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1. STABILITY IS AN ESSENTIAL QUALITY ATTRIBUTE FOR DRUG PRODUCTS

“There never was anything by the wit of man so well devised or so sure established which hath not in the continuance of time become corrupted . . .”

Thomas Cranmer

Everything made by human hands—from the sublime Parthenon to the trivial milkshake—is subject to decay. Pharmaceuticals are no exception to this general statement. If there is any functionally relevant quality attribute of a drug product that changes with time, evaluation of this change falls within the purview of the pharmaceutical scientists and regulators who quantify drug product stability and shelf life.

The rate at which drug products degrade varies dramatically. Some radiopharmaceuticals must be used within a day or so. Other products may, if properly stored and packaged, retain integrity for a decade or more, although in many