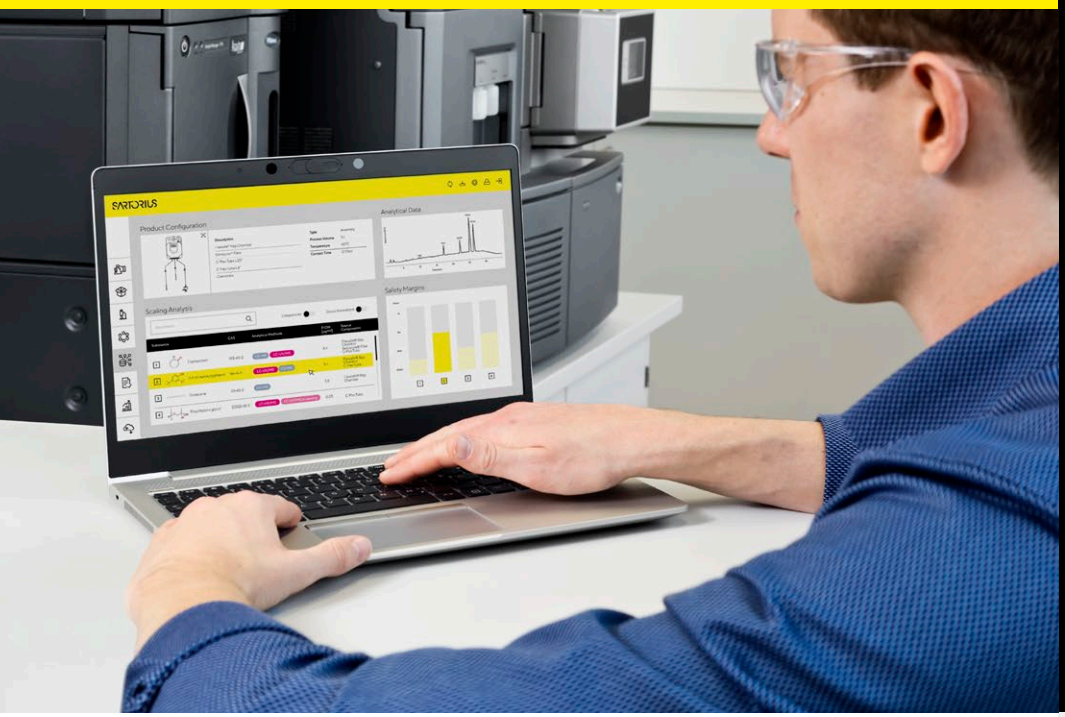
SARTORIUS

Customer Case Study

Reducing Validation Effort Using Extractables Simulation Supported by Sartorius ExSim



Customer Profile

Company Name:
Horizon Therapeutics

Company Type:
Biopharmaceutical Company

Industry:
Health Care

Company Size:
2,000 Employees

Company Revenue:
$3.22 Billion

Company Profile:
www.horizontherapeutics.com/company/about-us

Customer Challenge

Horizon's main objective with this study was to fulfill the validation approach agreed with the FDA for the technology transfer from the American to a European site. The test methods and protocols of the previous validation at the American site had to be replicated. They also faced a tight timeline of five months, between the order and the planned FDA approval.

HORIZON

Background Information

This Extractables study aimed not only to replicate the validation approach of the previous service supplier but also to enable discussions with the FDA at the earliest possible. The possibility to provide regulatory-compliant Extractables Assessments for all assemblies to be tested just 4 weeks after the received order was an important deciding factor to go with the suggested approach from Sartorius.

This validation project shows how physical tests and the prediction of extractables concentration, by the Sartorius Extractables simulator (ExSim), complement each other ideally. This ensures regulatory conformity, decreases the validation effort and enables fast lead times. Eleven single-use assemblies consisting of seven different components, including various tubes, bags, and connectors, had to be validated.

Provided Solution

Horizon divided its validation into two parts: The creation of extractables assessments for all assemblies with the support of the Sartorius Extractables Simulator (ExSim) and extractables studies for all individual components with multiple solvents.

The ExSim provided assembly-specific extractables data which were reported in process step-specific risk assessments, taking into account process module sizes, customer batch volume, and the drug solution to support drug product submission. The complexity of assemblies with up to 16 components could only be mapped into an assessment thanks to ExSim. Thousands of calculations were required to obtain a total extractables concentration of up to 180 different substances (per assembly). Nevertheless, a turnaround time of the assessments of only four weeks enabled early discussions with the FDA.

At the same time, the specific required test methods and protocols were implemented and validated in Sartorius' in-house E&L lab to replicate the previous validation approach.

Project Key Indicators

Keywords:
- E&L validation
- Extractables scalings
- Extractables simulation

Success Criteria:
- Regulatory conform E&L validation
- Fast provision of validation results

Provided Solution:
- Customized validation methods based on a previous validation for another site
- Provision of Extractables Assessments to reduce testing effort

Result:
- Reduction of testing effort from 44 to 28 extractables studies
- Cost savings of 30%
- Simplified future validation of assemblies using the same components thanks to the Extractables Assessment approach

Outcome

By choosing the ExSim-based validation approach instead of a traditional test-only approach, Horizon was able to reduce the number of performed extractables studies from 44 to only 28, resulting in a 30% cost savings. The Extractables assessments further reduced the workload by already providing the rationale and report needed for durg submission for each assembly to regulatory authorities.

Another benefit is increased flexibility for the future: each assembly consisting of the tested components can be validated with a new Extractables assessment in less than a week.

"I can only reiterate that we very much appreciate Sartorius' support. Especially with a request like this. We expected delivery on time, but we were fully aware that the scope of testing was outside what can be called a "standard study order."

Sonja Nicoll
Director, Biologics
Technical Development

At a Glance

Decreased testing effort
28 instead of 44:
– 30% testing effort

Assessment results available
2 months prior
the study results

Raw
Cost savings of €250,000

Before: Common approach – without ExSim

- High testing effort: 11 × 4 = 44 extractables studies
- Not in harmony with component testing approach
- High customer effort in processing data for drug submission

After: With Extractables Assessment Approach

- Decreased testing effort: 7 × 4 = 28 extractables studies + 11 EAR
- Regulatory compliant reports for each assemblies reduced the customer effort
- Cost savings of 30% (= €250,000)
- Future assemblies consisting out of tested components can be validated in less than 1 week, based on EAR
- First Assessment results available 2 months prior the study results

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