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**REASONS FOR DESIGN/BUILD OF CLEANROOMS – ESPECIALLY USP797 ROOMS - and "how to select a cleanroom design/build firm"**

*The following are the reasons design – build contracts are beneficial over separate design and separate construction contracts based on bids.*

1. **SINGLE PARTY LIABILITY** - By conducting separate bids one can end up with a different construction company and a different design company. This usually ends up in conflicts with each party blaming the other. To alleviate this potential situation the design company or a third company is hired to conduct project oversight. This usually results in higher costs without achieving the full advantage of single party liability.
2. **CLEANROOM CONSTRUCTION IS NOT GENERAL CONSTRUCTION** - Unlike general construction, cleanroom construction is far more complex. Each subsystem has to be work to specific design parameters which are monitored continuously. For example room temperature, relative humidity and pressure have to be with ALERT bands so that alarms do not trigger. The triggering of an ACTION alarm usually involves righting up an Excursion report etc. In general construction, there is no such critical performance expectation.
   CLEANROOM CONSTRUCTION IS MORE LIKE CONSTRUCTING A CUSTOMIZED MACHINE, THAT MUST WORK TO SPECIFIC PARAMETERS, RATHER THAN SPACE CONSTRUCTION. In fact the cleanroom is considered to be the largest and most expensive PROCESS EQUIPMENT in the facility. Hence the selection of a design/build firm with significant cleanroom design and build experience is critical, and of course single party liability becomes more important. Additionally, cleanroom construction is done in a different manner and order than regular construction work. The components have also to be installed in particular manner and be tested along the way, to assure that the systems will work correctly.
3. **SYSTEM INTEGRATION** - All systems, Mechanical, Electrical, Controls and Monitoring and Architectural components must INTEGRATED and Commissioned to work in unison. For example a leaky door can affect the room pressure. Commissioning and Operation Qualification involves all systems and the Basis of Design & specifications, thus making single party liability more important. THERE IS NO WIGGLE ROOM IN CLEANROOM PERFORMANCE TO SPECIFIC STANDARDS (e.g. ISO 14644-1 – this is implied within USP 797).
4. **INTRICACIES OF USP 797** - The cleanroom company must not only have expertise in cleanroom design/build (involving demolition, architectural work, mechanical and electrical expertise and control experience) but must also be knowledgeable with the

requirements of USP 797 – which is relatively new. We have seen too many so called USP 797 designs that obviously don't meet the requirements of USP 797 – and its expected proposed revisions.

5. **COST ADVANTAGES** - When a design/build contract is implemented some costs are reduced (in preparing bid quality documentation and in terms of making construction bids). This savings can be passed on readily to the Buyer.

When considering all these factors there is only one company that has all the skills and is local – Technovation. The risk of contracting with a construction company that may not have expertise in cleanroom construction is very high. This risk is insignificant if Technovation is contracted to do the design/build of USP 797 pharmacies since Technovation has successfully completed almost a 100 cleanroom projects world wide and has taken a leadership role in facility designs that will conveniently and practically meet USP 797. It should be noted that Technovation is currently designing USP 797 pharmacies for Walter Reed and MCV and has done preliminary designs for 7 Bon Secours hospitals and Chesapeake General.