Efficient Analytical Validation Using Britest Visualisations As Protocols

Challenge

Liquid Chromatography (LC) is widely used in the Pharmaceutical industry to assess both active pharmaceutical ingredients (APIs) and drug products. For GMP applications, method suitability must be thoroughly demonstrated according to demanding standards. Validation assessments typically require the preparation and analysis of a large number of solutions across multiple concentrations, with replicates from independent weighings and stock solutions, and with solutions containing both API and excipients.

The text-heavy validation protocols typically provide little to no guidance on preparation, and hence the chances of errors in execution are high. This necessitates inefficient mitigations such as additional error checking steps, or provision of extra API for simplified (but duplicated) dilution schemes. For early stage or accelerated development projects, the resources to enact these mitigating measures may simply not be available.

Approach

Presenting the dilution schemes visually using a Britest 'Rich-PrISM' (a combination Rich Pictures and Process Information Summary Map), has made the dilution schemes far easier for analysts to follow, minimising API consumption and resource requirements for mitigation, whilst improving both efficiency and 'right first time' metrics.

Benefits

- The need to (re-)interpret the validation protocol is removed; the dilution scheme includes the practicalities of sample preparation.
- Pre-populated concentration calculations allow results to be added directly into a corresponding colour-coded spreadsheet.
- Time to collect/order glassware reduced (Rich-PrISM acts as a 'shopping-list'). Glassware labelling burden drastically reduced.
- From the first four validation packages completed, the overall resource and lead-time required was <50% down on normal, API use was reduced by 80 to 98%, and all protocols were executed 'right first time'.

Key Features:

Client - AstraZeneca

Industry - Application Area

Pharmaceuticals - Analytical method validation, Process efficiency, Operational excellence

Challenge

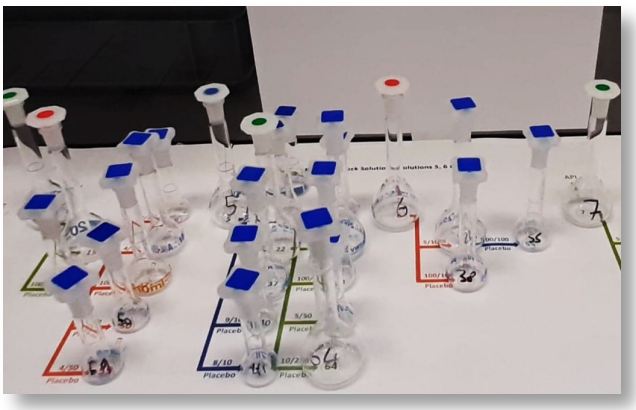
Protocols for LC method validations under GMP often require complex dilution schemes with many opportunities for errors in execution. This necessitates inefficient extra checks, and duplication of work (further consuming valuable API).

Solution

Presenting the dilution schemes visually using a Britest 'Rich-PrISM' has made the dilution schemes far easier for analysts to follow.

Outcomes

From the first four validation packages completed using the Rich-PrISM template, the overall resource and lead-time required was <50% down on normal, API use was reduced by 80 to 98%, and all protocols were executed 'right first time'.



Printed at A3, the dilution scheme can be used as lab 'placemats' enabling multiple analysts to work on the validation package simultaneously, whilst minimising execution errors.

"Feedback from the analysts who executed the experimental work was extremely positive. They found the Rich-PrISM far easier to follow than previous protocols."

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Generating value from process understanding

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