

# LSO's Packaging Checklist

**To meet with our LSO's packaging experts to discuss your project, contact us by visiting our website or request a quote today.**

1. What is your device/project name?
2. Will the device be sterilized?
  - a. If yes, how will it be sterilized? If sterile, a protocol will be needed.
  - b. If not sterile, sometime a protocol is not needed/wanted. In either case, if the report is going to be used for a regulatory submission, then a protocol should be used.
3. How many sterile barriers are there?
  - a. Single
  - b. Double
4. Are they pouches or trays?
5. What is the material of the sterile barrier?
6. Is there a shelf carton used?
  - a. If yes, size? How many device per carton?
7. How many cartons per shipping box? Size of the shipping box?
  - a. If no cartons are used, how many devices are put into a shipping box?
  - b. Does the shipping box have less than 275lb burst or 44 ECT (Edge Crush Test)?
8. For distribution simulation (DS), at what assurance level (AL) is needed?
9. Is accelerated aging needed (shelf-life)?
  - a. If yes, at what aging temperature is desired?
  - b. Is there a RH requirement?
  - c. How many time points are needed?
10. Is real time aging (RTA) needed (shelf-life)?
  - a. Inform them RTA is needed for a ISO validation. How many time points are needed?
11. Number of samples (finished devices) per time point (DS, AA, RTA)?
  - a. We suggest 30 per time point. If its an implant or high-risk device, we suggest 60 per time point.