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Don’t Bet on Quality by Chance Part III: Validating for the Long Haul

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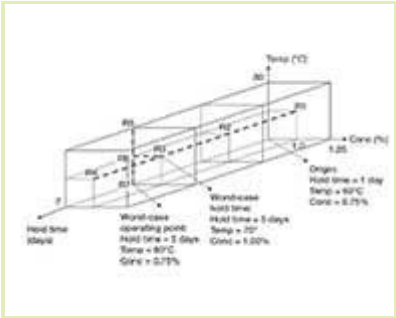

INTRODUCTION

Part I of this series discusses the application of quality by design (QbD) to the development of cleaning cycles (1). An important element of QbD is cleaning characterization at small scale. The small-scale data can be used to predict cleaning times at full scale. The data can also be leveraged to streamline validation requirements for multiproduct equipment.

Part II of this series discusses the criteria for developing a small-scale model to determine relative cleanability (2). The model was used to decouple the effect, on cleaning efficacy, of the soil from that of the cleaning cycle. This concept enabled us to design small-scale experiments to identify a worst-case soil for cleaning validation.

Part III develops an experimental strategy for identifying the worst-case operational conditions within the control space of the cleaning process. This paper also describes a validation strategy for demonstrating that the process meets the imposed performance requirements if it is operated within the established control space. The application of this criterion to release equipment in real time and to thereby obviate the need for time-based revalidation is also discussed.

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