



How to Prepare for & Manage Regulatory Inspections in Healthcare

Insight into how best to prepare for an inspection and how automation can benefit the process.



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Solving the Regulatory Puzzle

A Day to Day Struggle

Managing regulatory inspections, whether announced or unannounced, can be very time-consuming and difficult for healthcare organisations of all sizes.

Trying to pull the right people and the right data together on a short notice can be a real headache for quality managers and responsible individuals associated with the inspection.

From years of working with social care providers, hospitals, nursing homes and other regulated entities across Ireland, the UK and the US, we've learned a lot about the commonalities inspectors look for and expect during a regulatory inspection.

In this article, our Healthcare Business Development team from the EU and US outline the key criteria inspectors look for both during and after an inspection. The team explores how quality management automation has transformed the process, making it easier for organisations to provide the data and evidence needed during inspections.



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Topics Covered:

**The Power of
Data - Knowing
Your Strong &
Weak Points**

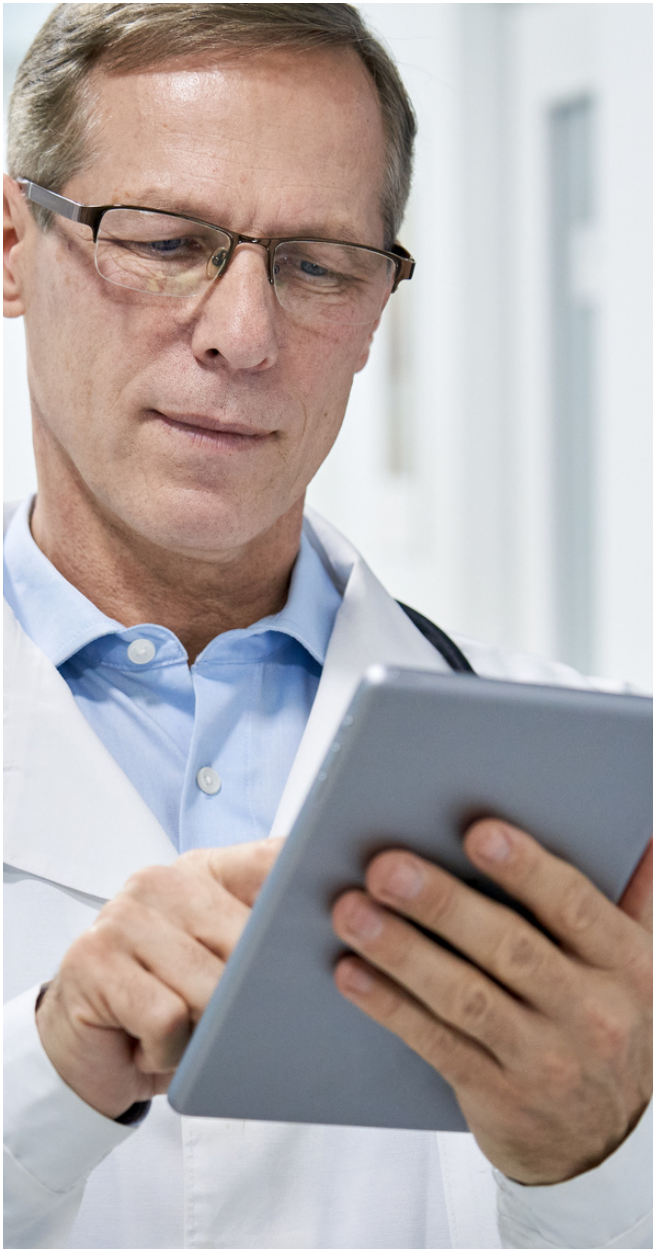
**Spotting the
Trends - Where to
Focus Your Time**

**Closing the Loop -
Creating/Closing
Corrective
Actions**

**The Benefits of
Automation -
How Others
Utilise Tech**

01

The Power of Data



Knowing Your Strengths and Weaknesses

One of the toughest tasks for quality managers is trying to pull together all the data required for an upcoming regulatory inspection. Where are the latest audit results, surveys, incident reports? All questions that lead to a hectic couple of days trying to track down the relevant information.

You must also be ready to explain the findings to the regulator, showing them that you know exactly what is happening in your organisation. This is not an easy task and an area that organisations often fail to get across to inspectors during inspections.

How Automation Helps

Let's take a minute to look at those organisations that utilise Quality Management software such as ViClarity.

The first benefit they reap from having a system is the ability to quickly and easily locate data and report across multiple



The Problem with Spreadsheets

Click the play button to watch the video.

locations and audits on evidence based findings. Being able to efficiently pull data together over any given period, gathering results from all audits, incidents, complaints and anything else requested is extremely powerful.

Understand the Data

Most importantly, it's key to be able to show your understanding of that data. Many of our clients have received inspection reports that complimented their ability to explain audit findings and quality management activities.

ViClarity's system enables you to demonstrate your ability to identify what's gone right and catch risks, as well as explain corrective actions needed based on evidence and examination. Showing the inspector that you have full oversight of all the compliance shortfalls goes a long way during an inspection. Later in the article, we explore the next step of closing the loop on these shortfalls.



02

Spotting the Trends

Gathering data from audits, incidents and other components of day-to-day quality initiatives is a good start, but often not enough for quality managers and their organisations. You may find yourself spending too many hours chasing teams for data and not having enough time to analyse findings, identify key trends, and explore the reasons behind the data.

Proactive or Reactive?

Not being able to spot trends leads to a culture of being reactive rather than proactive when it comes to non-compliances or even re-occurring incidents. Those organisations who don't get the time to properly analyse the data from their quality initiatives often fail. Failure leads to inability to identify which locations or areas of the business require the most attention regarding, follow-ups, additional training and resources for compliance mitigation.

How Automation Helps

Let us explore how automation can help organisations become proactive rather than reactive by easily spotting trends in their data. As mentioned earlier, tools like ViClarity automate the collection of data across groups and locations.

The automation also provides real-time data and statistical analysis on multiple levels, which allows quality teams to see which locations or units are improving and which are facing negative trends.

Identifying this early is key, as the quality team can prioritise their time to focus on those locations that may need an extra helping hand to bring them up to speed before the regulators come in and issue a negative report.



Quality Automation v Manual in a Healthcare Setting

Click the play button to watch the video.

03

Closing the Loop

Creating and Closing Out Corrective Actions

The final piece of the regulatory puzzle is managing corrective and preventative action (CAPA) plans. If you are lucky enough to be on a quality team that has navigated through points 1 and 2 described on the previous pages -- meaning you have collected all data and spent time analysing trends and reports -- the next step is defining actions. These actions will be used to resolve and mitigate any of the non-compliant issues found during the auditing process

The process of creating and managing actions manually can be a nightmare for quality teams. You all know what needs to be done, but as new actions come in, how do you ensure that we have closed out on all actions created for other issues in the last few months/years? Along with that, how do you prove to the regulators that these actions have been completed, where is the evidence?



How Automation Helps

Automation can bring corrective action plans to life and really give quality teams full oversight of the progress they are making toward completing and closing out actions across the organisation. Using tools like ViClarity, actions can be created automatically and sent to specific users. These actions are tracked through automated reminders down to the exact due date for completion. When actions are overdue, the system sends weekly summary reminders to staff members and management teams for review.

From a quality team's perspective, they are equipped with real-time reports to see the status of all actions across the organisation, with full oversight on what is completed, in progress, and overdue. Having a system to manage this ensures no actions fall through the cracks.

Finally, from a CAPA perspective, we have seen many clients take recommendations from regulatory reports and turn them into corrective actions to be completed on the system. That way, the organisation can provide progress reports on the recommendations given against what is being completed and closed off.

04

Completing the Puzzle

Pulling it All Together for a Regulatory Inspection

Across multiple geographies and regulators, organisations that can successfully pull all of the above together, to tell one end-to-end story, usually receive very positive feedback in their inspection reports. Tracking on an automated system allows the quality manager to tell a very informed story to the regulators during an inspection.

First, having all data in one place allows you to quickly point out any particular areas of non-compliance and, importantly, the exact reasons for them. Following that, you can show the actions taken to fix those areas of non-compliance and the status of those actions. Finally, and perhaps most impressively, you can show improvements over time through the trends and statistics on the system. These improvements are driven by the quick identification of issues and completing actions to close them out.



In summary, being able to tell the full story bodes well for any organisation going through a regulatory inspection. It's not about showing how perfect you are, it's about showing that you know where the organisation's weak points are and that you have workable actions in place to address and resolve them. Inspectors typically walk away on a positive note, knowing that the organisation has the right plans in place to capture any issues and close them out quickly and efficiently.



Thank You

To learn more about how ViClarity helps organisations streamline their quality management initiatives.

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ViClarity



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