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The Importance of a One-Stop-Shop

6 QUESTIONS TO ASK YOUR FLUID MANAGEMENT COMPONENT SUPPLIER

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Many of us stay with an insurance firm for years, assuming it's a one-stop-shop dedicated to meeting our ever-changing needs. Smart consumers don't make assumptions. They regularly evaluate and reassess the relationship.

For manufacturers and research firms in the biotechnology and pharmaceutical sectors, the same need exists to regularly evaluate suppliers of single-use technology for fluid management.

Why risk teaming with a fluid-management manufacturer you haven't thoroughly vetted? One that may not be the one-stop-shop you think it is? One that may react, rather than be proactive, when industry changes occur?

To be certain you receive the preeminent and safest single-use component, take time to evaluate your fluid-management supplier or a supplier under consideration, by asking the following 6 questions.

Your supplier's answers will help determine if the company is a steadfast partner and one-stop-shop committed to helping you pass FDA validation.

YOU ALSO WILL LEARN YOUR SUPPLIER'S WILLINGNESS TO PROVIDE:

- the best and safest possible product;
- expert knowledge, advice and education when industry test standards change;
- a streamlined, more efficient process to provide the product your end-users want; and
- significantly reduced costs.

A ONE-STOP-SHOP ASSURES QUALITY, STREAMLINES PROCESSES, & LIMITS COSTS:

1. Available 24/7 to take your order.
2. Follows the industry's toughest testing standards to assure highest-quality fluid-management components.
3. Comprised of industry experts deeply involved with the Bio-Process Systems Alliance (BPSA). Provides trusted advice and education if new or updated testing standards are introduced.
4. Conforms to Bioprocessing Equipment standards from the American Society of Mechanical Engineers (ASME-BPE).
5. Assures smooth manufacturing transitions when changes occur.
6. Provides internal testing results at no cost.
7. Works only with FDA-certified GMP or GLP labs to potentially reduce testing burdens for customer.
8. Quickly provides product-testing data so customers can rapidly customize products for their end users.
9. Documents all testing and manufacturing processes to ensure consistency.
10. Believes in transparency. Confidently shares information about technologies, processes, etc. with customers.
11. Committed to constant 2-way communication (in person, telephone, electronically and/or video conferencing) with customers.
12. Welcomes customer visits and performance reviews.
13. Available to be part of customer's team that interfaces with client.
14. Welcomes inclusion in customer's strategic decisions that involve the supplier's product.

Questions to Ask:

1. WHEN DID YOUR COMPANY IMPLEMENT BPSA'S EXPANDED SINGLE-USE TESTING GUIDELINES FOR CONNECTORS, FITTINGS, AND DIAPHRAGM VALVES?

The Bio-Process Systems Alliance (BPSA) is adding 24 additional product test categories to its already exhaustive testing guidelines matrices. BPSA will recommend that suppliers of single-use technology for fluid management implement the new recommendations.

Progressive suppliers deeply involved with BPSA already are familiar with the additional test method guidelines and have applied them. These firms are ahead of the game. They have put systems and processes in place to meet the guidelines and are better able to provide the most all-inclusive test data to customers in a timely fashion.

2. WHAT BPSA TESTING GUIDELINES DOES YOUR FIRM FOLLOW?

A supplier considered a one-stop-shop follows all BPSA testing methods, including the original guidelines announced in 2007 and any additional guidelines. Among the 24 additional BPSA testing guidelines announced in 2014 are:

- Leak tests for connectors and fittings are additional guidelines for Burst Test and Integrity (Leak) Tests. The tests thoroughly determine if maximum pressure components will withstand at a given temperature, and confirm the integrity of the component's seal or assembly.
- Extractable tests that identify chemical compounds that migrate from any product-contact material (including elastomeric, plastic, glass, stainless steel, or coating components) when exposed to an appropriate solvent under exaggerated conditions of time and temperature.
- Bacterial Challenge/Soil Testing that identifies a bacteria's ability to breach a seal.
- Biological Reactivity In Vitro, which evaluates the response of mammalian cell cultures to extracts of polymeric materials.
- Biological Reactivity In Vivo, which evaluates the interaction of medical devices with blood or the biological reactivity of animals to polymeric material.
- Particulate Matter that evaluates the presence of particulates in or on a sample.
- Physiochemical Test with and without Alternative Extract, which evaluates the physical and chemical properties of plastics and their extracts.
- Endotoxin Claim that evaluates the presence of bacteria endotoxin on a device.

In 2014, BPSA also expanded its guidelines for quality tests for sterilization and product regulatory compliance, which best-in-practice suppliers had already incorporated into their processes.

Also essential is Bioprocessing Equipment conformance from the American Association of Mechanical Engineers (ASME-BPE). ASME regularly examines and updates its certification standards. Top-notch suppliers promptly inform customers of any certification guideline updates.

3. HOW INVOLVED IS YOUR FIRM WITH BPSA AND ASME-BPE?

Quality focused suppliers have executives, researchers, or other professionals serving on the BPSA board and/or committees. The supplier is involved upfront with significant decisions that affect the industry and knowledgeable about industry issues and changes that could affect manufacturing. Your supplier's involvement with BPSA and ASME-BPE ensures you immediately receive information on the latest testing guidelines. In addition, they can work alongside you to ensure a smooth transition when changes are underway.

4. DOES YOUR FIRM TEAM WITH GMP OR GLP-COMPLIANT LABS?

Best-practice suppliers work only with GMP or GLP-compliant labs, which undergo rigorous FDA certification.

5. WHAT EVALUATION SYSTEMS ARE IN PLACE TO ENSURE CONSISTENT PRODUCTION OF A HIGH-QUALITY COMPONENT?

AT A MINIMUM, TOP-NOTCH SUPPLIERS HAVE INSTITUTED THE FOLLOWING EVALUATION SYSTEMS:

- Detailed documentation of procedures for each step in the manufacturing process.
- Tough quality control measures that include, but are not limited to:
  - inspections to detect any contamination of incoming resin;
  - continuous monitoring of filtration system to remove fibers; and
  - post-handling process that remove loose plastics from parts.
- ISO (International Standardization Organization) certification.
- Customer surveys.
- Open to customer evaluation at any time.

A FLUID-MANAGEMENT COMPONENT SUPPLIER THAT IS A TRUE ONE-STOP-SHOP WORKS DILIGENTLY TO:

- deliver the best and safest component possible;
- provide expert knowledge, advice, and education when industry testing guidelines and standards change;
- institute a streamlined and more efficient process to provide the product your end-users want; and
- significantly reduces costs.

6. HOW DOES YOUR FIRM COMMUNICATE WITH A CUSTOMER?

A TRUE ONE-STOP-SHOP:

- Takes orders 24/7.
- Encourages face-to-face meetings, telephone calls, emails, and video conferences.
- Provides updated data to you whenever requested. You get an immediate response to a request, not a “No problem. We’ll look for it in about a week.”
- Is transparent – an open book – continually informing you of such items as work underway, status, technologies used, and documentation of all processes.
- Welcomes on-site visits from customers.
- Welcomes performance reviews by customers.
- Available to be part of your team that interfaces with your client.

About Nordson MEDICAL

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market.

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