## Building Blocks Available To Help You With Your Risk Assessments

<table>
<thead>
<tr>
<th>Assessment Topics *</th>
<th>Supporting Documentation</th>
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| **Package Design Validation** | - 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** | - 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 |

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