

PCL's Packaging Planning Checklist

Please keep in mind this is a high-level list of what should be considered early on in your project launch in terms of your packaging. To meet with one of PCL's packaging professionals to discuss your project, contact us at info@pkgcompliance.com or request a quote today!

- **Where will your device be sold?**
 - Just US? Or US & EU?
- **What is your anticipated launch date?**
- **When will your device be at a design freeze?**
 - TIP: Once your device is at design freeze is the best time to start working on packaging design. Before then, you should start vetting labs and request quote so you can hit the ground running as soon as your design is at Design Freeze.
- **What will your projected annual volumes for the first few years?**
- **What are the performance requirements for your packaging?**
 - Do you know where it will be shipped?
 - Do you know how it will be shipped?
 - Do you know where it will be stored?
 - Do you know what the conditions will be like where it is stored?
 - Do you know what the conditions of use will be? (IE: ambulance, ER, military)
 - Do you require cold chain packaging?
- **What aesthetic/marketing requirements does your packaging have?**
 - Does your branding need to be printed on your shelf carton?
 - Does your label need color or does it just need black in?
 - Does your shelf carton need to be shrink wrapped?
- **Questions to help you drive your packaging material decision:**
 - What is your sterilization method?
 - Does your device have any sharp or abrasive features?
 - Does your device have sensitivities to environmental factors (IE: moisture, light, air)
- **Equipment requirements**
 - Tooling will be required for thermoform tray sealers
 - Do you require a form fill seal (FFS) machine?
 - Does your packaging require vacuum seal capabilities?
- **Packaging Validation Sample Size**
 - Sample size is determined by your confidence and reliability. Our clients typically have a 95% Confidence/ 95% Reliability which ends up being 60 samples per each non-attribute test and 30 for attribute tests.
- **Packaging Validations**
 - Sealing Process Validation
 - Distribution Simulation Validation
 - Shelf-Life Validation
 - Accelerated Aging (AA)
 - Real Time Aging (RTA) – Must be happening in parallel with your AA study.
- **Sterilization Validations**