

## Soil Spreading and Image Analysis Methods to Control and Quantify Soil Morphology and Establish Worst-Case Soils in Support of Risk-Based Cleaning Validation Strategies

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Bench-scale methods for assessing the relative cleanabilities of process soils are useful tools for applying a risk-based approach to full-scale cleaning validations, troubleshooting cleaning issues, and developing cleaning strategies. In this study, the authors explored a coupon soiling method, referred to as the “spreading method,” that controls soil size and shape during sample preparation. The spreading method was also used to generate test samples with repeatable dry soil morphologies for a variety of soils representative of typical mammalian and bacterial cell culture manufacturing processes. An image analysis technique was used to quantify surface-area coverage of a test coupon by the soil. Coupling image analysis with the spreading method enables the study of soil area-dependent properties that influence cleaning. Relationships between cleaning time and soil area showed differences in relative cleanabilities that could not be detected by simply observing cleaning time alone. The spreading and image analysis methods were therefore shown to be valuable tools for determining the relative cleanabilities of process soils. Based on these findings, an efficient, two-step strategy using the spreading and image analysis methods is proposed for establishing the relative cleanabilities of soils in a larger group.

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