

A MATHEMATICAL APPROACH TO EVALUATE EQUIVALENCY IN E&L ASSESSEMENTS OF SUS

Armin Hauk, Sartorius Stedim Biotech GmbH, Göttingen
armin.hauk@sartorius-stedim.com

Alexander Wildschütz, GWDG, Gesellschaft für wissenschaftliche Datenverarbeitung mbH Göttingen

Ina Pahl, Sartorius Stedim Biotech GmbH, Göttingen

Roberto Menzel, Sartorius Stedim Biotech GmbH, Göttingen

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Single-use systems (SUS) are applied in qualified GMP processes in DS and DP manufacturing. Changes in GMP process require rigorous requalification and are time- and cost-intensive. Unfortunately, they are occasionally unavoidable, for example in case of discontinuation or substitution of a raw material of a SUS, implementing a second sterilization modality (x-ray in addition to gamma) or introducing new or other components in a SU assembly.

The poster gives guidance how extractables data obtained from an equivalency study can be evaluated based on mathematical “equivalency” concepts and definitions. The aim is to overcome the common subjective or intuitive way of equivalency assessment, for example visually comparing chromatograms or bar charts from lists of compounds from the analytical tests.

We will provide examples how an equivalency definition taken from linear algebra, probability- and set-theory can be used to compare and evaluate extractables data as information-vectors or -datasets. Advantages and disadvantages of the different methodologies will be discussed for qualitative and quantitative comparisons together with methods to illustrate the results of equivalency studies with equivalency-correlation plots and heatmaps. As example we will use extractables dataset from an equivalence study for SUS after changing from gamma to x-ray sterilization including an equivalency evaluation of the E&L safety assessment.