

## OEM Disposable Medical Device Outsourcing – “Top Ten Vendor Tips +1” That Will Save You Money

Author: Donald J. Dobert, President, ATL Medical-Pharmaceutical

Follow these eleven tips. They will save you heartache, frustration, and money.

1. Clearly define your needs and the function of the product. Your vendor may be able to suggest cost efficient ways to improve product quality and lower unit price.
2. Select a well-established vendor that has been in business a long time.
3. Choose a vendor with a strong Quality Management System.
4. The prospective vendor must have some form of APQP (Advanced Product Quality Planning). APQP helps to prevent mistakes before they happen, and lays the foundation for evaluation of the four “M’s”: materials, methods, manpower, and machines. Thus, common mistakes that arise from miscommunication can be avoided: (such as die cut tolerances, elongation, measurement error, cleanliness, packaging, etc.).
5. The company selected must evaluate their vendors and their quality systems, particularly if they are ordering materials on your behalf. You don’t want poor quality in your device from a third party supplier.
6. If possible, select a company that is registered with the FDA as a Medical Device Manufacturer.
7. The prospective vendor should be cGMP compliant. This is a huge plus. This means they have IQ-OQ-PQ (Installation, Operational, and on-going Performance Qualifications) that validate your product.
8. The vendor should have an active “Systems Validation Protocol”. This ensures that everything that impacts your product (SOP’s, training of personnel, process controls, final release, etc.) are in-control and capable.
9. Top Management should be involved in the Quality System. A “DMAIC” (six sigma approach) will Define, Measure, Analyze, Improve, and Control (both the vendor’s system and your product).
10. Last, but not least, strive for a working partner relationship (between OEM and vendor). This will do wonders for product quality, value, and service.
11. This is the “plus one bonus tip”. For critical materials, tolerances, or inspection frequencies (AQL’s), have your vendor sign a “no-change agreement”. This means that when you both agree to product specification(s) the vendor cannot change the material composition (or any other critical item) without a written notice to you. This is very important because very minor changes in raw material(s) or product (process) variation can cause failure(s) in your product.