

thermoscientific



## Custom processing services

Cleaning excellence for your critical environment

**ThermoFisher**  
SCIENTIFIC

# The only thing in your container is what you add

Save wasted resources—dedicate your time to the manufacturing process, not cleaning

Thermo Scientific™ Processing Services have the flexibility to meet your container cleanliness requirements. We have the capability to clean glass or plastic containers, stoppers, closures, or other component parts up to 50 L in size. It has never been easier for you to:

- Choose from our wide range of Thermo Scientific products
- Send us your materials
- Ask us to order other products for you

All services and packaging are performed in our ISO 9001–registered facility using certified Class 10 packaging areas in Class 100 clean rooms with documented traceability and GMP compliance.

## Certificate definitions

Process	Definition
Certificate of Conformance	Certificates provided for base products (vials, bottles, carboys, components) from the original manufacturer
Certificate of Process	Certifies that a product was processed according to indicated methods
Certificate of Analysis	Certifies that a product was processed and tested according to laboratory procedures or validated protocols such as USP <788>



# Our services help enable cleaner productions

## Particulate washing service

High-purity water is filtered to submicron levels for particulate cleaning, resulting in product with less than 1/3 of the allowable particulates according to USP <788> and endotoxin levels below 0.25 EU/mL. Particulate cleaning, combined with packaging and sterilization services, alleviates contamination concerns when using downstream in production, for bulk drug storage, and when filtration is not possible. Your single-use critical-containment products are ready to use.

### Applications:

- Any container used in clean room environments to limit particulate entry into processes
- Downstream production of vaccine and biologics, where control of particulates in drug products, drug substances, or drug ingredients is required

## Packaging services

Our customized packaging services include double or triple bagging in the quantity and configuration of your choice—autoclave bags, clean room bags, autoclave wrap, heat-sealed, or tape-sealed bags—all performed in our Class 10 packaging area within the Class 100 clean room.

### Applications:

- Facilitate entry into clean room environments
- Protect product from contamination

## Sterilization services

We offer a number of sterilization services to effectively destroy all viable forms of life, including the option of a validated sterility assurance level (SAL) of  $10^{-6}$  according to USP <71>. Services include gamma irradiation or autoclave options. Several configurations are prevalidated; however, validation, packaging integrity, shelf life studies, and ship testing can all be part of the customized services package.

### Applications:

- Containers for bulk drug product, API, reagents, and media
- Stability studies

## Depyrogenated glass and depyrogenation service

We process glass vials and other containers to meet requested endotoxin levels according to USP <85>. Cleaning and packaging is performed inside a Class 1000 clean room. Depyrogenated vials and containers may also be requested with additional certifications.

### Applications:

- Nonparenteral uses such as water
- Sample and test endotoxins
- Store, transport, and package pharmaceutical or biological compounds
- Store lab reagents and media

## Low total organic carbon services

Total organic carbon (TOC) is a measure of the amount of covalently bound, organic molecules in a water sample. TOC vials can be cleaned and certified to contain fewer than 10 ppb TOC as background.

### Applications:

- USP <643> method testing
- Clean equipment and validate water
- Monitor low-level organic contaminants

## Silanization services

A methyl silylating agent is introduced by vapor phase deposition onto the surface of the disposable glassware. This treatment inhibits materials from adhering onto the surface of the container, allowing for maximum recovery of the contents. Silanization is a process that permanently covers the surface with organofunctional alkoxy silane molecules, reducing material retention and active-site interactions in glass containers.

### Applications:

- Trace organic analysis, such as during cleaning validations
- Store materials prone to adhering to glass
- Extraction glassware

# Critical environment

## Supporting information

### Process definitions

Process	Definition	Common applications	Typical certifications
<b>Particulate cleaning</b>	We use 17 Meg-ohm, pharmaceutical-grade water meeting USP <1231> water for injection (WFI) purity levels for the particulate cleaning process. This low-particle water is heated and used for cleaning processes.	Numerous applications in the pharmaceutical, biotech, medical, and semiconductor industries, and anywhere clean rooms or controlled environments are utilized	Certificate of Conformance Certificate of Process Certificate of Analysis (USP <85>)
<b>USP &lt;788&gt;</b>	Compliance to USP <788> requires that either a product is produced in a clean environment or a product is particulate-washed, such that a validation of this low-particulate limit can be achieved.	Validation generally includes a statistically significant sampling plan, multiple lots, and use of validated equipment/processes	Certificate of Conformance Certificate of Process Certificate of Analysis (USP <788>)
<b>Irradiation</b>	Application of a radiation dose to attempt to destroy all viable forms of life. A typical radiation dose is 25–40 kGy. Thermo Fisher Scientific irradiates glassware, stoppers, seals and certain closures, and plastic bottles. Statements indicating “irradiated” do not mean “sterile” (see “Steam or gamma sterilize” row below).	Injectable or parenteral drugs, lyophilization, and final packaging prior to drug delivery, stability studies, and clinical trials	Certificate of Conformance Certificate of Process
<b>Autoclaving</b>	Application of steam, heat, and pressure to attempt to destroy all viable forms of life, including bacterial spores. Thermo Fisher Scientific autoclaves polypropylene, polycarbonate, and some other plastics/resins. Statements indicating “autoclaved” do not mean “sterile” (see “Sterile” row below).	Numerous applications in the pharmaceutical, biotech, medical industries, and anywhere clean rooms or controlled environments are utilized	Certificate of Conformance Certificate of Process
<b>Certified steam- or gamma-sterilized (USP &lt;71&gt;)</b>	Application of steam or irradiation through a process/dose that has been validated to a Sterility Assurance Level (SAL) of 10 <sup>-6</sup> . Each product must be individually validated.	Wide range of applications, which require that the sterilization process is validated on a specific product	Certificate of Conformance Certificate of Process
<b>Certified depyrogenation (USP &lt;85&gt;)</b>	Destruction and removal of endotoxins. Endotoxins are fever-producing substances commonly found in the cell wall of certain bacteria. Depyrogenated products have reduced endotoxin content by at least 99.9% or 3 logarithmic units.	Injectable or parenteral drugs, lyophilization, and final packaging prior to drug delivery, stability studies, clinical trials	Certificate of Conformance Certificate of Process Certificate of Analysis (USP <85>)
<b>Certified low TOC (USP &lt;643&gt;)</b>	TOC is a measure of the amount of carbon covalently bound in organic molecules in a water sample. Thermo Scientific™ TOC vials are cleaned and certified to contain fewer than 10 ppb TOC as background.	Validation of water systems, equipment validations, cleaning validations, and monitoring low levels of organic contaminants in numerous applications	Certificate of Conformance Certificate of Analysis (TOC <643>)
<b>Silanization</b>	Silanized products have been treated to neutralize active sites in glassware. This process allows materials to remain stable and prevents them from reacting with the glass surface. It also prevents the components of the glass from leaching into the samples.	Proteins, assays of blood serum, and pharmacological assays of therapeutic drugs	Certificate of Conformance Certificate of Process

# Process specifications

## Critical environment final rinse water specifications

USP WFI: Containers

	USP specifications	Typical values
TOC	<500 ppb	10–20 ppb
Conductivity	<1.3 µS/cm	0.06 µS/cm
Bacterial	10 cfu/100 mL	0 cfu/100 mL
Endotoxin	<0.25 EU/mL	<0.06 EU/mL

## Certified platinum clean processing limits

USP <788> low particulate processing  
(Method 1, filtration and microscopic analysis)

Compound	Small volume (≥100 mL)	Large volume (>100 mL)
Particulates ≥10 µm	2,000/unit	6/mL
Particulates ≥25 µm	200/unit	1/mL

Focus on what you do best and leave the cleaning to us

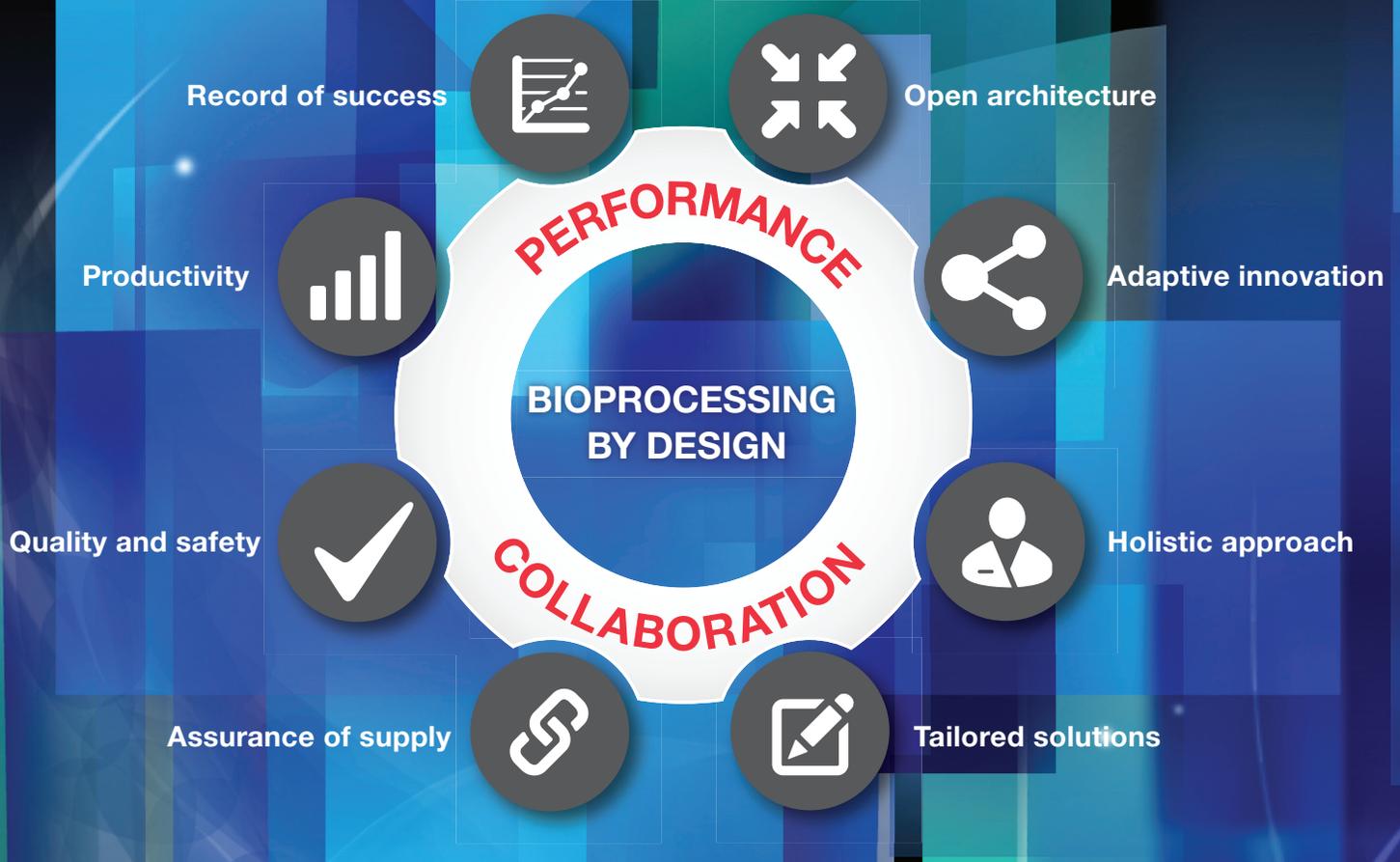
### Custom cleaning specification sheet

When an application requires customization of one or more products and services, request a quote by filling out our Custom Cleaning Specification Sheet, providing as much detail as possible. This sheet can be found via your sales representative, the QC code, or at [thermofisher.com/cleanrequest](http://thermofisher.com/cleanrequest)



If you have any questions, feel free to phone us Monday through Friday, 8:30 am to 4:30 pm ET at 1-800-228-4931 (outside the US: +1-865-717-1986)





# Bioprocessing by Design

## Driving performance through collaboration

To meet the increasing demand for biologics worldwide, you need to expect more from suppliers. It isn't just about the products we deliver, but how we do business together.

With a collaborative approach that is grounded in our technical knowledge, we work with you to achieve optimal bioprocessing outcomes. Committed to identifying the technologies and services that address your needs, from drug development through large-scale commercial production, we provide integrated and tailored solutions that improve the overall biomanufacturing experience. If a solution doesn't exist, we'll build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance. Through technical engagement, innovative product design, and strategic sourcing programs, we deliver productivity, quality, and assurance of supply so that you can have complete confidence in the efficiency and speed of your biologics development and manufacturing processes.

**That's our commitment to you, and it's what we call Bioprocessing by Design.**

Find out more at [thermofisher.com/cleancontainers](https://thermofisher.com/cleancontainers)

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