

# US Food & Drug Administration (FDA) - PQ/CMC Conceptual Model

Note: This model version is Work-in-Progress. This model represents majority of the PQ/CMC structured data elements that have been released by the FDA through the Federal Register Notice (FRN) process.

Does NOT yet represent Drug Product or Drug Substance Manufacturing data elements.

Scope: All Application Types for Solid Oral Dosage Form (SODF)

PQ/CMC Terminology is registered in NCI Thesaurus and can be publicly accessed from here <https://evs.nci.nih.gov/ftp1/FDA/PQCMC/>

For all other information about the US FDA PQ/CMC project see <https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-quality-chemistry-manufacturing-controls-pqcmc>

