

## Pharmaceutical Technical Transfer Checklist<sup>®</sup>

We've prepared this checklist to help you assemble all the information you will need to provide to us to make a successful Rx or OTC manufacturing technical transfer. Providing the most information listed below is essential to making your project technical transfer a success!

<b>Analytical</b>		
Analytical Test Methods for Excipients	<input type="checkbox"/>	
Analytical Test Methods for Finished Product	<input type="checkbox"/>	
Cleaning Methods	<input type="checkbox"/>	
Reference Standards	<input type="checkbox"/>	
Safety Data Sheets (SDS) and any Known Safety Precautions	<input type="checkbox"/>	
<b>Manufacturing</b>		
Product / Master formula (and sample if available)	<input type="checkbox"/>	
Equipment needed	<input type="checkbox"/>	
Excipients and Source / Approved Suppliers (Company, address, phone numbers)	<input type="checkbox"/>	
Manufacturing Work Instructions	<input type="checkbox"/>	
Dedicated Processing Equipment Needed (e.g., blenders, tanks, transfer hoses, etc.)	<input type="checkbox"/>	
Forecast/Volumes	<input type="checkbox"/>	
<b>Packaging</b>		
Source / Approved Suppliers (Company, address, phone numbers)	<input type="checkbox"/>	
Specifications / Certificates of Analysis	<input type="checkbox"/>	
Primary Packaging Components and Specifications (including PI) (bottles/caps/tubes/foil/film)	<input type="checkbox"/>	
Secondary Packaging Components and Specifications (cartons, shipper, coding format)	<input type="checkbox"/>	
<b>Product and Stability Testing Specifications:</b>		
	<b>Micro</b>	<b>Chem</b>
Bulk Product Specifications	<input type="checkbox"/>	<input type="checkbox"/>
Finished (Released) Specifications	<input type="checkbox"/>	<input type="checkbox"/>
Stability (including Stability Indicating Method, required time points, and storage conditions)	<input type="checkbox"/>	<input type="checkbox"/>
Unique Handling Needs (if applicable)	<input type="checkbox"/>	

Please contact us at [info@bora-corp.com](mailto:info@bora-corp.com) or at 1-866-6PHARMA if you have any questions.