



# SherpaPharma

Short Manual





**SherpaPharma**

The Sherpas are known to help climbers reach the top. Thanks to them, the most important landmarks of climbing have been achieved.

SherpaPharma pursues this same philosophy and is developed to help pharmaceutical companies to successfully carry out environmental monitoring processes easily and safely.



## SherpaPharma

SherpaPharma uses an application and a mobile device with barcode reader that are in continuous synchronization.

Through the web application the plant and the users are configured, samples are planned and tracked. Reports and trend graphs can be generated.

The mobile device works inside the clean rooms and laboratories and collects all information from sampling, incubation and reading of samples.

## Access to the system

Access to the web application is done through Google Chrome. SherpaPharma has two environments, Pre-production, used for testing and training, and Production.

The application is accessed through the following links:

Pre-Production > <https://dev.sherpapharma.com>

Production > <https://app.sherpapharma.com>

## Support pages

Access to the User's Manual with explanations of the fundamental aspects of each of the SherpaPharma sections can be found in the upper right corner of the screen.

<User name> ▶  **User Manual**

There is also a page with interactive videos that define, step by step, the most common processes and actions within the SherpaPharma software. It is accessed through the menu mentioned above.

<User name> ▶  **Training videos**

For any technical question, you can send an email to our support team: [support@sherpapharma.com](mailto:support@sherpapharma.com)

### Register users

Users can be registered from the User management section accessible with the Supervisor profile.



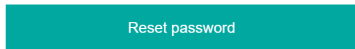
### Activate your account

Users will receive an email from SherpaPharma with a link that will redirect them to the SherpaPharma home page to define their access password. In SherpaPharma, your username is your email address.



Dear: User 1

This is an automatic message form SherpaPharma.  
Click on the link below to reset your password.



Best regards  
Your Sherpas team

### User settings

User settings such as changing the language of the application or updating the password can be found in the Settings tab within the Administration section.



### Audit Trail review

From the moment of sampling, until its incubation and reading, the system maintains the complete traceability of the process. To approve a specific Audit Trail action, check the box to the left of the row and click on approve. \*

The screenshot shows the 'Audit Trail' section of the application. It includes a sidebar with navigation options like 'GENERAL', 'MASTER MAINTENANCES', and 'ADMINISTRATION'. The main area displays a table of audit trail entries with columns for Date, Action, Object, Name/Code, User, Modified field, Old Value, and New Value. The first row is highlighted, and the 'Approve' button is visible above the table.

Date	Action	Object	Name/Code	User	Modified field	Old Value	New Value
2018/02/21 16:01	Modify	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Cfu Molds		0
2018/02/21 16:01	Modify	Sample Session	Plant-EN-2018/06/06-16EE	user.1	Status	Samples Completed	Results Compl
2018/02/21 16:01	Modify	Result	RES_CODE_Plant_EN_3672	user.1	Status	Sampled	In Incubation 1
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Incubator		Inc001
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Time Start		15:01
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Start User		Mar.Ribera
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Date Start		2018/02/21
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Temperature		30
2018/02/21 16:01	Create	Incubation 1	RES_CODE_Plant_EN_3672	user.1	Date End Estimated		2018/02/21 16:01
2018/02/21 16:00	Modify	Result	RES_CODE_Plant_EN_3672	user.1	Media Id		100001153012c

\* Audit Trail elements can only be approved from the Supervisor or Approval profile.

### Types of sampling points

The following types of samples are compatible with the system:

- Air (settle plates and dynamic samples)
- Surfaces (contact plates and swabs)
- Water
- Gas
- Personnel
- Product (raw materials, intermediate product, finished product)

### Modification, approval and deletion of elements

The following commands are located at the top of each table: edition, approval and deletion of items. Select an item using the selection boxes and click on the desired action.

GENERAL

- + Samples Management
- + Sampling Plan
- + Calendar
- + Import Excel

MASTER MAINTENANCES

- + Organization
  - Plants
  - Departments
  - Areas
  - Rooms
  - Units

#### Areas

New Approve Delete Show Deleted

Select Page Select Current Filtered Clear Selection

Name	Description	Approve
<input type="checkbox"/> Zone A-B		Approve
<input type="checkbox"/> Zone B		Approve
<input type="checkbox"/> Zone C		Approve
<input type="checkbox"/> Zone D		Approve
<input type="checkbox"/> Personal		Approve

Showing 1 to 5 of 5 entries

Show 10 rows

### Filters, reports and trends

Any of the filters in the sample table can be used for sample analysis.

#### Samples

Plan Sample Media Incubation Result Identification Products

From: 2018/04/17 To: 2018/06/01 Reload Table

New Approve Delete Show Deleted Data Analysis Reports

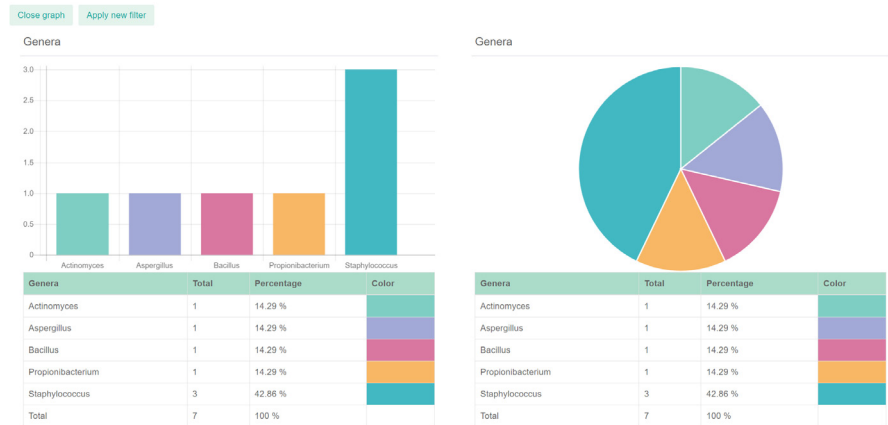
Select Page Select Current Filtered Clear Selection

Result	Sample Type	State	Sample Session	Planned Date	Point	Alert	Action	Class	Room	Department	Area	Plant
<span>⊘</span>	Settle	IN INCUBATION 1	Plant-EN-2018/04/03-NRIP	2018/04/03 09:00	F. Iso. -TA3	1	1	A	Pack. Iso.	Production	Zone A-B	Plant EN
<span>⊘</span>	Settle	PLANNED	Plant-EN-2018/04/17-NRIP	2018/04/17 09:00	F. Iso. -TA3	1	1	A	Pack. Iso.	Production	Zone A-B	Plant EN

### Trends per point



### Identification graphs



Genera	Total	Percentage	Color
Actinomyces	1	14.29 %	
Aspergillus	1	14.29 %	
Bacillus	1	14.29 %	
Propionibacterium	1	14.29 %	
Staphylococcus	3	42.86 %	
<b>Total</b>	<b>7</b>	<b>100 %</b>	

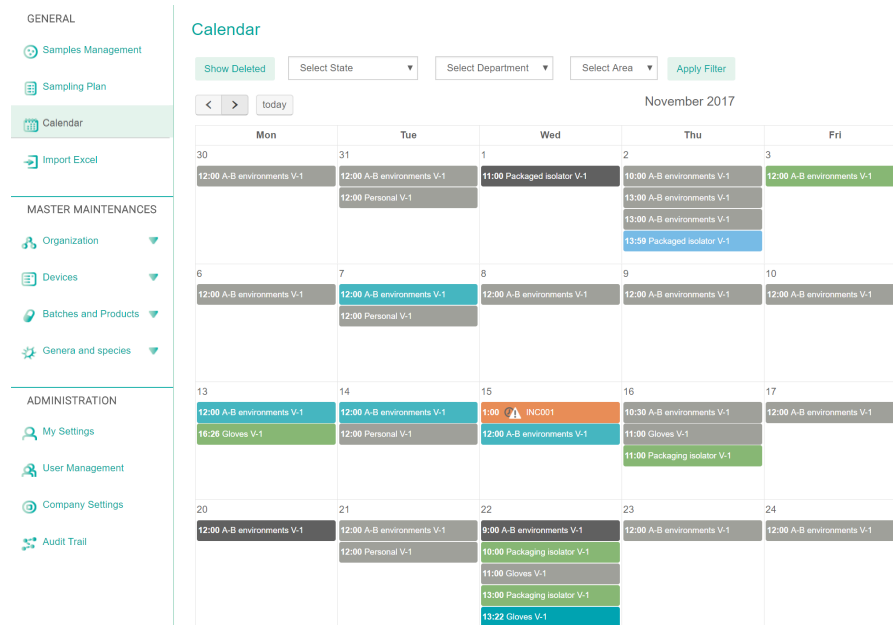
## Sampling Plans

A sampling plan is a set of sampling points that a company wishes to group to sample periodically.

You can access the sampling plans from the menu on the left of the screen.

GENERAL ▶  Sampling plans

Sampling plans can be defined in the system according to their NTPs and planned in the calendar through sampling sessions. From then on, you can follow the complete life cycle of the samples (sampling, incubation, reading, identification, review and approval).



The screenshot shows the SherpaPharma interface. On the left is a sidebar menu with categories: GENERAL (Samples Management, Sampling Plan, Calendar, Import Excel), MASTER MAINTENANCES (Organization, Devices, Batches and Products, Genera and species), and ADMINISTRATION (My Settings, User Management, Company Settings, Audit Trail). The main area displays a 'Calendar' for November 2017 with a grid of sampling sessions. Each session is represented by a colored block with a time and activity name, such as '12:00 A-B environments V-1' or '11:00 Packaging isolator V-1'. A 'today' button is visible above the calendar grid.

## BCR buttons

1


It is used to lock or unlock the screen in case it is off.


2

They are used interchangeably to read the barcode. The barcode reader will be active when ACTIVE SCANNER is displayed on the BCR screen.

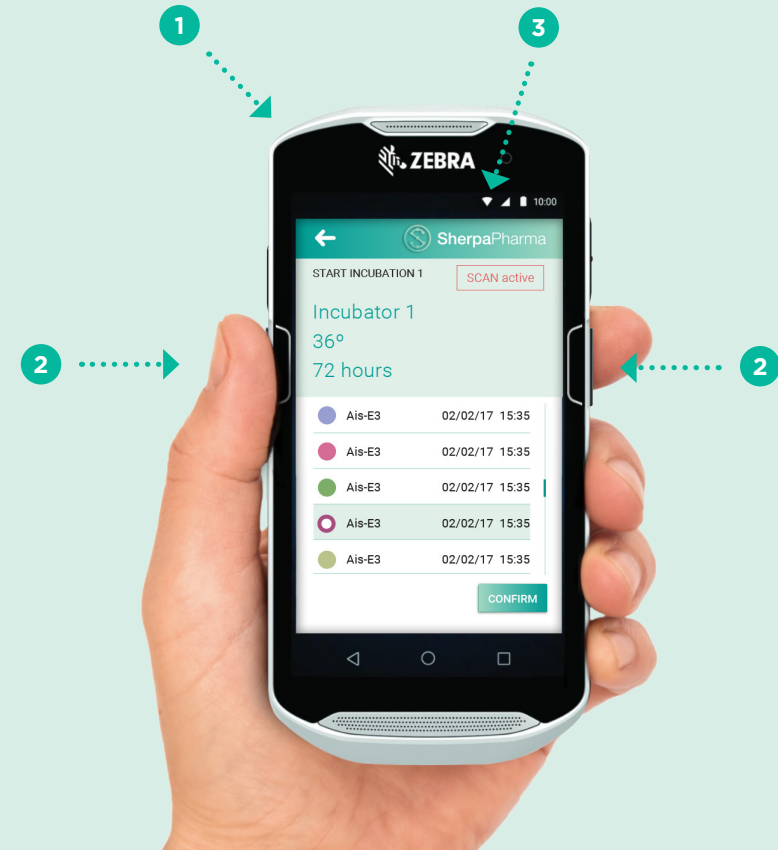
3

For the SherpaPharma software to work properly, the Wi-Fi signal must appear active. If the Wi-Fi is inactive, access to the software will not be possible.

 Active Wi-fi

 Inactive Wi-fi

ACTIVE SCANNER



## BCR disinfection

The cleaning agent you select for BCR disinfection must contain one of the active ingredients approved in the following table:

### ACTIVE INGREDIENTS OF CLEANING AGENTS

APPROVED	
✓	Isopropyl alcohol
✓	Bleach/sodium hypochlorite
✓	Hydrogen peroxide
✓	Mild dish soap
✓	Ammonium Chloride
NON-APPROVED	
✗	Ammonia solutions
✗	Compounds of amines or ammonia
✗	Acetone
✗	Ketones
✗	Ethers
✗	Aromatic and chlorinated hydrocarbons
✗	Aqueous or alcoholic alkaline solutions
✗	Ethanolamine
✗	Toluene
✗	Trichloroethylene
✗	Benzene
✗	Carbolic acid
✗	TB-lysoform

The cleaning of the BCR is done daily and follows the following steps:

- 1 Dampen a soft cloth with one of the approved cleaning agents listed above or use pre-moistened wipes:
  - Never apply liquid directly to the BCR device.
  - Do not let liquid pool around the display window or any other area on the device.
- 2 Gently wipe all surfaces, including the front, back, sides, top and bottom - do not wrap the device in the cloth or pre-moistened wipe.
  - Special instructions when cleaning the front of the device:
    - Be sure to clean the keys and between the keys (use a cotton-tipped applicator to reach between the keys).
    - After cleaning, immediately dry the display with a soft non-abrasive cloth to prevent streaking.
- 3 Allow the unit to air dry before use.



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.





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