661.2 Compliance – Leveraging Supplier Relationships to Help Reduce Risk

Keeping patients safe by ensuring products meet or exceed established regulations requires communication and transparency between packaging material suppliers and pharmaceutical manufacturers. This is especially true when developing and executing a strategy to ensure compliance with USP 661.2. Pharmaceutical manufacturers need to understand the intricacies of the changes, questions to ask their suppliers and best practices for ensuring a successful transition. Working with a supplier that fully understands these new regulations, has experience manufacturing USP 661.2 compliant films and offers full transparency can help API and excipient manufacturers avoid common pitfalls and prevent production delays due to non-compliance.

Understanding USP 661.2 Regulations

USP 661.2 specifies test methods related to a packaging system's chemical suitability for intended use with respect to patient safety. Packaging systems are defined as containing or intended to contain pharmaceutical drug products and include primary packaging components that come into direct contact with the pharmaceutical product and secondary packaging components that may interact with the pharmaceutical product at some point during manufacturing, distribution, storage and use. The implementation delay from 2020 to 2025 removed the grandfather clause for packaging systems that had historically been deemed compliant, which means all packaging used during API and excipient manufacturing must be tested and prove compliance with the new standards.

	All Plastic Pharmaceutical Packaging is Impacted			
	R&D + MANUFACTURING	**DISTRIBUTION**	**STORAGE**	**PATIENT USE**
EXAMPLES	Packaging & Films Used During API & Excipient Manufacturing Bin Liners Transfer Tube Liners Sample Bags	Packaging & Films Used During Bulk API & Excipient Distribution	Packaging Used to Store Ingredients, Excipients or Final Drug Products	End-Use Packaging Used by Patient to Administer or Consume Product

Questions to Ask Your Pharmaceutical Film Supplier

Working with a company that manufactures USP 661.2 compliant film is critical, but how a supplier answers the following questions about their policies and procedures can give pharmaceutical manufacturers critical insight into the nature of a potential relationship.

1. Do you distribute or manufacture USP 661.2 compliant films? If so, for how long?
2. What type of air is used in your pharmaceutical blown film extrusion process?
3. Do you have and provide customers lot traceability information?
4. What is your notification of change policy and timing?
5. Do you supply customers with Drug Master Files, Certificates of Conformance and documentation on your cGMP procedures?
6. Do you use USP 661.1 compliant materials to manufacture your USP 661.2 film?
7. Do your resin suppliers provide datasheets and 661.1 documentation for the products you purchase?
8. Do you provide customers with performance data for your amine-free, anti-stat USP 661.2 compliant films?

"Transcendia provides all of these things as a matter of practice and offers customers an opportunity to visit our manufacturing facilities for quality management system audits. We have been using the same resins to produce our TRA150 pharmaceutical films and bags, which have been used by global pharmaceutical manufacturers and tested with multiple drug products, for over 30 years. Due to our meticulous resin selection process, our films were 661.2 compliant before the 661.1 regulation revisions were introduced in 2017. And our newest amine-free, anti-stat TRA120 film already carries 661.2 compliance. These regulations aren't new to us." stated Jason Eckel, Vice President of Sales, Healthcare for Transcendia.

Reasons to Start Now

When considering the time and resources required to requalify pharmaceutical films against new 661.2 testing requirements, 2025 isn't that far away, especially if companies have to test multiple drug products for interactions with their associated packaging systems. Waiting too long to start the implementation process puts companies at risk for product recalls and launch delays and can negatively affect their brands. Pharmaceutical manufacturers using industrial films need to consider their new packaging systems may not earn compliance during the first round of testing, which will put them back into the testing queue.

There are pharmaceutical film suppliers and distributors who have approached decisions around compliance implementation timing by asking themselves, "How much risk are we willing to take?" That isn't the right question. When quality and safety are paramount, as they should be in all aspects of pharmaceutical manufacturing, the only question to ask is "Have we done everything possible today to ensure our products are safe for people to use? And that answer should always be, "Yes."