



Template for the Development Safety Update Report (DSUR) with Guidance Notes for Completion.

This document is the template to be used for your DSUR with brief notes on the completion of each section. The full guidance document (if required) is available as an associated document to Standard Operating Procedure UoA-NHSG-SOP-013; alternatively the full guidance can be located via:

http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/developmentsafety-update-report.html

All sections should be completed; when no information is available, this should be stated.

All instructions are in italic and should be deleted when the report is finalised. If there have been no Serious Adverse Reactions or other safety issues within the reporting year, there is still a requirement to send the annual DSUR to the Medicines and Healthcare Products Regulatory Agency (MHRA), NHS G R&D department and the Sponsor or Co-sponsor. The executive summary should be sent to the ethics committee which provided the favourable opinion for the trial.

This page should not be included as part of the submission.

# **Understanding Development Safety Update Report 201**

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me feedback on these product flow charts it would be greatly appreciated we are in the process of formalizing our food safety plan to conform to the fsma requirements

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web process machinery requirement flow chart machine name description machine image batter mixture this machine simplify mixes the raw material ingredients i e flour with other raw materials to produce the required batter baking oven it san oven with integrated conveyor in which food is cooked as it moves through the oven over conveyor

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web figure 4 shows the process flow for baking each cupcake this indicates how each cupcake was baked under the different

scenarios for example using the same recipe for the batter but  $% \left( x\right) =\left( x\right) +\left( x\right) +\left($ 

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