Filter Validation SERVICE

Hall Pyke

At Hall Pyke, we offer filter validation services for customers who need to switch from their incumbent due to technical issues or supply chain issues. Whatever the reason, we are here to assist.

What is filter validation?

Filter validation is the process of confirming that the filter used to sterilize a pharmaceutical product does so adequately by efficiently removing microorganisms. It is a critical step in developing and manufacturing pharmaceuticals that use final filtration as the method for sterilization.

Filterability test

The filterability trial aims to define and confirm the correct sizing and performance of the filter cartridge/capsule in the specific process conditions according to the proposed filtration pathway.

Compatibility test

Compatibility validation studies aim to have documented evidence demonstrating that the filtration process, under simulated worst-case processing conditions, will not affect the filter's physical structure or its ability to perform its stated function; Integrity testing, where applicable, is a "physical test" that relates to microbial retention and is a determinant of compatibility.

Particle Release test

Particle release validation studies aim to have documented evidence of the determination of the quantity of particles that can be released from a filter into the specific product liquid during the filtration process.

Extractables test

Extractables validation studies aim to have documented evidence demonstrating that the process components (filters) used in the specific process will not alter the drug product in terms of safety, identity, strength, quality or purity beyond the official or other established requirements.

Adsorption test

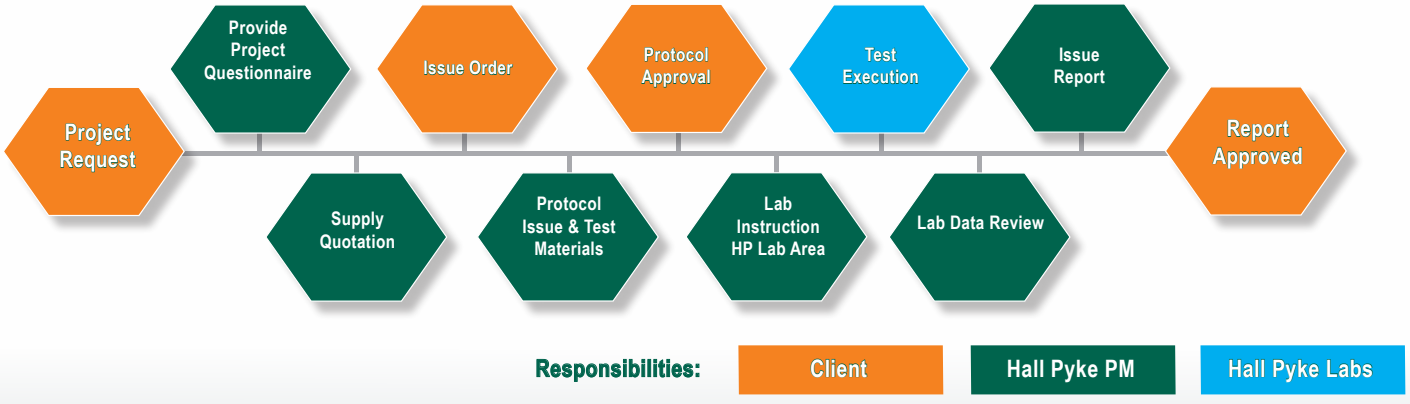
Adsorption validation studies aim to have documented evidence demonstrating that the filter used in the specific process conditions will not bind drug components because this may cause the product to fall below specifications for these ingredients; therefore, if an adsorption phenomenon occurs, this should be addressed.

Bacterial retention test

Bacterial retention validation studies aim to have documented evidence demonstrating that the filtration process will generate a sterile effluent and consistently remove a high level of a standard bacterium suspended in a specific product or surrogate fluid under simulated worst-case processing conditions.

Product-wetted integrity test

A Product-wetted Integrity test aims to determine and provide the specific product's bubble point and forward flow parameters.



Filter validation turn-around time

Our filter validation service allows for quick turnaround times following our 11-step process.

Our lead time offerings are as follows:

Standard lead time: 10-12 weeks

Fast lead time: 8-10 weeks

Fast Plus lead time: 6-8 weeks

Visit us at

www.hallpyke.ie

for more information or to view our full range of services

If you would like to talk to us about your filter validation requirements please email us at info@hallpyke.ie or call us on +353-1-4501411