

Brand Owners—You Should Care What Equipment Your Contract Manufacturer Uses

by Michael Finamore

When supplement brand owners tour contract manufacturing organizations, they will be shown a lot of fancy equipment, e.g., blenders, encapsulators, tablet presses, bottling lines, etc. However, a contract manufacturer's style and type of equipment is a small part of the equation of producing a quality dietary supplement at a fair price. This is where a visit/audit of the contract manufacturer becomes more than a tour—it also encompasses a review of the systems surrounding the equipment to ensure the contract manufacturer is capable of making a quality product.

For starters, the brand owner should be comfortable with the scale and capacity of the facilities to be sure it's the right fit for the organization. Not only is the overall size important, but also important is making sure the optimal batch sizes, core competencies and the various manufacturing services offered by the contract manufacturer match the brand owner's needs. If inefficiencies are on either side or additional business cannot be absorbed, it's better that this is understood up-front to save both parties additional work, expense and aggravation down the road.

Once a brand has determined the contract manufacturer has equipment that meets its needs and the capacity to handle future requirements, it is ready to place orders, right? Not so fast! A few more equipment matters need to be examined before moving ahead.

The first concern would be the condition of the equipment, both with what is visible and the environment in which it operates. While "shiny and new" appears perfect to the untrained eye, a true review of the equipment would ensure that not only can it perform as designed, but whatever inherent variability the machines have are within the acceptable limits required by the brand owner.

Besides what is obvious to the naked eye, the review should encompass the installation, operation and process qualification (IQ/OQ/PQ) documentation of the equipment. This inspection helps

establish that the contract manufacturer is using "industry best practices," showing the equipment was installed correctly and can operate in the facility to its design specification. While the familiar terms of IQ/OQ/PQ have now been supplanted by "stage I/II/III" considerations (requiring ongoing verification) in the pharma world, the basic premise for equipment qualification for the dietary supplement industry remains the same. These steps have to be performed for all equipment in the manufacturing process.

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The IQ ensures the equipment is designed in accordance with appropriate industry/regulatory concerns, is suitable for the facility and can run effectively within its assigned footprint. OQ begins once the installation is complete. It is a challenge to have the machine work as designed and where all of the parameters required for the operation of the equipment have been tested and confirmed. A failure or a missed specification in either of these evaluations requires the contract manufacturer to investigate and resolve the issue before the equipment is ready for use.

The PQ is more specific to the way the equipment will be used in the facility. In this case, the parameters established by the IQ and OQ are harmonized with the contract manufacturer's operational practices to show the equipment will perform within the ranges the contract manufacturer will want to use the equipment. A proper PQ will also challenge these subjective ranges by "pushing the envelope" to demonstrate that even if the equipment falls gently outside the targeted range for a period of time, its ability to operate correctly is not compromised.

An important area to include in the examination of the contract manufacturer is

a review of the cleaning procedures in use and to determine whether they were validated to show the equipment has been proven clean. Further, examining the operators and their qualifications required to operate key pieces of equipment is also important. It is acceptable to request the training records of select operators to ensure they are qualified. Qualified, trained equipment operators are as essential to making good supplements as is the actual equipment.

Brand owners need to remember that choosing the correct contract manufacturer

is about creating a partnership, and thus sharing the inherent risks. Any item, equipment or process that involves a brand's product and potentially puts that business at risk needs to be examined and understood. As we have seen, everything from synergy of organizations to handle future growth to failure of the manufacturer to properly document its practices can cost the brand owner both now and in the future. So, when visiting or auditing a contract manufacturer, look past the bright lights and shiny equipment to what is really behind the curtain. In the long run, you will be glad you did. 



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