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BPC-Stat: An Integrated Software Ecosystem for Automated Process Characterization and Statistical Modeling – Seth Clark, Song Liu, Melissa Matzke, Merck & Co.

Process Characterization (PC) is a critical activity in the biopharmaceutical product development lifecycle, essential for establishing a robust commercial manufacturing process control strategy under a Quality by Design (QbD) framework. PC involves the rigorous evaluation of how process parameters affect critical quality attributes. However, the statistical modeling required to support this evaluation—historically executed via manual point-and-click JMP implementation—is often characterized by long, tedious, and error-prone workflows. To address these systemic bottlenecks, we have developed **BPC-Stat**, a fully integrated JMP add-in designed to function as a comprehensive software ecosystem. In this presentation, we will demonstrate how BPC-Stat intersects with the core pillars of the CMC lifecycle. We will showcase its capability to manage complex **Data** architectures via cloud integration; its use of unified, multi-language **Software** (bridging point-and-click JMP with code-based Python and R) for reliable execution in regulated environments; its application of robust statistical **Methodologies** for process characterization; and its automated generation of compliance-ready reports designed to support seamless **Regulatory Reviews**.

