odology provides the necessary basis to establish functional equivalence between the tested units. After establishing functional equivalence, it is expected that testing requirements and process validation protocols can be optimized, resulting in considerable savings of time, resources, and capital. Such a procedure is extremely desirable in large manufacturing operations, where multiple lyophilizer units are employed for processing of a common lyophilized product.

Conclusions

An overview of types of TTs from development to validation of the lyophilized product is discussed. A detailed consideration of various activities that must be performed for successful TT of lyophilized product is also described. Evaluation of functional equivalency among lyophilizers as a tool in transfer of lyophilization cycles is reviewed and described. Such results provide the basis to establish functional equivalence among different lyophilizers. Once established, functional equivalence can facilitate successful implementation of scale-up and transfer of lyophilization cycles. Such equivalency procedures are desirable in large manufacturing operations, where multiple lyophilizers are used for processing a common lyophilized product, and reduced validation campaigns based upon a matrix approach can save considerable resources and time.

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