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Partnering for Integrated Fluidic Platforms

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For some applications in medical devices, an OEM may consider adopting an integrated fluidic platform.

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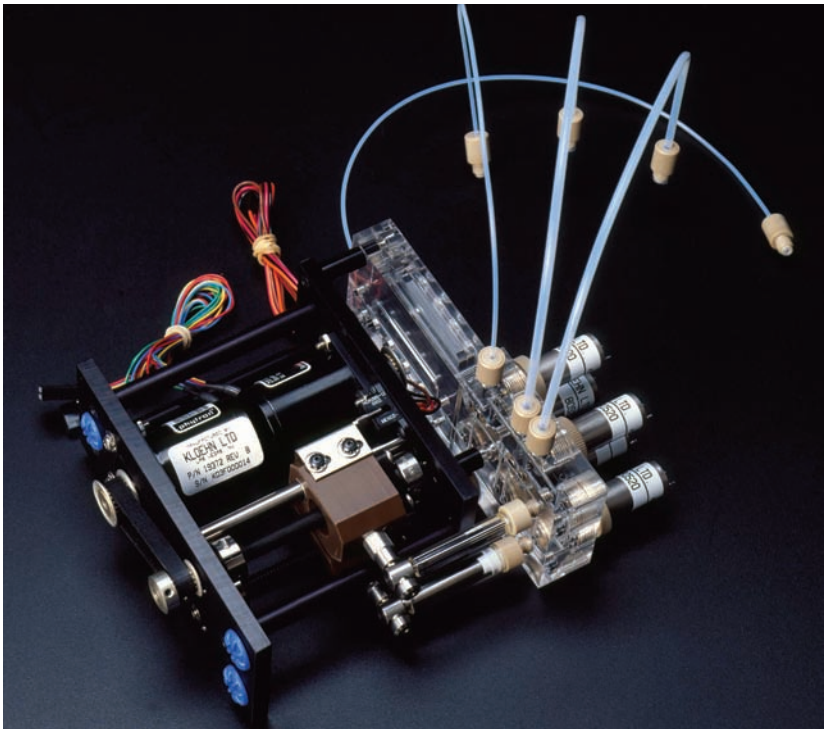
There is a growing demand for application-specific miniature precision pumps, valves, and components. This is especially true for OEMs that develop point-of-care, immunoassay, and biomarker diagnostics instruments, as well as individual diagnostic-driven therapies. Such diagnostic products include protein analyzers that work on a very small scale. Many of such instruments are being installed in individual clinics, small hospitals, and remote areas around the world, creating added pressure for greater reliability and repeatability. Simplified preventive maintenance cycles and longer service life are also increasingly important. In response, OEMs are looking to suppliers for smaller, more-robust pumps and valves that function longer and require less power than older components.

In order to liberate scarce resources to focus on their own core competencies, product development engineers rely on strategic suppliers for functional subsystems such as precision fluidics.



Shown here is an integrated fluidic platform (IFP) codeveloped and manufactured by Kloehn Inc., a partner of Norgren Fluidics.

Integrated Fluidic Platforms

The process of finding and qualifying the right component can be daunting enough. The number of components required to design and assemble a precision fluidic subsystem in-house adds to the complexity. OEMs can reduce design cycle times and costs by working with a single strategic partner to supply pumps and valves or to codevelop application-specific integrated fluidic platforms (IFPs). IFPs

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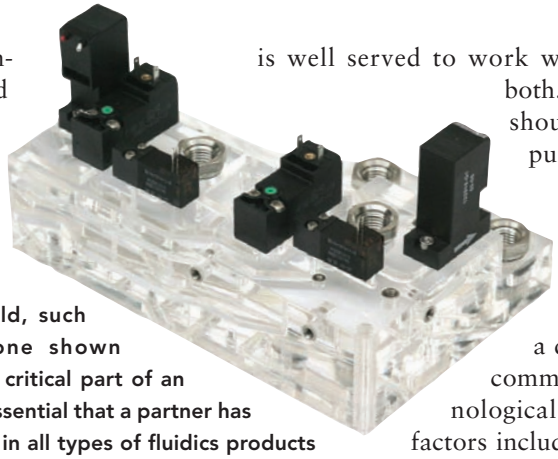
are subsystems that include all the components needed to perform the fluid control function under a single part number. An IFP can include pumps, valves, syringes, and manifolds, all in one part. The benefit of such a design is that it encourages miniaturization, such as for devices that use microfluidics. It can also increase response times and reliability of the part.



A manifold, such as the one shown here, is a critical part of an IFP. It is essential that a partner has expertise in all types of fluidics products to create a customized single part.

Engineers that work with a codevelopment partner to design and qualify an IFP should expect to reach three easily quantifiable value-based objectives. First, they should expect a precision fluidic module optimized for their instrument. Second, the IFP should be fully tested, validated, and qualified using the criteria and specifications provided by the OEM engineering team. Third, the OEM engineering and technical resources should focus on the system or instrument design objectives. The result is improved performance in meeting the OEM development project milestones and stage-gates to get to market quickly.

IFPs or Discrete Components?

In some cases, it makes more sense to search out discrete components than to design an entire IFP. For example, OEMs working with a stable fluidics design with high reliability in an existing instrument may need new components only for incremental performance improvements. Incremental improvement is not as simple as it sounds, especially because there are usually competing design objectives such as reducing instrument size, shortening cycle times, improving reliability, or adding new features. A strategic supplier can build on its base of standard pumps and valves to develop an application-specific custom component.

Alternatively, if a whole new precision fluidic subsystem is required, serious consideration should be given to working with a codevelopment partner to design, test, and manufacture an IFP. In most situations, an IFP is best when designing a new instrument, but it could also be an option if competitive pressures create demand for a significant technological leap forward.

When deciding whether to buy discrete components to assemble a fluidic subsystem or to codevelop an IFP with a supplier, the OEM team must assess its own level of fluidics expertise. It should ask whether it can profitably divert engineering and technical resources away from the core science to design, prototype, assemble, and test the subsystem. In many cases, there is greater value in deploying resources directly to project milestones for innovation and performance, leaving the fluidics to a partner specializing in that technology.

The choice between using discrete components or IFPs may vary from instrument to instrument, so an OEM is well served to work with a supplier that can offer both. Optionally, a potential partner should manufacture a full line of pumps and valves and have the engineering expertise to codevelop and supply IFPs.

Finding a Fluidics Partner

Partnering with a supplier is a decision based on business and commercial factors as well as technological considerations. The business factors include such aspects as total cost of ownership, availability, and global supply. Commercial factors have to do with the supplier's abilities to help the OEM meet its customers' requirements for timely and consistent delivery. The technical factors that go into choosing a partner to codevelop precision fluidics include engineering expertise, industry experience, and component quality.

The OEM has a role to play in this partnership as well. To derive the most value from working with the supplier it selects, the OEM needs to invest time and thought in defining the desired outcome. What are the performance and output requirements of the finished instrument? To meet those requirements, what exactly is demanded in terms of output of the precision fluidic system? Answering such questions in the early design stages and then asking the supplier to develop the components or IFP will help the OEM avoid costly mistakes, maximize instrument performance, and, most importantly, concentrate resources on driving product differentiation and competitive advantage. In other words, the OEM should define the problem, and then find a fluidics partner it can rely on to develop the platform.

An IFP is best when designing a new instrument, but it's also an option if competitive pressures demand a significant technological leap forward.

A partner capable of executing the design and manufacture of the precision fluidics system must have several competencies. One is a comprehensive range of precision fluidic products—pumps, valves, syringes, and accessories. In addition, it should have capabilities in process-compatible manifolds to integrate the components into the most efficient assembly. A fluidics partner must have high-level engineering expertise to be able to work with OEM engineers on fluidics design and help them integrate the

subsystem with the rest of the instrument. And it should have the capacity to manufacture and supply components and IFPs at a scale and speed that match the OEM process.

Product Breadth and Depth

The place to start evaluating potential fluidics partners, whether searching for components or IFPs, is with the product line. Does the supplier manufacture all or most of the components required, including pumps, valves, syringes, and manifolds? Some large suppliers simply aggregate components from various sources. The result of such a practice is components that are not optimized to work together. For example, a valve manufacturer that must send components to a manifold supplier for assembly loses control of that part of the process and is not able to adapt the manifold for multiple uses. Even worse, if something goes wrong, it may be hard to identify the source of the problem.

Developers of homegrown fluidics usually lack easy access to the latest advances in pump and valve technology.

In contrast, the right partner will have enough components of its own manufacture or from trusted third parties to engineer them into a single higher-level part. Using its own parts, the supplier can customize components as needed and combine them under a single customer-specific part number. The IFP is assembled and tested by one manufacturer and there is continuity of test data all the way back to the component level. The supplier controls all the inputs and takes responsibility for the whole subassembly, reducing risk for the OEM. The capability for high-level, application-specific integration is what sets a true codevelopment partner apart from a supplier that simply aggregates parts.

Industry Expertise

The right codevelopment partner will also have expertise in fluidics for in vitro diagnostics, rather than attempting to apply pump technology from other industries to this highly specialized and regulated field. Such experience and industry knowledge is crucial for recognizing and adapting to product trends. For example, one current trend is the movement to minimize internal volumes and carryover to increase accuracy with smaller sample sizes. Another is the constant pressure to reduce the instrument footprint, a development that requires smaller pumps and valves that consume less energy and generate less heat. OEMs are also looking for faster valve actuation response times and for improved performance from in-line pumps. To keep ahead of these trends and to be properly prepared to respond to new ones, a supplier must prove that it has fluidics expertise specific to the diagnostics field. It also helps if the supplier operates on a global level with project managers who see what is happening in all markets and can deploy resources and technologies to match.

Manufacturing and Testing Capacity

The OEM needs to look beyond a potential partner's product line and evaluate its manufacturing and testing capabilities as well. This can be done by answering the following questions:

- Do the manufacturing methods and quality control meet the same standards as the OEM's?
- Does it have the capacity to dedicate a manufacturing line or cell to the OEM's assembly?
- Can it demonstrate compliance with ISO requirements and other industry and regulatory standards?
- Are the scale of manufacturing and the pace of delivery adequate?
- Are business policies and corporate culture compatible with the OEM's?
- Can the supplier deliver the appropriate testing data and certifications to meet both OEM and customer requirements?

Answering these questions before beginning a partnership can save a lot of time and frustration.

A three-way media separated valve is optimized for integration with other components and manifolds. It is suited for use in OEM-specific designs and as a replacement valve.

Let the Experts Handle the Fluidics

There are several reasons for OEMs to partner with a fluidics supplier rather than designing and assembling the subsystem on their own.

First, OEMs are experts in their own science, not necessarily in precision fluidics. They may spend a lot of time searching for pumps and valves and still end up with less-than-optimal results. They may not know which specific component is best for their application, or they may choose one developed for another industry and try to insert it into a diagnostic application without realizing its shortcomings.

Second, when a fluidic platform is developed in-house, there is no infrastructure for technical support if problems arise later in the process. Some common problems include leaking, short component life, and failure to meet overall performance objectives. Developers of homegrown fluidics

usually lack easy access to the latest advances in pump and valve technology.

Third, the cost of failure can be significant. If the system fails to perform as required, it is very costly to bring in a precision fluidics expert to try to solve the problem, particularly after equipment parameters are set. Not only is this expense additional to the cost of developing the system in the first place, but options for corrections are limited now by the existing design.

OEM engineers still need to be involved with the fluidics design. They must be prepared to give their codevelopment partner a complete fluidic circuit diagram containing all the specifications necessary. Then the two groups should continue to work together to get the best instrument performance overall. In the most advanced example of this level of partnership, an OEM keep an engineer from its fluidics partner onsite to ensure rapid communication and complete integration.

Conclusion

Identifying the right partner to supply pumps and valves starts with deciding whether to purchase discrete components, IFPs, or both. Then the OEM must find a supplier with the right range of products and engineering expertise to meet specific requirements. Finally, the OEM needs to determine whether the supplier has the capacity to manufacture and deliver the components and assemblies as required, with the right testing and certification in place.

Once the supplier has been selected, the OEM can get the most benefit from the relationship by explicitly defining specifications and performance outputs, then allowing the supplier to develop the components or IFP to meet those requirements. Early involvement will help the OEM avoid making design decisions that might prevent the fluidic system from delivering optimum performance.

Upgrading pumps and valves in existing designs offers incremental improvements. The biggest advances in miniaturization, response times, and reliability come from IFPs.

Working with a codevelopment partner to design and supply the entire precision fluidic system ensures the highest-quality fluid control while liberating OEM engineering resources to focus on its own core competencies. ■