Mastering GLP& GMP Audit Readiness

An Expert's Roadmap to Compliance and Best Practices

Written by Nathan Roman, US Director of Marketing and Global Brand Ambassador at Ellab.

Introduction

In the ever-evolving landscape of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) regulations, maintaining audit readiness is paramount for companies striving for compliance and excellence.

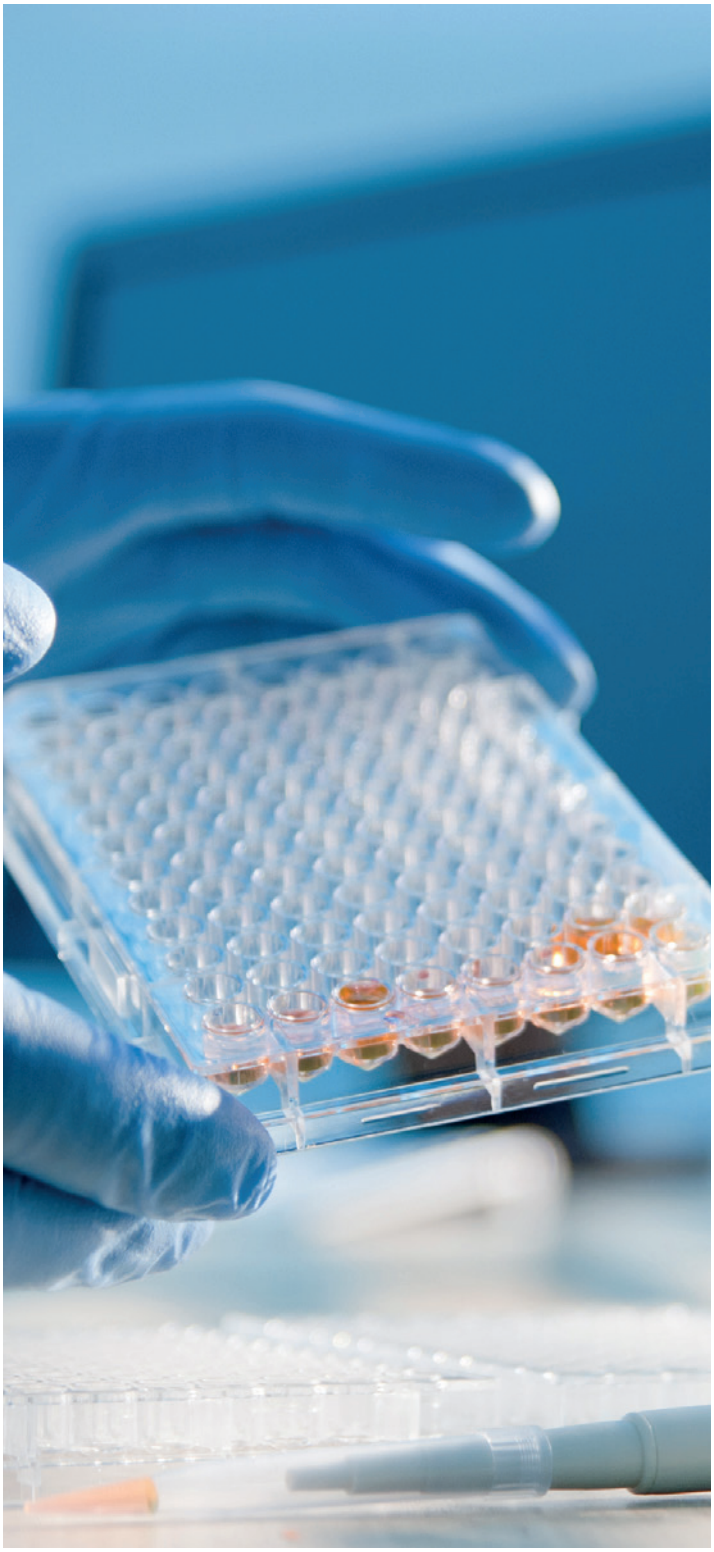
To provide deeper insights, we spoke with Nan Huddy, a regulatory expert serving the pharmaceutical and biotechnology industries. Her expertise offers valuable guidance on ensuring compliance with EPA, FDA, and international regulatory standards.

This guide provides actionable advice to help your team stay ready for inspections and maintain operational excellence.

About Nan Huddy

Nancy M. Huddy is a regulatory specialist at SciReg, Inc., providing a wide range of quality assurance and regulatory services to EPA-, FDA-, and internationally-regulated clients. Her extensive background includes serving as a quality assurance auditor in GLP regulations. Before joining SciReg, she worked as an independent quality assurance consultant, auditing GLP and GCP vendors, laboratories, and contract research organizations. Ms. Huddy holds a master's degree in biotechnology and an MBA from Johns Hopkins University, as well as a bachelor's degree in French and secondary education from Kalamazoo College. She is a certified Registered Quality Assurance Professional in GLPs (RQAP-GLP) and a member of the Society of Quality Assurance (SQA).

Background and Experience



Question:
Can you tell us about your background and experience in GLP/GMP auditing?

Nan Huddy: "My expertise is in GLP quality assurance. As far as equipment validations and temperature mapping, it's very similar to GMP qualifications and processes, but my expertise is focused on GLP, which is mainly concerned with safety studies for new drugs and test substances. I've been in quality assurance for 20 years, starting in the lab and transitioning to GLP compliance."

Question:
What motivated you to become a GLP/GMP auditor, and what do you find most rewarding about this role?

Nan Huddy: "I quickly realized I was well-suited to compliance and quality assurance due to my detail-oriented nature. I enjoy teaching and helping clients understand regulatory expectations and how to comply with them."

"It's all about providing proof. You hired this person. How do you know they're right for that job? Or how do you know they're ready for a particular task?"

The Importance of Audit Readiness

Audit readiness is not just a regulatory requirement; it's a critical component of operational excellence and risk management.

"It's all about providing proof. When you hire someone, how do you demonstrate they're the right fit for the role? How do you confirm they're equipped and ready to handle their specific responsibilities?"

Companies in the pharmaceutical and biotech industries must be prepared for unexpected inspections to ensure compliance, protect their reputations, and maintain the integrity of their products. As Nan Huddy emphasizes, "It's all about providing proof. When you hire someone, how do you demonstrate they're the right fit for the role? How do you confirm they're equipped and ready to handle their specific responsibilities?" Ensuring the right documentation—such as training records, certifications, and competency assessments—is critical to proving audit readiness and maintaining compliance.

This interview aims to provide practical insights and expert advice on mastering GLP/GMP audit readiness, drawing from Nan Huddy's extensive experience. By implementing these best practices, companies can enhance their audit preparedness, streamline their operations, and ultimately safeguard public health.

Preparing for a GLP/GMP Audit and Managing Documentation

Achieving audit readiness requires proactive and continuous preparation, focusing on both initial steps and meticulous documentation management.

According to Nan Huddy, companies should be ready for unexpected audits at any moment.

The preparation process begins with ensuring that all Standard Operating Procedures (SOPs) are up to date and well-organized.

Two critical roles need to be decided ahead of time: a designated host to interact with the auditor, and a scribe to take detailed notes throughout the audit.

Additionally, maintaining a back room for private discussions and document organization can greatly enhance the efficiency of the audit process. Documentation and records are the backbone of audit readiness. Inspection readiness should be an ongoing effort, with SOPs being one of the most vital elements. It is essential to have clear definitions of roles and responsibilities to avoid any ambiguity. Training records are equally important; they must demonstrate that all staff members are adequately trained for their tasks. Keeping comprehensive training files, including job descriptions and CVs, and ensuring that these documents are regularly updated and never discarded, is key to proving compliance.

Furthermore, making the SOP revision process straightforward and frequently updating documents can help maintain a state of constant readiness.

"Common findings include issues with training files, not removing former employees from electronic systems, not securing archives or data centers, and using the wrong version of an SOP or form."

Conducting Internal Audits

Question:
How important are internal audits in the preparation process, and how should they be conducted?

Nan Huddy: "Internal audits are crucial. You should always look at training files and SOPs. Review documentation, what forms are being used, what SOPs are being followed. Is the SOP accessible to the employee? Are they following the right version? Internal audits help identify gaps and ensure everything is in order."

Question:
What common findings from internal audits should companies address to avoid non-compliance during the actual audit?

Nan Huddy: "Common findings include issues with training files, not removing former employees from electronic systems, not securing archives or data centers, and using the wrong version of an SOP or form."

Training and Education

Question:
How can companies ensure their staff is adequately trained and prepared for an audit?

Nan Huddy: "Ensure they are trained for their assigned tasks and know their responsibilities. For audit readiness, practice is key. Conduct mock audits, run-throughs, and practice answering questions and being audited."

Question:
What are some effective training programs or methods you recommend for audit readiness?

Nan Huddy: "Usually, the quality assurance department prepares people. Internal audits provide practice. There aren't many formal training programs, but internal preparation is essential."

Common Compliance Issues

Question:
What are some of the most common compliance issues you encounter during GLP/GMP audits?

Nan Huddy: "A lot of training file issues, which is one of the first things inspectors ask for. It's easy to not keep that up to date. Other issues include not removing former employees from electronic systems, not securing archives or data centers, and using the wrong version of an SOP or form."

Question:
How can companies proactively identify and address these issues before an audit?

Nan Huddy: "That's where internal inspections come in. Frequent internal audits help prepare for the real inspection. Don't look at QA as the enemy; they're there to help you prepare."

Facility and Equipment Readiness

Question:
What aspects of facility readiness are crucial for passing a GLP/GMP audit?

Nan Huddy: "General facility maintenance, defining responsibilities, and ensuring equipment is maintained and calibrated. Identify who's responsible for maintenance and calibration and keep documentation of all activities."

Question:
How should companies ensure that their facilities meet all regulatory requirements?

Nan Huddy: "Consider having an external auditor perform a validation if you've never done it before. Maintain purchasing records, maintenance records, and ensure equipment is calibrated and functioning as expected."

Equipment Maintenance and Calibration

Question:
How important is equipment maintenance and calibration in audit preparation, and what best practices can you recommend?

Nan Huddy: "Very important. Ensure equipment is installed, tested, maintained, and calibrated according to manufacturer recommendations and your SOPs. Document everything."

Question:
What common equipment-related issues do you find during audits, and how can they be prevented?

Nan Huddy: "Equipment not being calibrated or maintained appropriately. Ensure all equipment has documentation and is maintained according to requirements."

Best Practices and Expert Advice

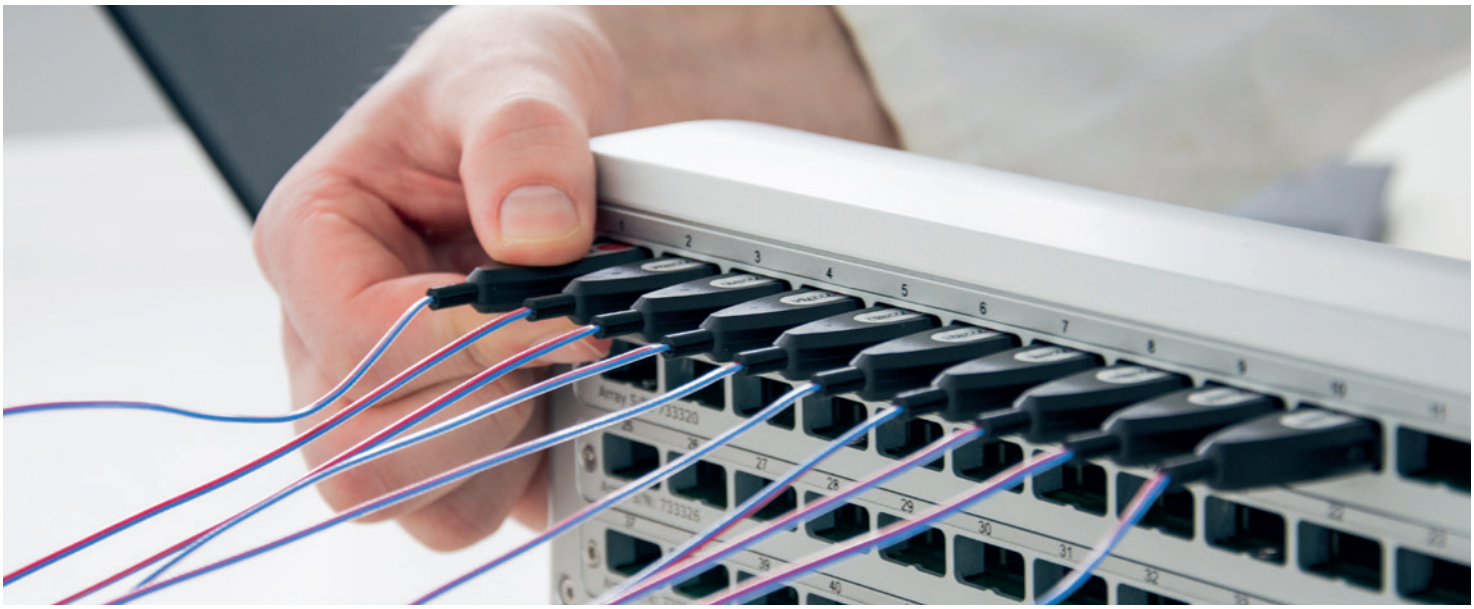
Maintaining continuous audit readiness throughout the year is crucial for ensuring compliance and excellence. Nan Huddy emphasizes the importance of maintaining comprehensive documentation for the entire life of equipment.

Regularly updating SOPs and conducting frequent internal audits are essential practices. It is also important to ensure that SOPs and forms are easy to revise as needed. Continuous improvement should be a cornerstone of audit readiness, with a focus on addressing any gaps identified during internal audits.

One of the most important pieces of advice we can give is to document everything. Initial and date all entries to ensure there is a clear record of all activities. Being organized and prepared can significantly enhance the audit experience.

A successful audit is one where the inspector leaves with their questions answered and feels that nothing is being hidden.

"Don't look at QA as being the enemy. They're there to prepare you for when the real inspection happens."



Closing Thoughts

Question:
How can companies best utilize the audit findings to improve their overall quality and compliance processes?

Nan Huddy: "Look at why the issue occurred and how to improve the process or training. It's not always about retraining; sometimes the process or form needs to be revised to capture necessary information."

Question:
Do you have any final thoughts or additional tips for companies aiming to achieve audit readiness?

Nan Huddy: "Remember, regulations were written to prevent fraud. Always be prepared to prove you did what you said you would do."

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Ellab's Comprehensive Support for Audit Readiness

At Ellab, we understand the complexities and challenges associated with maintaining GLP-GMP compliance and achieving audit readiness.

Our extensive suite of solutions and services is meticulously designed to support companies at every step of their compliance journey, ensuring they are always prepared for audits and inspections.

Be always audit-ready with Ellab thanks to our services:

Temperature Mapping Services, crucial in maintaining uniform and stable controlled environments.

Validation Solutions a comprehensive service for equipment, facilities, and processes, with IQ, OP, and PQ protocols.

Monitoring solutions, to ensure compliance through continuous log data and monitoring.

Calibration services, including regular calibration maintenance schedules, ensuring your equipment remains accurate and reliable.

GxP services, where we offer consultations and training, enhancing your compliance efforts, and ensuring you can handle any regulatory challenges.

Does your firm need assistance in preparing for an FDA or other regulatory agency inspection?

Ellab can help with GLP /GMP audits and beyond. By partnering with Ellab, you can leverage our expertise and state-of-the-art solutions to ensure you're always audit-ready. Our commitment to quality, compliance, and continuous improvement helps our clients achieve regulatory excellence and maintain the highest standards in their operations.
For more information on how Ellab can support your audit readiness efforts, visit our website or contact our team of experts today.

"Be ready for the unexpected. They can show up at your door at any moment."