AUDIT RESILIENCE IN A VIRTUAL WORLD

A Practical Guide



# AUDIT RESILIENCE

## Be Compliant With Required Regulations and Ready to Demonstrate That in an Audit

Highly regulated companies, like medical device companies, need to be prepared for remote audits.

Drawing from case studies, customer successes and lessons learned, and expertise from within Arena, we have resources on how to build an organization that is compliant with regulations. In this eBook, we share ideas on how to effectively prepare for audits so that you can demonstrate you follow compliant practices.



# GOOD REMOTE AUDIT PRACTICES

## Define Online Compliant Processes

Design your product processes from design to release and sustaining to comply with or exceed your regulations. Regulatory bodies include ISO for any company and FDA for U.S.-market medical device companies. Each country, economic union, and industry has its own regulatory bodies as well.

## Automate the Processes With Date/Time Stamps and User Information

How do you show that users and partners are following your compliant processes as designed? Logbooks and spreadsheets fall short in today's fast-paced, high-expectation industries. Online systems automatically record users' activities, leaving a record of who has done what and when.

**“We are prepared and confident for audits. We link all QMS information and product records. We structured the data to support our processes. Everything is searchable and we can quickly find the documents and records an auditor needs.”**

– Michelle J. Potvin, ASQ CQA Director, Quality Assurance & Regulatory Affairs,  
Swan Valley Medical



### A QUICK READ

What are the Benefits and Barriers  
When Performing Remote Audits?  
from Advisera, 9001 Academy



# BETTER REMOTE AUDIT PRACTICES

## Document Your Remote Audit Procedures

Consider the audit plan so you know every outcome can be met remotely. Design a procedure to simplify and optimize the audit time. Choose the screenshare software and determine how to orient the auditor on that platform. Refine your procedures by incorporating lessons from an internal remote audit.

## Manage All Products to the Strictest Regulation

You need to comply with a wide variety of regulations that address different goals: safety, quality, environment. And, for every country where you market your product, you need to comply with their unique regulations. Make a compliance matrix of all these regulations and manage to the strictest one.

**“Morey Corporation must comply with quality, safety, and environmental regulations that vary based on industry, geography, and year. In addition, we must comply with our customers’ unique set of standards. Our customers benefit because we manage our entire operation to the most stringent levels of regulation.”**

– Ginger Butz, Director, Sales Operations, The Morey Corporation



# BEST REMOTE AUDIT PRACTICES

## Extend Compliant Online Processes to Your Supply Chain

When partners play a key role in your product's lifecycle, your product's environmental, safety, and quality compliance depends on your partners' compliance. Make compliance part of your supplier selection process. Include partners in your compliant online processes and audit them to make sure you can provide evidence that they are compliant as well.

## Be Ready for New Regulations

A new situation, like a pandemic, a new industry, or a new geography, leads to new regulations. Even if these factors remain constant, established regulations change over time. Practice for audit. Train new team members on the processes. Test the training. Schedule a regular review of your regulations to find changes and adjust your processes as needed.

**“At Hyalex, Arena facilitated us to remain compliant with our processes and convert to 100% remote overnight. Additionally, we were able to use the training feature to quickly train on new procedures including new COVID operating procedures to allow re-entry.”**

– Richard Balano, VP of Quality at Hyalex

**“In a post-pandemic market, the companies that thrive will be the ones that are resilient, fully digitized and understand how to drive sustainability and business harmony, regardless of economic conditions.”**



### **FROM A CHALLENGE READ**

An Unexpected Risk of COVID-19:  
Canceled Supplier Audits Sylvain  
Guyoton, senior vice president of  
research, EcoVadis

# BUILDING THE SOLID FOUNDATION FOR COMPLIANCE

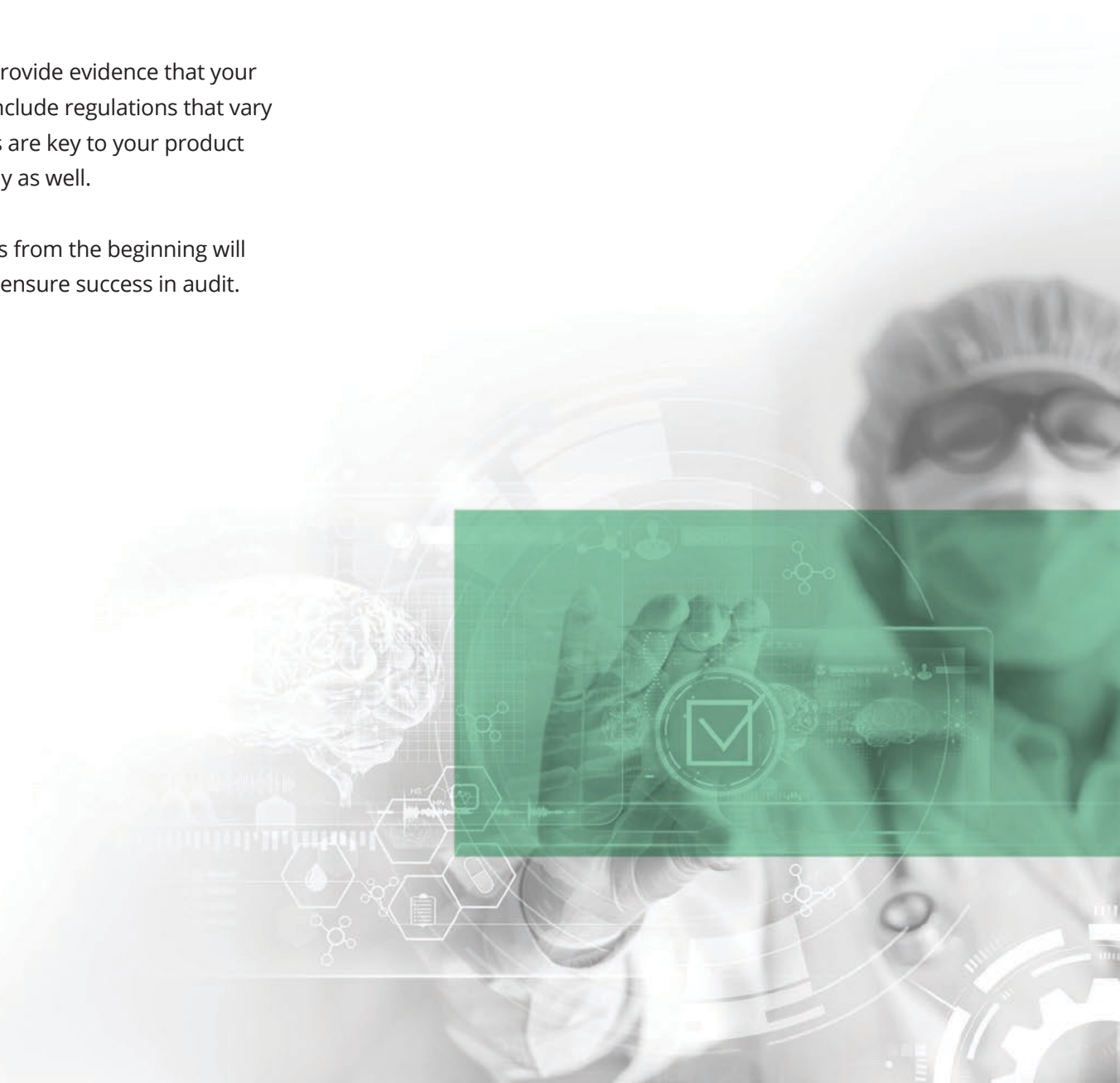
In summary, audit resilience means being able to provide evidence that your company follows compliant practices. Challenges include regulations that vary year to year or across geographies. When suppliers are key to your product development and release, you need them to comply as well.

Building disciplined processes with audit awareness from the beginning will ensure you have the practices, data, and people to ensure success in audit.



## RESOURCE

[Audit Primer for your teams ASQ Audit Review](#)



# HELPING INNOVATIVE COMPANIES CHANGE THE WORLD

At Arena, we help you design, produce, and deliver complex products to market by connecting your product record, quality processes, and supply chain partners. This helps you create innovative, safe products to change the world.

For more on Arena and to discover a wealth of resources and best practices, visit [ArenaSolutions.com](https://arenasolutions.com).

**"I think that the auditors are learning with us."**

– Tony Bairos, Global Documentation & Training Compliance, Insulet Corporation



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IN ACTION**

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