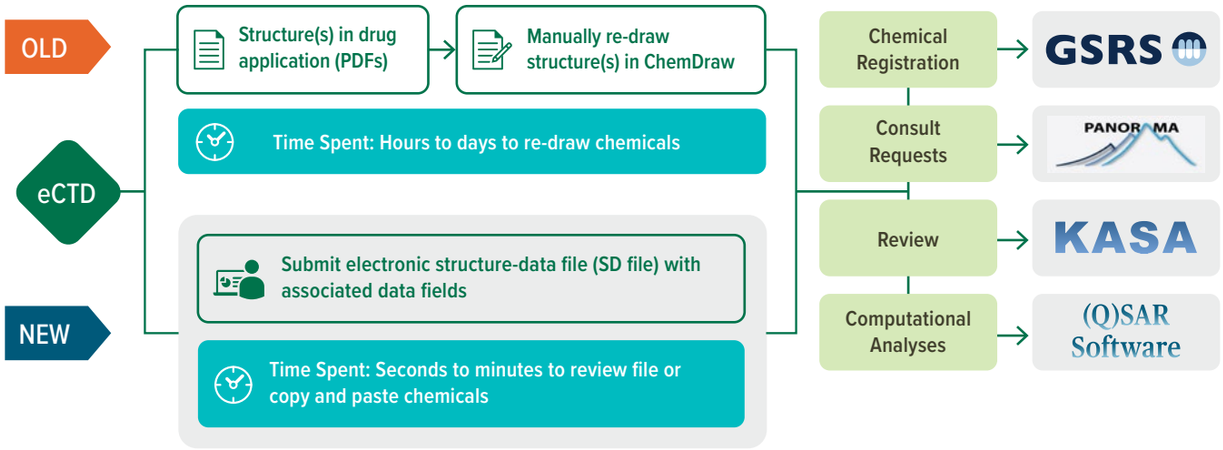
VERISTAT

# Successfully Prepare Structure-Data Files (SD File) for Regulatory Submissions

Sponsors are now required to submit an electronic record of chemical structures to FDA through the eCTD as a single structure-data file (SD file) for NDAs, ANDAs, and Drug Master Files (DMF) for the FDA's KASA review program. It is also strongly recommended to submit SD files for other Chemistry, Manufacturing, and Controls (CMC) submissions. The SD file format is a computer-readable format that helps regulatory reviewers save time by eliminating the need for manual redrawing of structures and enabling efficient chemical registration, computational analyses, and easy extraction of structures for further review.




## Guidelines for Creating an SD File

Must have the proper software for SD file generation and the knowledge to use it.

A single SD file is submitted and placement in the eCTD is dependent on the content.

File(s) must include the application number, structural information of the drug substance(s), and all relevant structures, including starting material(s), intermediates, and impurities.

## Ensure a Successful Submission for Your Drug or Biologic

Without a sound strategic manufacturing plan and proper documentation, your submission risks being delayed. To give you an advantage, Veristat's team of regulatory CMC experts is poised to support your marketing applications by integrating the required content and generating SD files.

**CONTACT VERISTAT TODAY**

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