

A smart way to manage compliance, briefing and withdrawals

Ask yourself the following questions:

- Are you looking for an easier way to manage sales force compliance?
 - Do you feel the need to streamline your material briefing and withdrawal process?
 - Are you struggling to meet regulatory demands?
 - Have you factored material compliance and auditing into your growth trajectory?
 - Can you ensure your sales teams are only using the latest approved content?
 - Is hosting content on multiple devices and platforms costing you too much time and money?
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The problem

The pharmaceutical industry grows more and more digital every day, but companies are still struggling to manage their internal and external material compliance, especially when it comes to approved content, briefing and withdrawals.

By failing to fully implement and monitor the activities associated with field sales and marketing operations, you increase several business and compliance risks; from failing to meet product marketing statutes, falling short of industry standards or violating anti-bribery laws. Beyond the strict financial penalties which can be incurred, you also need to consider the impact of reputational loss with regulators, patient groups and your customers from non-compliance.

We all know how difficult and time consuming it can be to email briefing documents, chase-up receipt of acknowledgment and ensure all team members have understood the action. It is also

no longer good enough to simply demonstrate a briefing note was sent: you must prove it was read and, most importantly, understood.

When you add the challenge of distributing content to different devices and platforms you can never really be confident that everyone has access to the latest approved content they need. It then becomes even harder to know if withdrawn or non-compliant content is still in circulation.

As a growing pharmaceutical company, it is critical to have a system for managing and auditing material compliance built into your growth trajectory.

Without a system in place, you will struggle to fully address these challenges.



Challenge 1

Managing internal and external material compliance

The biggest challenge growing pharmaceutical companies face is managing their internal and external material compliance. However, there are ways to address this.

Work on a strict permissions basis

Fundamentally, you must ensure you are only giving teams the right materials.

As materials have become increasingly digital, the risk of them being shared with the wrong person or saved long after they should be withdrawn has significantly increased (though it has to be an improvement on the piles of sales aid in the boot of an old company car!).

You need to ensure that you are providing materials in a way which only gives access to the relevant team or individuals at the times when they should have access.

Control access to materials

With materials which need an associated briefing, you need to ensure your team have read and understood requirements before they start using the new materials.

Traditionally, this means getting the team together in a physical location for training – which is expensive, time consuming and lacks flexibility, for example, if a new license indication is approved two weeks later. More often now, teams send the materials and briefing documents out via email and have to trust instructions are being followed or spend considerable time chasing responses.

This, of course, doesn't remotely meet requirements for proving any sort of compliance.

So what should you do?

1. Ideally, you need to link briefing documents to materials and only unlock the material when your users have read and confirmed receipt and understanding of the brief
2. You should also deadlines for when users have to confirm receipt and understanding of the briefing document and make 'chasing up' an automatic process

Apply clear deadlines and expiry dates for materials

The flip side to getting the right materials into your teams' hands, is making sure you stop them using it following approval expiry.

Every single piece of promotional or regulatory material comes with limited approval and you are legally required to ensure they are either reapproved or are no longer used once this date has passed.

This was a well-established problem with print materials which should have been solved by the advent of digital, but is now an even bigger issue as materials proliferate across email, personal computers and file sharing systems.

You need to manage your materials in a way which allows you to set an expiry date where the material will automatically be withdrawn from the user. The materials should only be accessible in the location you have decided – it's no good if they've emailed themselves a copy which then sits on their home computer for the next 10 years.

Track access and make sure you have proof!

One of the biggest advantages of digital is that everything anyone does can be tracked.

Take advantage of that fact, and ensure you are capturing this tracking data, hugely streamlining and improving the efficiency of your compliance process.

If you want to be fully on top of any potential audit, make sure you report on the following areas:

- The users with access to each material
- Who has read and acknowledged briefing documents (before deadline)
- Who has read and not understood a briefing document

A system that will automatically capture the time any action was taken, which will offer a comprehensive report for any auditing needs.



Challenge 2

Hosting a range of multi-media content in one place

A growing challenge for companies is hosting a wide range of multi-media content across different devices. You can never be sure of what content is in circulation and on which device.

Even now, you find some KAM's or sales reps still carrying around laptops and hard copy materials, struggling to focus and convey the right message during the precious little time they get in front of a customer.

Even those with newer technology, such as iPads, sometimes still have to open different materials and resources across emails, apps and software tools, often causing delays and making them seem unprofessional.

The more hardware and software you have to monitor and maintain, the more expensive and time consuming it can be – and, of course, adding complexity further increases the risks to managing compliance.

To address this and be effective and compliant with your materials, you need to be able to host different multi-media content in a single place that your full team can rely on.

They should be able to access it quickly, within one single application and know that the material they are viewing is compliant and the most up-to-date version.

These materials also need to be available regardless of where your team is using them. No-one wants to see 'no network connection' when trying to get to a critical piece of supporting data. If your materials are not available without an internet connection, then you are limiting your team.



Challenge 3

Data safety

The final challenge is ensuring you retain control and ownership of your data and files.

The core question to ask is where are the actual servers which hold your materials? You need to know if they meet your required data security standards and if they are resourced for your needs (capacity, up-time, access).

There are a number of excellent, audited and high standard hosting organisations, such as Amazon AWS, who are suitable partners. However, there are many more which do not meet the standards a pharmaceutical company must meet, which can leave you open to serious compliance risks.

Another key factor is understanding who "owns" data once it is uploaded to the service.

You have to carefully examine any cloud-based file sharing system.

A free system almost always means you lose absolute control of anything you upload to it. If you're using a paid service, you must also fully understand ownership and legal entity location before engaging their services

Remember – you are ultimately responsible for maintaining control of your data!



Case Study



How Sanofi addressed these challenges using Congrego

Congrego is an iPad application specifically designed to relieve compliance and material management headaches. Sanofi implemented Congrego to:

1. Simplify the briefing and withdrawal process for all roles:

- Congrego replaced the former paper-based briefing acknowledgement process with a new, streamlined digital process
- Users could then see all of their outstanding briefings in one simple inbox, and could read and acknowledge briefings in just a few taps

2. Provide a list of active materials and their associated briefing documents:

- Congrego offers field-users a snapshot of the currently active materials available to them at any given time
- Users can then tell with ease whether or not a digital or physical material in their possession is appropriate to use compliantly with a customer
- The app also provides an easy-to-use platform to demonstrate multi-media materials

Implementation

Within three months Sanofi were set-up with a customised version of Congrego, including over 600 approved materials and accounts for over 500 members of staff across the UK.

Their head office had full training and the roll-out was successful for all parties.

Testimonial

"We use Congrego to manage field force compliance and streamline our sales material life cycle. It allows our head office staff to accurately maintain an active materials list for the field, ensuring they are using only compliant materials with their customers.

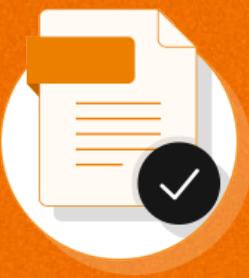
Their support agents have been critical in training and supporting a fast and successful rollout of this app across the UK."

Multichannel Engagement Lead, **Sanofi**

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Compliance



Approved Content



Multi-Media



To find out more about Congrego or to arrange a free consultation, visit:

www.congrego.co.uk