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web dec 16 2020 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 impact on product quality system integrity or personal safety

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web feb 5 2020 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 science snippets blog

kevin o donnell ph d market compliance manager irish hpra - Feb 11 2022

web sometimes deviation procedures give very rigorous classification examples and staff lose the ability to assess each deviation on a case by case basis e g all granulate drying time excursions are assigned a level ii classification with no consideration to other aspects of the product 1 root cause analysis work cont d