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Regualtory compliance & notified bodies inspection readiness

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Inspection Readiness" is a site-preparation activity often done in anticipation of an upcoming third party audit, due diligence activity, FDA inspection, Notified Body inspection, or other Regulatory Agency inspection. FDA inspectors have a limited amount of time at a facility to gather a large amount of data and evaluate your respective product/facility/quality system. Similarly, pharmaceutical companies have a limited amount of time to make a positive impression with the inspection team, convey relevant information, and ensure a favorable outcome. Inspection Readiness is the best way to prepare for an onsite inspection. Inspection Readiness is not typically an activity that is done internally. Having an outside perspective is a critical component to effectively evaluating your quality systems, facilities, and personnel. Inspection Readiness is one of the best ways to utilize an outside resource. Experienced consultants that have worked with a variety of companies will give the best perspective. FDA inspections are assigned for many different reasons. Safety (risk to health) plays a major role in how FDA selects firms for inspections. Firms can estimate their likely risk status in terms of FDA's regulatory interest. Once a firm is selected for inspection, how the inspection is conducted becomes a make-or-break situation. Inspections are designed to find problems. They are inherently uncomfortable for the people who host the investigator during the inspection. Predicting what an investigator will do during an inspection becomes helpful in how you manage a difficult situation to avoid a potentially disastrous and costly result. In order for Inspection Readiness to be effective, it must be objective and have the full support of senior management

Biography

Mayra has two BS, (1) in Chemistry, and (2) in Chemical Engineering from the University of Puerto Rico, and a Master of Sciences, in Thermodynamics and Materials Sciences Engineering from the University of Cincinnati, OH. She is the President of GK Regulatory Compliance Corp., and the Chairman of GK Bio-Pharmaceuticals CMO - PR a premier Bio-Pharmaceuticals Contract Manufacturing Organization locaded in Vega Baja, PR. She has a track-record of accomplishment for consistently meeting goals and delivering a high level sustained performance, proven the ability to build strong customer/client relationship including conducting vendor audits and contract manufacturing oversight. She has been a key element in the Regulatory Compliance Readiness for Major Pharmaceuticals, APIs, Biotech, Biosimilars, CMOs.

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