

Transition Guide



Building Partnerships That Last with
Solutions That Work

When process change or new process development involves exploring different filter vendors, we'll help simplify your search.

Evaluating new filter vendors can be an intensive mission. This guide will help you decide if pursuing a partnership with Critical Process is in your best interest. It will walk you through the topics that companies ask us about most often. If this is your first introduction to Critical Process Filtration, we say, welcome!

Starting with the filtration needs of your company, you'll learn the different ways we address process change and new development. Next, discover the collaborative process of evaluating and solving those needs with our unique offerings. Finally, explore our company's qualifications and experience to determine if a meeting to review your filtration needs is the right next step.

If it is, we look forward to hearing from you.

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MAKING A CHANGE OR DEVELOPING A NEW PROCESS

We Support Simple to Complex Filtration

Direct Filter Replacement

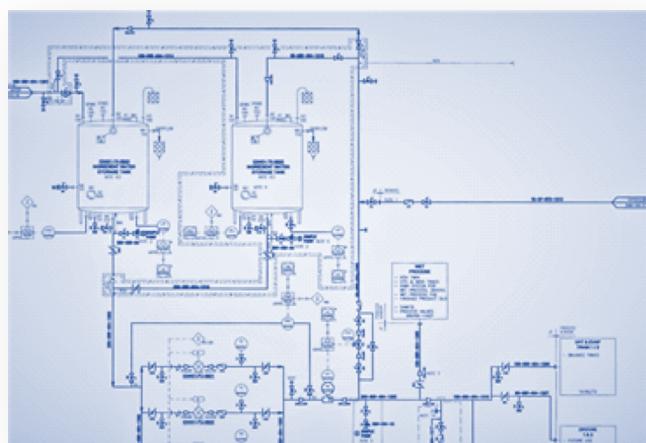
Replacing your current filter that doesn't require validation with an equivalent Critical Process filter can be done simply and quickly. Our library of filter information includes specifications and performance levels of other manufacturer's filters, which helps us match or improve performance of your current filter. In these situations, we typically send you a filter sample to test in your environment to ensure equivalent results. When further testing is needed we provide additional consulting and work together until we achieve the best fit.

Process Redesign

Poor filtration performance is often the result of changes made to a process or an upset that impacted the behavior of the filter. Other times it's the consequence of installing the wrong filter somewhere in the stream. Either way, filtration problems are corrected with adjustments to the type, number and placement of better suited filters.

New Process Development

Developing a new process from scratch is the perfect time to enlist our technical services team. Whether you are investigating filter suppliers for the first time or are already engaged with a preferred vendor, now is the time to evaluate other solutions that in the end, gives you the best performance and saves you money.



Validated Process Change

When validated process changes are required our team is experienced in managing the testing and documentation needed to assure performance requirements are met. We understand that validating process change is a significant project for your team. As your filtration partner we help shoulder the load so you can keep production moving. Validating your fluids in our environment saves your staff time and supports companies without laboratory capabilities. As a filter manufacturer we can respond to your results and configure custom media solutions so that your targeted performance becomes reality.

We begin by **addressing change feasibility** to determine if the process can accommodate the new filter and required changes. We evaluate housing compatibility, sterilization process, endotoxin and other relevant extractables.

Our team **qualifies the operation of the filter** to assure proper functionality within the process operating window. We closely examine what the filters can withstand in sterilizing and operating conditions such as temperature, pressure, flow rate, etc., in order to meet the target processing times and volumes.

After **validating the performance of the filter** your process team is assured of a filtration process that meets your requirements -- that sterility, turbidity, potency and toxicology of the drug product are all validated as required, and risks have been addressed. Once all parameters for validation are confirmed, implementation is scheduled.



STEPS TO CONFIGURE YOUR SOLUTION

Listening, Recommending, Testing, and Installing

Process Review Call

Once we connect, a member of our customer service team will ask you a few questions and then schedule a phone meeting between your process team and our application engineers.

At this initial meeting we do most of the listening, and you do most of the talking. Be prepared to tell us about your operation:

- Do you need new or replacement filters?
- Role of the filter (sterilizing, particle removal, etc.).
- Filter sizes and types in use.
- Types and amounts of fluids being processed.
- Issues you are experiencing.
- Quantities of filters needed.
- Validation or other testing requirements.
- Deadlines.
- Questions.

Before concluding, we will determine if there is a good fit for our companies and identify next steps. Our application engineers may email/call you with clarifying questions as needed.

Technical Evaluation

Based on the process review data and your requests for information, the CPF team will discuss your application, research ideas/options to meet your goals, and when necessary, conduct testing and analysis.

Types of activities may include:

- Testing of fluids
- Evaluation of current procedures
- Risk assessment support
- Validation/Qualification Plan
 - Determine testing requirements
 - Create validation/qualification plan
- Compare filtration devices
 - Materials of construction
 - Performance specifications – bacterial or other retention
 - Operating specifications – pressure, temperature, sterilization process
 - Biocompatibility



Findings & Recommendations Review



At this meeting, we will present our findings and recommendations for your company. It will include product specifications, testing data summary, pricing and an estimated timeline.

This meeting can be the springboard for major projects or may be enough to reach consensus before placing an order. Either way, it is the beginning of a partnership between your process team and Critical Process that focuses on your operation meeting your filtration goals. We can meet by phone, video or in person.

It's also the time to invite your team members that were not at the process review meeting. We can address additional questions, educate those who are newer to the operation and keep working to fine tune details.

Next steps are determined after reviewing this information.

Customer Service and Ordering

Once all requirements have been met, product ordering begins. Our process is simple and we haven't lost the personal touch. A member of our team will email you a quote. When you return the approved quote with a

purchase order we will acknowledge receipt, provide your ship date and product assembly begins. Our production team follows the order through to fulfillment and shipping.

Future orders are as easy as an email or phone call with a purchase order. A member of our Customer Service team processes your order correctly and on time.



Installation Support



Critical Process offers installation support services. This service is especially important to new processes and redesigned systems. Be assured of knowledgeable workers that understand your goals and deliver exactly what you ordered. The same technical staff that you started with will work with the installer of your system. This is just another way we partner with our customers. Our company's "get it right the first time" mantra directs all our efforts. Once the system is up and running we are confident it will perform as expected until there is a process change.

OUR COMPREHENSIVE APPROACH

Products

Our product line includes cartridges, capsules, laboratory micro capsules and disc filters that are configured with multiple types of membranes and depth media. Filter sizes range from 2 to 40 inches and multiple media is available in a broad selection of pore sizes. Media can consist of single or multiple layers depending on the application. High performance filters are integrity tested and validated, while our general service filters are economical and help to lower overall filtration costs. Critical Process also offers housings for industrial and sanitary environments.

Pricing

Pricing is rarely the first question you'll ask when inquiring about process filters. Determining the right combination of filters to meet your performance goals is the priority, and it's what truly delivers cost optimization. When it comes to competitive bidding on a model to model basis with popular large vendors, our prices are up to 25% lower. When comparing CPF products with catalog dealers that stock limited products & configurations, we win some and lose some. If pricing is your only priority, an off-the-shelf supplier may be your best bet. However, if pricing and performance are equally important, Critical Process can help you lower your overall filtration costs and improve performance.

Delivery

We know how important product availability is to process teams. Products typically ship within 5 business days of receiving your order. More than 98% of customer orders shipped as promised and Customer Delivery Surveys report greater than 95% satisfaction for on time delivery.

Technical Consulting/Services/On-going Support

From initial inquiry through the life of the process, our team of experts will support your filtration operation. When challenges and system upsets occur, or if you just have questions, you can contact us by email, or phone from 8am – 5pm ET. When further services are needed we manage all testing activities conducted in our lab, third party labs and on your site as requested.

BUSINESS OVERVIEW

Our History

In 1998, one of our founders, who had spent decades working in the filtration industry, determined to build an organization that would address the unmet needs of companies with critical processing operations. The painful consequences of slow delivery and lack of technical consulting plagued the market. As science and technology expanded opportunities for newer, safer and better products in many industries, the role of process filtration became more demanding.



Kristen Ramalho & Fred Arbogast, Co-Founders

Solving the delivery issues of the day could only be achieved through a dedicated manufacturing process and business commitment to get product out the door in less than a week. It meant shipping certified high-performance process filters that quality assurance, process engineers and industry regulations demanded. Our ISO 9001 certified operation was built with proprietary equipment and manufacturing processes that produce industry compliant products from general service filters to custom filtration solutions.

Access to sought after filtration expertise was the missing link for many Process Engineers. Our response was to make our application engineers the first line of contact for a customer's process team. Being solution focused more than product sales driven meant greater service for our customers and steady, sustainable growth for the company.

Today, we are honored to serve a long list of customers, many of whom have been with us from the company's inception. Having sold millions of filters to major corporations across multiple industries, the company forges ahead with a comprehensive approach to process filtration by partnering with companies like yours who require a filtration supplier to:

- Manufacture high-quality, proven products that meet customer performance requirements
- Provide filtration consulting and technical support so customers get real solutions and avoid the pain and expense of guesswork
- Deliver products fast so customers maintain flexibility and control of their inventory
- Offer very competitive pricing and lower the customer's overall filtration cost

Quality Management System

Critical Process Filtration's Quality Management System is ISO 9001:2015 certified. Raw materials are carefully selected to ensure compliance with biosafety regulatory requirements: USP <88> (Class VI), <87>, <85> and <661>. All suppliers are qualified and monitored with change control agreements in-place and participate in our vendor management program.

Products are manufactured in a controlled clean room environment (ISO class 8) with continuous tracking of quality at each major production step. All components are fully traceable. Change control policies and procedures are well documented and apply to the full product life cycle.

Absolute rated membrane filter cartridges are 100% tested for integrity. Hydrophilic membrane products are tested using industry standard diffusion tests. Hydrophobic membrane products are tested using either water intrusion or bubble point (pre-wet with IPA/Water). Bacteria, yeast and mold retentions are validated to correlate with the integrity test results following ASTM F838-15 protocols. General grade membrane and pleated depth filter devices are sample tested during manufacturing to ensure consistent quality and performance.

Certificates of Assurance (COA) are included in the packaging of: pharmaceutical, biopharmaceutical, food and electronics grade filters that meet USP TOC and conductivity; toxicity compliance; and FDA non-fiber releasing and repeated food contact use requirements.

Business Continuity & Risk Management

Critical Process Filtration was established 1998. We are a privately owned, financially independent, woman-owned business experiencing steady growth. Our established banking and insurance relationships and long-term contracts with major suppliers assures business continuity and stable supply of raw materials.

We Welcome Your Audit Process

Your quality control process is an important part of our relationship. By providing your list of requirements, our quality team will deliver necessary documents. On-site quality audits are welcomed.



Preferred Vendor Status

Ordering and receiving filters quickly is seamless when working with a Preferred Vendor.

This has been most appreciated when process teams experience an upset and filter inventory is inadequate for starting a new product batch. While industry norms can take 6-12 weeks for delivery, our highly efficient manufacturing operation typically ships products within 5 business days.

We are a preferred vendor for several large corporations in many industries. When planning for filter needs, build in downtime protection and flexibility for new opportunities by qualifying Critical Process products and adding us to your Preferred Vendor list.

CASE STUDIES

Here is sampling of actual customer case studies. These stories describe their filtration challenges, the steps taken to rectify the situation and the final results.

[Solving a Mystery and Preventing Random Filter Clogging](#)

[Improving Upstream Prefiltration and Converting Sterilizing Filters in New Process Design](#)

[Removing Heat Resistant Mold from a Beverage Ingredient](#)

[Filtering a High Value Liquid with Settling Solids](#)



One Chestnut Street
Nashua, NH 03060
603.880.4420

CriticalProcess.com

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