Current Good Manufacturing Practice (cGMP) Compliance: Thoroughness and volume of regulatory inspections are anticipated to increase worldwide

cGMP INSPECTION AND ENFORCEMENT TRENDS:

- Life sciences companies can expect a more robust on-site inspectional effort from regulators worldwide; at the same time, regulators continue to utilize remote-evaluation and record-request tools employed during the COVID-19 pandemic.

- Because of the inspectional backlog due to COVID-19, regulatory authorities are likely to focus their inspectional efforts on sites that:
    + have not been inspected recently and have past cGMP inspectional issues;
    + are critical in the supply chain for important drug products; or
    + have applications pending.

- Manufacturing sites situated in countries with less visibility from corporate headquarters are likely to be particularly vulnerable.

- Life sciences companies are likely to see additional risks arising from regulatory compliance issues.

In 2022, life sciences companies are likely to face a raft of regulatory challenges relating to cGMP: the manufacturing of safe, quality products. We anticipate a more robust inspectional effort from regulators worldwide. This is largely due to the fact that most regulators restricted inspections during the COVID-19 pandemic, resulting in a significant inspectional backlog, and numerous sites around the world that have not been inspected in several years.

Given the fact that significant issues may have arisen in the lag between inspections, investigators are likely to be even more vigilant. Regulatory authorities, meanwhile, will face pressure to verify the companies' systems and the quality of their products. Manufacturing sites situated in a different country from corporate headquarters are likely to be particularly vulnerable, as issues may have developed due to reduced resources during the pandemic, travel restrictions, and the loss of experienced staff.

Regulatory agencies have acknowledged that delays in inspections caused by the pandemic have created backlogs of pending applications because on-site pre-approval inspections of manufacturing sites are required in most instances. The increase of in-person inspections warrants greater focus on inspection readiness, especially because, if problems are found, investigators may not return for longer intervals than they did pre-pandemic, as they work through the remaining backlog (as well as any new backlogs that occur if the pandemic continues). Such delays can impede bringing new therapies to market and disrupt the distribution of existing products, including with regard to attempts to gain approval for changes to optimize current manufacturing processes.

Many agencies are employing new alternatives to on-site inspections, including relying on inspections by other regulatory authorities, conducting remote evaluations, and requesting and reviewing documents remotely. We expect these efforts to continue and to be an overlay to the increased on-site inspections in 2022. Regulatory agencies will also likely offer more regulations and guidance on cGMP in 2022, including efforts to increase focus on critical supply chain sites, especially those with compliance issues,

as well as other areas of changes in the life sciences industry that require analysis and input.

We anticipate that companies will be looking to invest in more reliable sourcing options, with a focus on less-extended supply chains. This may mean investing in retooling existing manufacturing facilities or building new state-of-the-art facilities. It also means updating manufacturing processes through the application of new technology, such as continuous manufacturing models, which would involve utilizing one continuous process to manufacture a product in one facility without hold times, leading to lower manufacturing costs and shorter production times.

It is likely that all companies will face additional regulatory scrutiny with the resumption of significant on-site inspection activities, along with regulators' continued use of remote evaluation and record review tools that were rolled out during the pandemic. Ensuring that manufacturing sites are prepared for detailed on-site inspections — particularly after not having been inspected for years due to the pandemic — will be critical to avoiding the consequences of unsuccessful inspections that can lead to regulatory enforcement, commercial losses from the failure to deliver products, and investor lawsuits related to disclosures. Life sciences companies in particular may experience additional risks arising from regulatory compliance issues, particularly from whistleblowers with regard to issues related to data integrity and product quality, or manufacturing problems related to resource shortages. These issues should be thoroughly reviewed — and addressed if necessary — prior to any regulatory inspection.

cGMP COMPLIANCE TIPS:

- Companies facing inspections should verify that they have executed on prior regulatory commitments and continue to implement robust corrective and preventative actions in response to deviations.

- Life sciences companies that can establish and maintain a reliable supply chain have a competitive advantage.

- Life sciences companies should look to invest in more reliable sourcing options, with a focus on having less-extended supply chains. This may mean investing in retooling existing manufacturing facilities or building new state-of-the-art facilities. It also means updating manufacturing processes through the application of new technology, such as moving toward a continuous manufacturing model.

- Companies should reinforce existing compliance programs and prepare diligently for inspections.

Contacts
Ray Bonner, Jim Johnson, Dave Ludlow, and Raj Pai