SherpaPharma.com

tiselab
Soluciones GMP

SherpaPharma has been developed by a group of companies lead by Tiselab.

Tiselab has been working closely with pharmaceutical companies since 1994, providing them with a range of products and solutions to address their contamination control needs for aseptic processing. Over these years, we have gained an excellent understanding of their requirements and noticed that there was a common lack of tools to properly manage the environmental monitoring process.

V1.1 ENG

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SherpaPharma

Environmental Monitoring Software for the Pharmaceutical Industry

SherpaPharma is a software solution for managing the Environmental Monitoring process in a pharmaceutical company.

SherpaPharma offers you the following benefits:

Time saving
Generate Environmental Monitoring reports instantly, generate trends and statistics on historical data by filtering under any criteria.

Keeping your data secure
Any data modification will be tracked with no deletion possible. Avoid any data losses or transcribing errors. Comply with 21 CFR Part 11 and EU cGMP Annex 11.

Focus on your process
Understand how your facility is working, baseline microbial contamination and excursions, instead of dedicating your efforts to copying data and preparing documents that can be generated automatically.

Mobile device and barcode reader

SherpaPharma uses a mobile app running on a mobile device to track any actions carried out on plates or other media. Keep track of every sample from the moment it is taken to incubation and reading. Use the PC application to plan your samples, track the whole process, and analyse your results.

SherpaPharma improves the quality of the Environmental Monitoring process saving a lot of time.

Features

The following features will help you improving the quality of your Environmental Monitoring process while saving a lot of time.

Extremely easy to use
Quick configuration and scripts to import and validate clean room data, sampling points, and historic results, allow you to start analysing and trending data very quickly.

Data analysis
After results are securely stored in the system, you can instantly start trending historical data, filtering under any criteria or period. Statistics can be automatically generated for each point. Generating statistically based alert values is extremely easy and quick. Information is readily printed in a variety of comprehensive report formats.

Flexibility to adapt to any type of installation
Your production areas and departments can be configured in the system together with clean rooms, sampling points, etc., even independent production plants for the same company. The system accepts the following types of samples: air (settle plates and dynamic sampling), surfaces (contact plates and swabs), water, personnel, compressed gas, products (raw materials, intermediate products and final products).

Data Integrity
The software has been designed with data integrity requirements in mind as well as for full compliance with FDA CFR21 Part 11 and EU GMP Annex 11. From the moment data is entered into the system, any modification will be fully tracked through a filterable audit trail.

Developed for users
From the very beginning of its development, SherpaPharma has been designed according to the requirements and advice of real users in pharmaceutical companies. We continuously listen to our users and evolve the system to meet their needs.

Cloud or on-premises computing
You can benefit from having a fully validated installation in the cloud or, if you prefer, a local server and in-house installation. Both options are available.

Flexible pricing to adapt to any installation size
SherpaPharma is not only designed for pharmaceutical factories generating hundreds of thousands of samples per year but also for medium and small facilities which also require an effective tool to control their Environmental Monitoring process.

Planning
You can use your SOPs to define your sampling plans in the system and schedule them on the calendar. You are then able to follow the entire lifecycle of the process (sampling, incubation, reading, identification and approval).

Tracking
The system tracks every plate, linking it to the point and the operator responsible for each sample. When receiving plates in the lab, the software tracks the defined incubation process, reading of results and identification. Alerts are generated if results are higher than limits. Plates are easily read using a cleanroom compatible barcode reading device.