

## HOW CAN YOU CHOOSE THE RIGHT MEDICAL CONTRACT MANUFACTURER? (Part 1)

To choose the right partner you need to ask some questions?

1. Does my product require a clean room, or at least a portable clean room?
2. Does the partner I am looking for make molds and run production?
3. Do they follow standardized validation procedures like IQ, OQ, and PQ?

Does my process need a clean room?

By the way, it can be said or written either way “clean room” or “cleanroom” according to Wikipedia. However ISO, the International Organization for Standardization uses the term “cleanroom” so in this article we will stay consistent with ISO.

A cleanroom is a facility designed to minimize and maintain a standardized level of airborne particulates. Cleanrooms are labeled most commonly by the ISO standard that is defined by the maximum particles per cubic meter of air in that particular room. The rating standards go from ISO 1 (10 particles per cubic meter  $\geq 0.1$   $\mu\text{m}$ ) to ISO 9 (35,200,00 particles per cubic meter  $\geq 0.5$   $\mu\text{m}$ ). At TechNH we have both a modular cleanroom and a portable cleanroom both class ISO 7.

Does my prospective molding partner make the molds and run production?

Some medical molders run production only. This may be fine for your need, however if there are any wear issues with your mold or you need to improve or change your design in any way then that would need to be done at a mold maker shop. TechNH has both a mold shop (also known as “tooling capability”) as well as production capability. TechNH can help with designing your parts to achieve your production needs by assuring the design is production friendly.

Do they follow standardized validation procedures like IQ, OQ, and PQ.

Validation is a critical process that establishes documentary evidence that a process or procedure or any production activity maintains the desired standards. Normally any validation procedure will include the IQ, OQ and PQ. IQ – is the Installation Qualification of the mold. OQ - is the Operation Qualification of the equipment and process. The PQ - is the Performance Qualification of a production run.

TechNH has a complete quality and regulatory department ready to help you and your company.



This is the 1<sup>st</sup> in series of short articles to explain the sometimes very confusing world of jargon and terms used in medical molding.

Check back soon for the next installment.

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