



"Pre-Amendment" lack of any formal requirement or method of package testing

Passage of Medical Device Act and institution of industry GMP's

MDM industry begins to develop their own test methods such as burst, tensile and bubble tests

Widespread use of Tyvek and ETO sterilization requires test methods for process control

ASTM F02.60 test methods encourage uniformity and quantification of package test methods

FDA gives packaging the same standing as the medical device itself with QSR's

ISO-11607 represents major step in providing uniform testing standards worldwide

ASTM F02.60 documents & qualifies industry methods from ISO-11607; FDA adopts "consensus" standards

Ongoing need for exploring and developing new test methods and evaluating their credibility up front

V1-97
V2-200
V-3 2005

1970 1980 1990 2000