GRC Online Training Hub
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Webinar on

Capturing Justifications In Change Control, Risk Assessment, Validations, And Investigations

Learning Objectives

- *Be able to plan an investigation, change control, risk assessment or validation relevant to the area of study*
- *Be able to undertake the planned investigation, change control, risk assessment or validation using appropriate scientific principles*
- *Be able to collect, collate and analyze the results from the investigation, change control, risk assessment or validation*
- *Be able to draw conclusions from the investigation, change control, risk assessment or validation*

Areas Covered

- *How to propose a solution to the problem related to the deviation, change control, risk assessment or validation study*
- *Determine alternatives or options to the proposed solution*
- *Analyze costs, benefits, impacts, and risks of the proposed solution*
- *Validate the solution, assess product impact to the market*
- *Determine impact to the patient, system or firm as a result of your findings*

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In this webinar, you will learn about analyses which are regarded as compliant and convenient ways to justify and confirm projects such as Change Controls, Risk Assessments, Validations, and Investigations.

PRESENTED BY:

Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management Roles.

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On-Demand Webinar

Duration : 75 Minutes

Price: $200

Webinar Description

When there is a need to make some change to an environment and/or resolve a problem, we must think about a project that could implement the necessary change and address the problem. But we can't just run our project without proper justification. Justifying the project is a great mechanism to confirm that our project really addresses the need and paves the way for improvement. It helps us assure interested parties or stakeholders that the project implements a particular solution to the problem and explains why this solution is best, as compared to other alternative solutions. But how do we do a project justification? In this webinar, you will learn about analyses which are regarded as compliant and convenient ways to justify and confirm projects such as Change Controls, Risk Assessments, Validations, and Investigations.

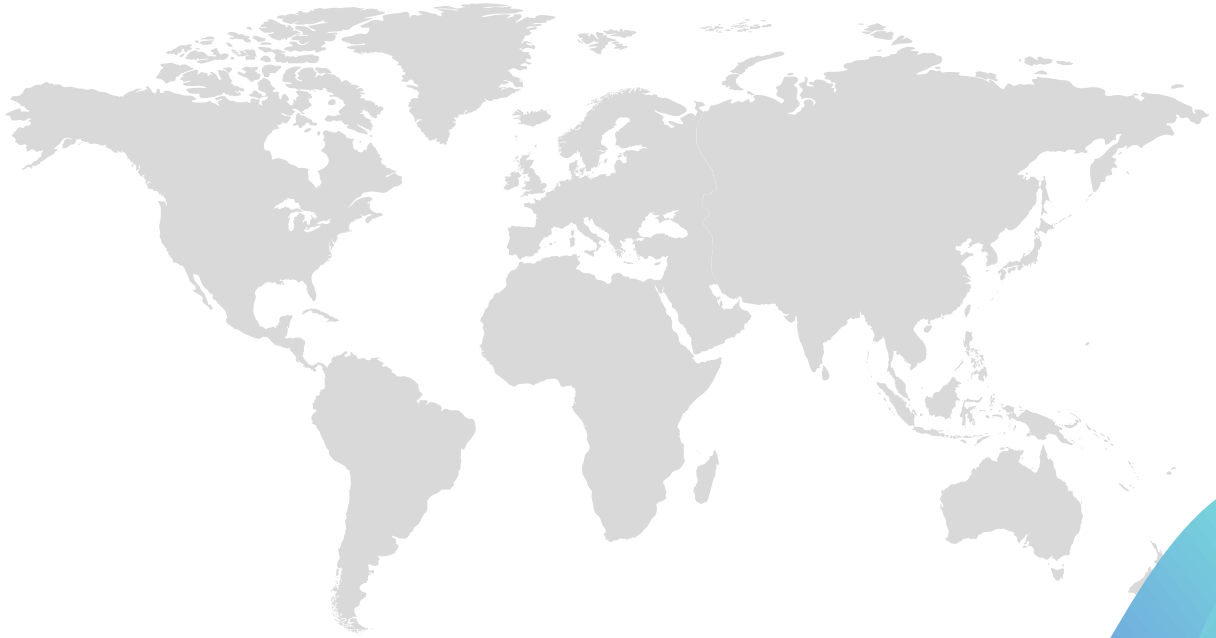
As regulations change and become more stringent, one aspect of compliance has not changed, and that is ensuring changes, deviations, validations and risk assessments are done properly and have a proper justification and rationale. It is easy to document what process has been performed, what has been investigated or changed or why something is a risk, but the difficult part is knowing how to explain or justify why it should be done or why a product should be released or rejected as a result. In this webinar, you will learn efficient and compliant ways to justify the validations, changes or deviations in a manner that will explicitly demonstrate to the reader why the process was performed the way it was.

Who Should Attend ?

Quality Assurance/Quality Control Directors, Managers, and Specialists

Regulatory Affairs/Regulatory Compliance Directors, Managers, and Specialists

Engineering/Development Directors, Managers, and Specialists



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support@grceducators.com
740 870 0321