

Why You Need a Strategy for QMS Oversight in the post-COVID Era

The temporary halt of routine onsite FDA inspections in early 2020 forced some drug and device manufacturers into product development limbo, and others had to rethink their strategy for QMS oversight. And while it wasn't quite Mardi Gras, the lack of routine inspections may have fostered a "laissez les bons temps rouler" atmosphere for some. With the FDA safely out of sight and out of mind, short-staffed and uber-stressed manufacturers may have been tempted to let their GMP and QMS documentation slide just a little, just this once, and just long enough to get product out the door.

However, now that COVID case numbers are dropping and travel restrictions easing, it's time for manufacturers to take a close and honest look at their practices over the past year and outline the strategy that will ensure their QMS is back online and fully inspection-ready well before FDA comes knocking again.

Maintaining GMP Oversight During a Pandemic

With domestic and international travel paralyzed, many manufacturers found themselves adrift without the structure that routine facility surveillance inspections and audits provide to their quality management activities – and product launch timelines.

FDA was well aware of the impact the halt on inspections would have on manufacturers and quickly took steps to alleviate industry concerns. While remote audits have been gaining in popularity in Europe, FDA has been slow to adapt to a more digital, online world. The agency did launch the [Medical Device and Single Audit Program \(MDSAP\)](#) to gauge the viability of some remote audits, and they strongly encouraged widespread use of remote audits whenever possible for the duration of the pandemic.

Then, in late July of 2020 the FDA resumed some domestic onsite inspections, focusing on "mission-critical" facilities and those geographical areas deemed virus-safe enough to send an inspection team. This strategy for QMS oversight provided much-needed regulatory feedback and a measure of normalcy to some manufacturers, but those who did not fall under the mission-critical umbrella were left to manage their own QMS and GMP without supervision – which is often a recipe for disaster.

FDA's Plan for Overdue Audits and Inspections

As of November 2020, the agency reported they were meeting 90% of pre-approval inspection deadlines, but also admitted that their limited ability to conduct reviews has led to some product launch delays. Manufacturers should expect even more delays as FDA plays catch-up with regulatory deadlines for applications submitted just before and

during COVID. Likewise, manufacturers awaiting reinspection due to their “official action indicated” status will be required to await an in-person, onsite inspection per the FDA’s current rules.

Once again, the FDA tried to remain ahead of the curve by releasing a host of guidance documents relating to the regulatory questions and challenges that arose during COVID. Most of these documents provided unprecedented regulatory flexibility in several areas - including some drug compounding situations and most clinical trials - that allowed manufacturers to continue operations provided they could justify and properly document any deviations from their standard processes.

Industry response was a mixed bag. Strategic manufacturers aligned their processes with the new guidance and maintained operations largely uninterrupted – for now. Other quick-thinking manufacturers chose the MDSAP remote audit option and gained a sizable competitive advantage by identifying the gaps in their QMS and GMP well in advance of the FDA’s next visit.

But what about manufacturers faced with COVID-induced staffing shortages or supply-chain issues? Manufacturers that were so overwhelmed with orders that they may not have had time for proper GMP documentation? Or any manufacturer who brought a COVID-related product or device to market under an Emergency Use Authorization (EUA) but may not have the documentation to support a full 510(k) submission? Will the return of the FDA GMP inspection truly bring the regulation-free party to an end for these companies?

Focus Now, Stress Less Later

It’s not too late. Manufacturers can still avoid being hit with a warning letter or Form 483 violation if they take the right action. While FDA issued far fewer warnings and 483s last year, the agency is expecting a sharp uptick in 2021 as they resume routine inspections, so it is in a manufacturer’s best interests to review their compliance status and address any gaps in their QMS or GMP now – before FDA has a chance to find them.

This is not the time to roll the regulatory dice, because the longer compliance issues go unchecked, the harder they are to address, and the bigger the eventual impact on the company. Manufacturers looking to stay in the FDA’s good graces would be wise to review their post-COVID strategy for QMS oversight and ensure they are aligned with applicable FDA standards and regulations. A detailed and well-documented plan to address any gaps will quickly get compliance back on track, and a company ready for the next scheduled inspection.



[Premier FDA Solutions](#) stands ready to assist manufacturers avoid FDA violations because they are passionate about one thing – helping life science companies maintain quality and regulatory compliance. They can leverage their extensive network of experts to provide the right compliance expertise at the right time to meet any need. Whether one compliance consultant for a day, or several for a longer-term project, Premier FDA Solutions has the scalable staffing solution to help manufacturers build and maintain great quality systems.

References:

<https://www.law360.com/articles/1356712/3-things-to-know-about-fda-s-evolving-drug-inspections>

<https://premierfdasolutions.com/remote-fda-inspection-audit-gxp-inspections/>