

Congrego - Your intelligent solution for compliance, briefings, and withdrawals management

Introduction

Material compliance is a critical aspect of any Pharmaceutical company. Failure to comply with regulatory requirements can have serious consequences, including legal and financial penalties, damage to reputation, and loss of business.

Therefore, it is essential for companies to establish an effective material compliance system that ensures compliance with all relevant regulations and standards. This white paper outlines the steps companies can take to establish an effective material compliance system.

As a growing pharmaceutical company, it is critical to have a system for managing and auditing material compliance.

*In the last 10 years, thousands of fines have been paid for off-label or unapproved content. The top 40 fines account for **\$40+ billion dollars.***

On the following pages are some steps that you can take to establish an effective material compliance system.

Scan QR code to learn more





Step 1

Establish a Material Compliance Policy

The first step in establishing a material compliance system is to develop a written policy that outlines the company's commitment to material compliance and the procedures for achieving and maintaining it. This policy should be clear, concise, and easily accessible to all employees.

The policy should also be regularly reviewed and updated to ensure that it reflects any changes to regulatory requirements or company procedures.



Step 2

Create a Material Compliance Team

The second step in establishing a material compliance system is to assign a team of professionals responsible for material compliance, including a designated Compliance Officer. This team should have the necessary knowledge and expertise to identify and assess material compliance risks, develop and implement compliance programs, and conduct regular audits.

The software is user-friendly and easy to navigate, with clear instructions and prompts to guide me through each step. It has helped me to manage regulatory compliance, monitor and document adverse events, and ensure proper storage and handling of pharmaceutical products.

~ Sanofi Quote





Step 3

Develop a Material Compliance Program

The third step in establishing a material compliance system is to develop and implement a comprehensive compliance program that includes procedures for identifying and assessing material compliance risks, monitoring compliance with regulations, and addressing non-compliance. This program should be designed to meet the specific needs and requirements of the company and should be regularly reviewed and updated to ensure its effectiveness.



Step 4

Perform Regular Audits

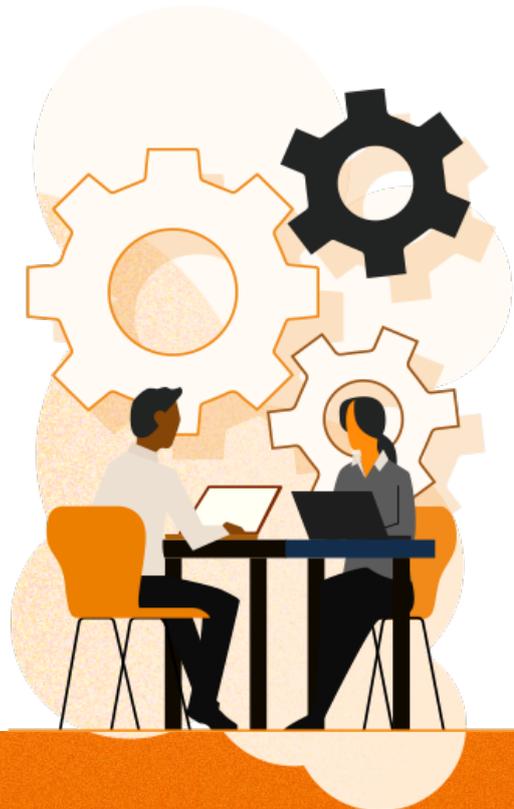
The fourth step in establishing a material compliance system is to conduct periodic audits of the company's material compliance program to ensure that it is effective and to identify any areas for improvement. These audits should be conducted by independent auditors or by the company's internal audit team.



Step 5

Keep Records

The fifth step in establishing a material compliance system is to maintain comprehensive records of all materials used, including their source, testing, and quality assurance data. These records should be accurate, up-to-date, and easily accessible.



What I appreciate most about the software is its flexibility and adaptability. It can be customised to meet the unique needs of my organisation, and it seamlessly integrates with our existing systems. This has saved us time and resources, allowing us to focus on providing quality patient care.

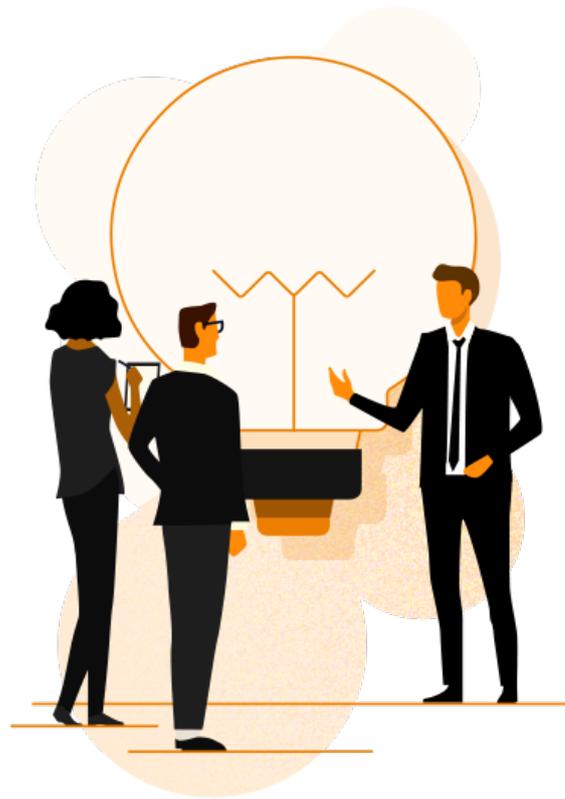
~ Sanofi Quote



Step 6

Train Employees

The sixth step in establishing a material compliance system is to provide regular training to employees on material compliance, regulatory requirements, and company policies. This training should be tailored to the specific needs of each employee and should be provided on an ongoing basis.



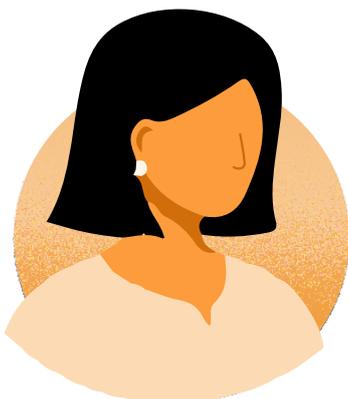
Step 7

Stay Up-to-Date

The seventh step in establishing a material compliance system is to stay informed about changes to regulatory requirements and update your material compliance program accordingly. This can be achieved by regularly monitoring regulatory updates, attending industry events and conferences, and consulting with legal and compliance experts.

As a pharmaceutical company, compliance is of utmost importance to us. The regulatory landscape is constantly changing and it can be a daunting task to ensure that we are always up-to-date with the latest guidelines and regulations. That's why we decided to invest in pharmaceutical compliance software and we couldn't be happier with our decision.

~ Jazz Pharma



Conclusion

By following these seven steps, companies can establish an effective material compliance system that will help them meet regulatory requirements, reduce the risk of non-compliance, and protect their business reputation. It is essential for companies to take material compliance seriously and to invest the necessary time and resources to establish and maintain an effective system. By doing so, companies can ensure the safety and quality of their products and enhance their overall business performance.



Compliance

Managing internal and external material compliance whilst streamlining your briefing process.



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