

Agile Data-Centric Validation - A Dynamic New Approach to Regulatory Compliance: Part 1. Overview

By **Eric Toburen** Feb 25, 2019 4:27 pm EST

While documents and documentation have been the mainstay of compliance in the pharmaceutical industry for years, the advent of new digital technologies is opening up vistas to a better approach to validation...one that does not rely on documents (paper or electronic), but instead focuses on the data, providing a more comprehensive, integrated, and collaborative effort. Recent statements by the FDA tout a renewed focus on “making risk-based regulatory decisions more modern, more scientifically rigorous, and more efficient.” This paper will focus on how a data-centric approach extends...

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