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 deviation means
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is any departure from an approved instruction procedure specification or standard historically the pharmaceutical industry has called a deviation by two other names either unplanned deviations or planned deviations however the regulators are asking industry to move away from that nomenclature as a best handling of pharmaceutical deviations a detailed case study - Sep 18 2022 web pdf on jan 1 2020 damini v

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identified key principles to build upon and clarify the definition of a protocol deviation and developed a holistic approach to protocol deviation management the approaches are flexible to suit a variety of indications study designs and investigational agents while also supporting consistent application within

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here are some key areas to focus on

improving the quality of your deviation investigation reports 1 the investigation deviation report should tell a story that can be easily understood by all parties well after the event and the investigation

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major deviation the deviation will or may have a notable impact on critical attributes of the product for example critical process and in

process parameter failure significant variation from standard output range minor deviation the deviation will not have any direct impact on the quality of the product

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deviation management is the process of identifying assessing and correcting deviations from approved instructions or established standards let us take an example in the context of the

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a deviation is a departure from standard procedures or specifications resulting in non conforming material or processes or where there have been unusual or unexplained events which have the potential to

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for pharmaceutical manufacturers a process deviation may not only mean a bad batch that affects a downstream process it can also risk a regulatory violation that leads to fines or expensive market setback or worse it could endanger the health of the patient this article is posted on our

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