



Question 1: Need to design a chamber to sterilize stainless steel carts with VHP. Chamber dimensions are 5x6x6. Two doors, one to class 100, one to class 10,000. Must be validatable. Any feedback?

Answer: First, you should generate some sort of User Requirements Document - a formal spec would be great, but a good 1-2 pages of descriptive key information could be quite informative too. Here is some of the information that you would want to include and/or questions to answer...

1. What are the carts going to be used for...
 - a. If they are going to be in contact with other product contact equipment, this is important.
 - b. Will the carts be empty, or loaded with supplies, etc... - if loaded, be as specific as possible with items and any surrounding packaging.
 - c. Is this a pass-through from a prep area to a sterile core or into a Class 100 isolator?
 - d. How will the cart be passed back? Does this need to be a one-way or two-way process?
2. What are your time limitations and throughput requirements? How much time do you have for the VHP cycle (including aerating to sufficient level to be opened)?
3. Are there any cleaning requirements for the chamber and the cart prior to running a VHP cycle? It does need to be clean and dry before starting.
4. Will this be at floor level or higher? Do you need any ramps, lifts, or other assistance for loading and unloading on either or both ends?
5. Is the area accessible for outside exhaust capabilities (this could significantly speed the aeration process, and perhaps allow the VHP system to be housed outside of the classified area, but controlled from inside)?

Once these main items are addressed, you can decide how fancy this chamber needs to be to get the job done within your required time and budget.