

***“AI Image Analytics for Topicals: Implications for Drug Delivery and Q3 Microstructure Equivalence”***

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**ABSTRACT:** The efficacy of modern drug delivery systems such as topicals are heavily dictated by their internal microstructures. However, many drug product development activities rely on a costly quality by testing approach to optimize formulation and process and fail to consider these microstructure attributes. For topicals, important properties like morphology, rheology, encapsulation, stability, and product uniformity can be key attributes to monitor and optimize. They also play an essential role in Q3 microstructural bioequivalence, a pathway for biowaivers through demonstration of product sameness. In order to incorporate microstructure considerations, adequate techniques are needed to both visualize and quantify them. This talk will provide a review of relevant imaging modalities for globule characterization, including their advantages and limitations, while also highlighting X-ray micro-CT as a non-invasive 3D imaging platform for globule visualization. In addition, AI image processing and quantitative morphology analysis workflows will be reviewed. Together, these techniques provide a robust pathway to quantify topical microstructures and provide a data rich suite of information for a quality by design drug development approach. Implications of the data usage for ANDA filings and product sameness demonstrations will also be discussed.