# Building Blocks Available To Help You With Your Risk Assessments

## Assessment Topics *

### Package Design Validation
- Packaging Performance
- Packaging Stability

  - Mechanical property comparison pre- and post-sterilization, after accelerated aging and real-time aging for 1073B and 1059B
  - Sheet stability testing (including sterilization) for 1073B and 1059B
  - MPTP stability testing over 60 + 18 cells for Pre- and Post-Sterilization, 1-, 3- and 5-year accelerated aging and 1-year real-time aging
  - CFDA Jinan sheet function equivalence confirmation

### Material Characteristics
- Biological Safety
- Food Contact & Pharmacopeia
- Particulate Matter

  - Biocompatibility, Food Contact and Pharmacopeia Testing
  - Particle generation properties
  - Regulatory letter available on request
  - Differential Scanning Calorimetry
  - Infrared Spectrum "Fingerprinting" via ATR-FTIR

### Sterilization Process Validation

  - Specification and miscellaneous property comparison English and Metric data sheets
  - Key point: Gurley porosity specification is not changing English and Metric data sheets
  - MPTP U.S. FDA Protocol and Phantom Protocol: no issues reported

### Packaging Process Validation

  - Sealing fingerprints
  - MPTP U.S. FDA Protocol and Phantom Protocol, cell selector tool
  - Various reports by SPMs participating in the protocol

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* Specific assessment topics and required supporting documentation depend on packaging applications and specific required design features to be determined by the manufacturer.