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2015.01.21.WED

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A SUMMARY OF SINGLE-USE EQUIPMENT IN THE BIOPROCESSING

Author: [GMP Platform](#)

| [Engineering](#) |

記事投稿: [VANASYL LLC.](#)

A SUMMARY OF SINGLE-USE EQUIPMENT IN THE BIOPROCESSING; Is Single-Use Equipment A Good Thing Or A Bad Thing?

Single-use equipment has a role in bioprocessing but you have to be very careful. There are five important questions (there may be more) to help decide when to use single-use equipment. First, you have to find out why you are looking at single-use equipment- what are you looking for? Are you having issues with the equipment you have now? Or are you wondering if you can save money? It is important to know why you are looking at single-use equipment. Second, you have to find out which single-use equipment is reliable. Then you have to find out which single-use suppliers are reliable. Then you have to find out what applications are appropriate for single-use equipment. Your next step is to find out what documentation is important. This article will give more details on each of these questions.

So why you are looking at single-use equipment- what are you looking for? Are you unhappy with your process equipment? Maybe you need to choose better process equipment but why are you choosing single-use equipment? Do you think single-use equipment will save you money? If you want to save money, single-use equipment might help; single-use equipment might not help. It is not single-use equipment that saves you money. It is the quality and operation of the process equipment. You have to look at the quality and the results quality will bring if you use quality equipment and the results if you do not use equipment with quality. Many people will show cost analysis between single-use equipment and stainless steel equipment. First, why does it have to be one or the other? Single-use equipment is not the answer to every problem. It could be the answer for some application but it depends on the equipment. Second, a cost analysis will be a waste if it does not give you an amount of money that it would cost if the equipment fails in any way. There is also a lot of vulnerability with some countries and new facilities in these countries. They appreciate the ideas of new facilities and companies look to make a small investment rather than a large investment. The question you should be asking- is any facility worthwhile, regardless of the cheaper price; if it does not produce medicines properly. No one asks this question. Why is that? Industry magazines and discussions often call single-use equipment cheaper. Most people have accepted this as the complete truth. They do not see that it is the application, the type of single-use equipment, and the supplier that will decide if you will save money with single-use equipment. In the drug industry, both with pharmaceutical and biopharmaceutical drugs, price is never about a brand. It is about quality. Price is related to the many choices you make in bioprocess equipment. Even if you use high quality equipment; if you don't follow instructions with its use, you can compromise your whole process. Thinking about choosing single-use

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equipment for the right application, for the right reason- the quality it may bring to your process- This is a start.

Now you have to find out which single-use equipment is reliable. What should you do? First, find out about the process contact materials. How is their material superior over the other materials in the market? What types of properties have been checked? What standards were used? What about the connections they use? What tests have been done on the connections? Problems: Ask them if they ever have problems with pinholes? Ask them if they have ever had problems with leaking? Ask them if they ever have problems with particulates? Ask them if they ever have problems with extractables? If the answer is a simple no to each of these questions, that is a good thing. But if there is even one question where, instead of a simple no, you hear explanations, stop right there. You now have a problem.

Then you have to find out which single-use suppliers are reliable. Who is coming to your meeting? Is it a salesman? How much technical knowledge do they have? Do they defend the quality of the material they use? Did they do research before choosing that particular material? Good quality does not happen overnight. Listen to the history. Do they have a history? Are they promoting single-use equipment for all facilities? This is a concern. How can you support one type of equipment? It is like saying all cars are good, all paper is good. Some cars are good. Some types of paper are good. Not all cars are good. Some paper has better quality than other paper. How can someone say one type of process equipment is good? Some people in the industry push single-use equipment in bioprocessing. They thought that if they join and push single-use equipment, more people will use it. It may have helped more people know about single-use equipment but it also caused confusion. How do we know which one of these suppliers is better than the others? If you ask them why are they better than their competitors, they will talk about tests; they will talk about quality agreements. They will not answer the question. They will avoid answering that question. Now you wonder about their reliability. But you need them to be reliable. If you use their single-use equipment, you will depend on them to continue providing your single-use equipment on time and the amounts of single-use equipment you need. How about transportation of single-use equipment within your facility? How does carrying affect the material? How does carrying affect the material when the container is large and there is much more weight? The suppliers are not discussing these issues. They simply claim perfection in everything they supply. You now have a problem.

Now think about the applications of single-use equipment. Is single-use equipment good for all applications? No. Single-use equipment is not good for all applications. A mix of stainless steel and single-use equipment may be the answer but it still depends on who the supplier is and the quality and design of both types of equipment. Now, is single-use equipment good for all sizes? No. Large sizes often weaken the materials. Larger sizes often make the material not fit for use. The welding is often weaker. The strength of the material is different with large sizes. The quality is weaker. Size is a problem for many reasons. You have more process contact surfaces. This adds more risk. Cell growth could be a problem. Biocompatibility becomes a problem. These problems exist because material biocompatibility tests and standard tests were not done with very large sizes in mind. What might come back positive in a test might be small enough to ignore but when there is so much material, what seemed small in typical use, suddenly grows because of the large amount of material. It is also important to look how single-use equipment could help and simplify your process or does it add more complications. Then you have a problem.

Now you have to ask questions about documentation. First, you have to know what documents are important. You also have to read the documents carefully. Documents are important if they put into writing what you were told verbally about the equipment. Documents are important to show the FDA why you chose this piece of equipment. Documents are not simply to prevent lawsuits. If you are a supplier and you do not want lawsuits, build quality into your design and be trustworthy. If you are a buyer, use only suppliers who follow the rules in the previous sentence. You also have to judge the single-use equipment looking at the documents together with the quality of the process equipment. Documents are not enough if a smart engineer can see the fault with the engineering design of the process equipment. Also, documents on connection validation/testing are very important. Often the quality of the equipment depends a

lot on the connection. This is important step.

So back to the title- when is single-use equipment good or when is single-use equipment bad?
As you can see from the article, it takes many questions, a lot of research, and a good brain.

Good luck.

Author: Tamara Fridman, member of the ASME International Standards Committee on Bioprocessing Equipment; Secretary of the General Requirements Subcommittee ; Vice Chair of the Polymeric and Nonmetallic Subcommittee; A co-owner and CEO of VANASYL, locations in the US and the UK.

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