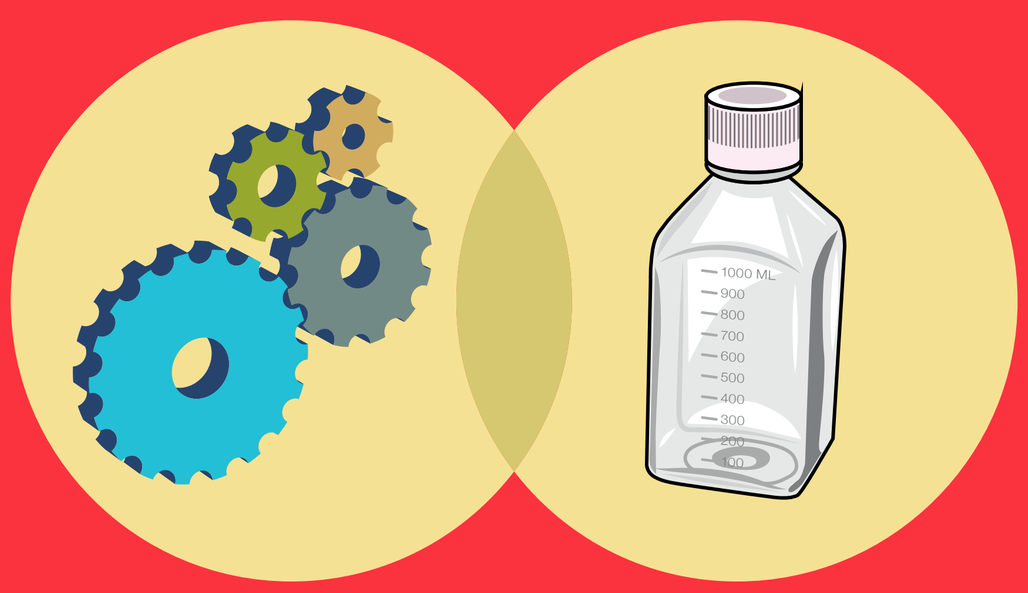
thermo scientific

No matter what supplier you are working with, there are several factors to consider when making the right container choice

Defining validation



Process validation

Product claim validation

First, understanding the validation of a process and its equipment (autoclaving, irradiation, washing, etc.) versus product-claim validation (SAL 10^{-6}, low particulate according to USP<788>, etc.) is key. While the former builds confidence that a process is repeatable, only the latter can confirm that a quantifiable product claim can be met repeatably and reliably.

The meaning of clean

Clean room produced

Provides a level of confidence in container cleanliness, but does not indicate any product certification

Washed

Can remove particulates and reduce endotoxins, but cannot qualify without validation

Irradiated/ autoclaved

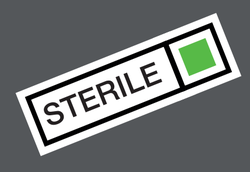
Indicates that a process was applied, but not that the product is validated as sterile

Low particulate

Validated compliance with standards such as USP <788> indicates a qualified particulate load and is likely lot-to-lot tested

Low pyrogen

Pyrogen levels can be validated according to USP <85> and may include lot-to-lot testing



Sterility assurance

Validated sterility ensures every lot meets a sterility assurance level as defined (e.g., USP <71>), but may include lot-to-lot testing

How to choose the right container

Container risks **Wasted time** **Wasted money**

- Select the right container early
- Choose a container based on your application, not just out of convenience
- Conduct studies based on the intended use
- Evaluate single-use options that will save time and resources

Collect and review data

Validation binders*

- Resin-quality information
- Testing and compliance data

Certifications and notifications

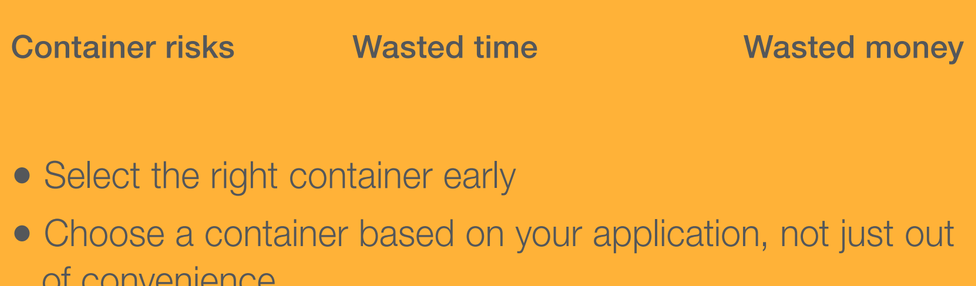
- Testing and processing certificates for sterility, particulates, etc., should be readily available
- Change-notification procedures may help maintain traceability and documentation

Extractables studies*

- Extractables studies may act as a screening tool for container selection
- Studies may be able to assist you in determining if further testing is required

* Forced extraction studies and validation binders from Thermo Fisher Scientific, where available, are provided under confidentiality agreement to assist customers in product selection. Customers are responsible for determining what studies are recommended for its specific applications.

Summary



- Clearly understand process vs. product-claim validations
- Define the certifications and requirements for your application
- Determine necessary documentation for your product application
- Make an informed choice to get the containers and suppliers that are right for you

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