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criteria based inspection plans are created to meet specific regulatory requirements and workflows depending upon where the product is in the manufacturing lifecycle online visibility and real time tracking of incoming raw materials parts and subassemblies are critical to successful inspections an effective quality management solution can

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as defined by the oecd process based inspections apply to procedures or processes of a repetitive nature these inspections take place when a process is undertaken very frequently within a laboratory and it is therefore considered inefficient or impractical to undertake study based inspections

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during production manufacturing finished goods inspection automate the process inspections are a detailed process of many steps the data gathered during the inspection can not only help correct existing problems but also provide a view of potential issues and enable informed decision making

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this process for performing subsystem inspections is based on a top down approach to inspecting the subsystem based on discussions between the device in dustry and the agency we have

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an inspection is an activity such as measuring examining testing or gauging one or more characteristics of a product and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic this definition comes from the iso 2859 standard which is derived from mil std 105 e

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in the oecd glp principles process based inspections are performed independently of specific studies and take place when a process is considered inefficient or impractical to under take study based inspections

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in layman s terms evergreening is the process of ensuring your inspection data management system idms matches what is physically in the field and correctly models the processes contained in those assets an rbi program must be constantly updated as changes to assets and processes occur the importance of evergreening

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what are the components of process based investigations in general a process based investigation can be divided into the following three major activities 1 preparing for the investigation 2 conducting the on site inspection 3 reporting investigation findings the following guidance is organized by the above three activities

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the frequency at which a facility is prioritized for inspection is based on multiple risk factors although being selected for an inspection does not planning effective 2023-03-27 4/6

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necessarily signal a quality issue

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by removing manual inspection processes and automating qc efforts with vision based inspection systems manufacturers especially those working in heavily regulated industries can significantly improve inspection accuracy speed and consistency this will lead to better product quality a reduced chance of a product recall and less waste

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1 benefit provides groundwork a defined risk based inspection process establishes the groundwork for risk management through coverage methodology and inspection frequency 2 benefit incident reduction a major benefit of risk based inspection is its potential to significantly minimize the risk of environmental safety and health incidents

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these requirements must include not only operating personnel but also support functions like maintenance inspection process engineering fire and safety laboratory and stores the number of competent personnel required must be identified for different phases of plant operation including normal operations abnormal operations emergencies

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