Analytical methods Quality by Design (AM-QbD) Risk Assessments undertaken within GlaxoSmithKline (World Wide Inhaled Product Development) for Orally Inhaled and Nasal Products

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Introduction

Fundamental to any method development is being clear on the design intent of the method. Method Performance Criteria and Method Operational Intent are two important aspects of this design intent.

Project Background

Throughout the lifecycle of a given Orally Inhaled and Nasal Drug Product (OINDP) method it is inevitable that there will be changes in the ‘method environment’ that can impact its operation. Changes/Improvements to a method should be made with reference to a method knowledge repository. GSK’s repository is entitled EMPACT (Experimental Method Parameter Assessment Control Tool).

Aims

1. Describe the repository and provide an overview of the analytical method risk assessment process used at GSK for OINDPs with some examples for MDI and DPI products.

2. Examples of the key method factors that have been identified and assessed for OINDPs.

3. Outputs from Prioritisation matrices and FMEA exercises that come out of AM-QbD Risk Assessments held in EMPACT templates.

Conclusion

As demonstrated, the AM-QbD Risk Assessment process for OINDPs has been fully considered to fully mitigate the analytical risk associated with testing OINDPs in different laboratories within GSK. Key to this process is the scoring system (for prioritising potential method factors that need to be mitigated) that has been developed, piloted and established within GSK R&D.