



*Knowledge, Skills and Passion.*

**PDBM** Project  
Data  
Base  
Manager

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# What is PDBM?

- PDBM is advanced data management **application** which provides **complete control of process data**.
- Application is **based on modular approach**.
- PDBM is **fully user configurable**.

The screenshot displays the PDBM software interface. At the top, there is a menu bar with options: Home, Work orders, Main recipes, Recipes, Access management, User management, Audit trail, Reports, and Configuration. Below the menu bar is a toolbar with icons for various actions like 'Set GMP status', 'Activate', 'Deactivate', 'Add', 'Edit', 'Edit SFC', 'Copy', 'New version', 'Delete', and 'Preview'. The main area is divided into two sections. The top section is a table with columns: Name, Description, Version, Product name, and GMP status. The bottom section is a process flow diagram showing a 'Start' node leading to three 'Operation\_test1' nodes, which then lead to two more 'Operation\_test1' nodes. On the right side, there is an 'Edit' panel with a 'Parameters' table.

Name	Description	Version	Product name	GMP status
Sample Recipe 1	Sample Description 1	1		In preparation - Deactivated
Sample Recipe 2	Sample Description 2	1		In preparation - Deactivated
Sample Recipe 3	Sample Description 3	1		In preparation - Deactivated

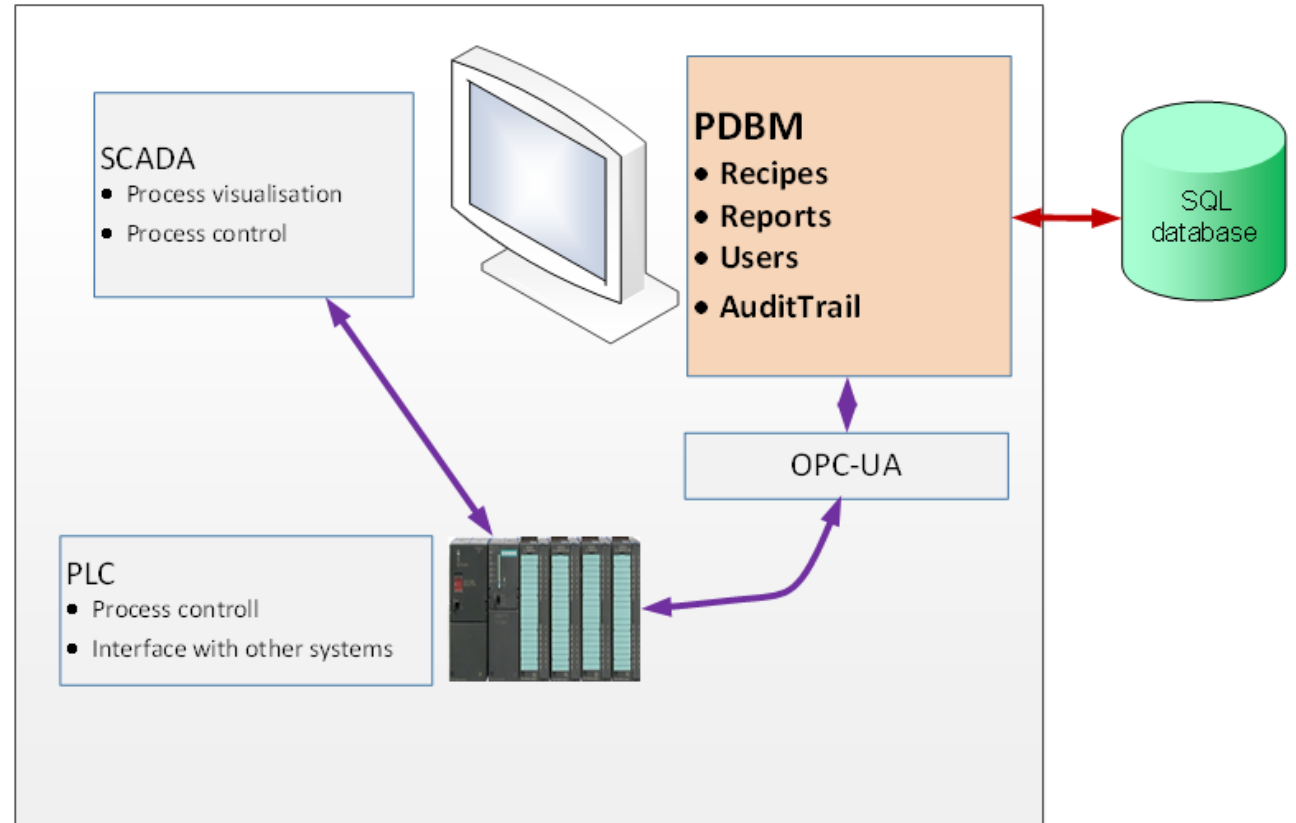
Parameter	Value	Minimal process va...	Maximal
Media Type	Off	-	-
Media quantity setpoint	50.00	0.00	1200.00
Homogenization time	00:15:00	00:01:00	24:00:00





# How does it work?

- PDBM manages data associated with an industrial automated production process **while communicating with external equipment** through OPC-UA data exchange standard.
- PDBM application uses **SQL database** as data repository.





# How does it work II?

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- Application **is used for full ERES compliance** and is managing recipes, reports, audit trail and user group rights.
- It can be deployed as **stand-alone Windows application** or **as integrated application into the SCADA environment.**





# Benefits & Advantages of PDBM

## **PDBM Benefits**

- Is fully user configurable
- Is CFR 21 Part 21 compliant (electronic signature, audit trail)
- Is intuitive and easy to use
- Provides graphical user interface
- Provides integration with Active Directory
- Provides multi-language support
- Supports touch screen displays
- Is based upon modern SFTW frameworks and practices





# PDBM Features

## PDBM Features

- Modules:
  - Recipes
  - Reports
  - Audit Trail
  - User management
  - Access management
  - Configuration
- Modern interface with hamburger menus and ribbon bars
- Industry standard OPC-UA communication





# Why PDBM?

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PDBM with modular approach provides the means to:

- **play the challenges**
- **reduce the costs**
- **mitigate the risks**

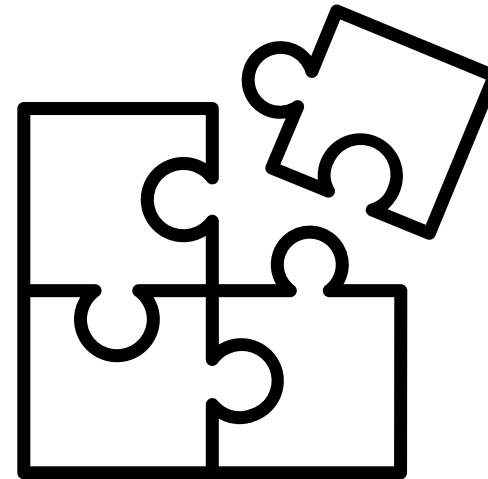




# Benefits of the modular approach

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- Flexibility
- High standardization
- Setup time optimization
- Efficiency
- Consistency



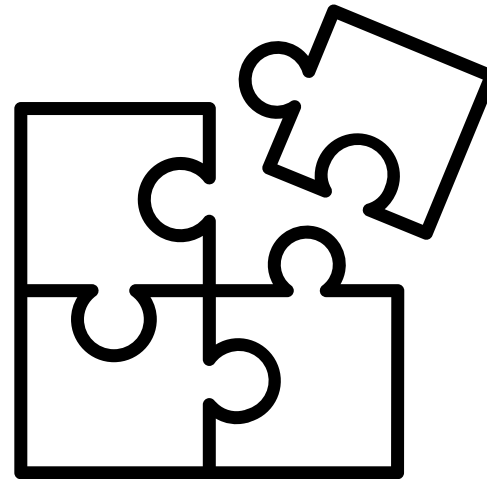




# Modules

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1. Recipes
2. Reports
3. Audit Trail
4. User Management
5. Access Management
6. Configuration





# 1. Module - Recipes

Industrial processes are usually executed according to a predefined recipe.

This module is used to create new, maintain existing and remove obsolete recipes for various types of production processes.

It supports SFC definition of recipes, recipe versioning, approval mechanism, organizing into batches and work orders and categorizing into recipe types.



# Recipe creation



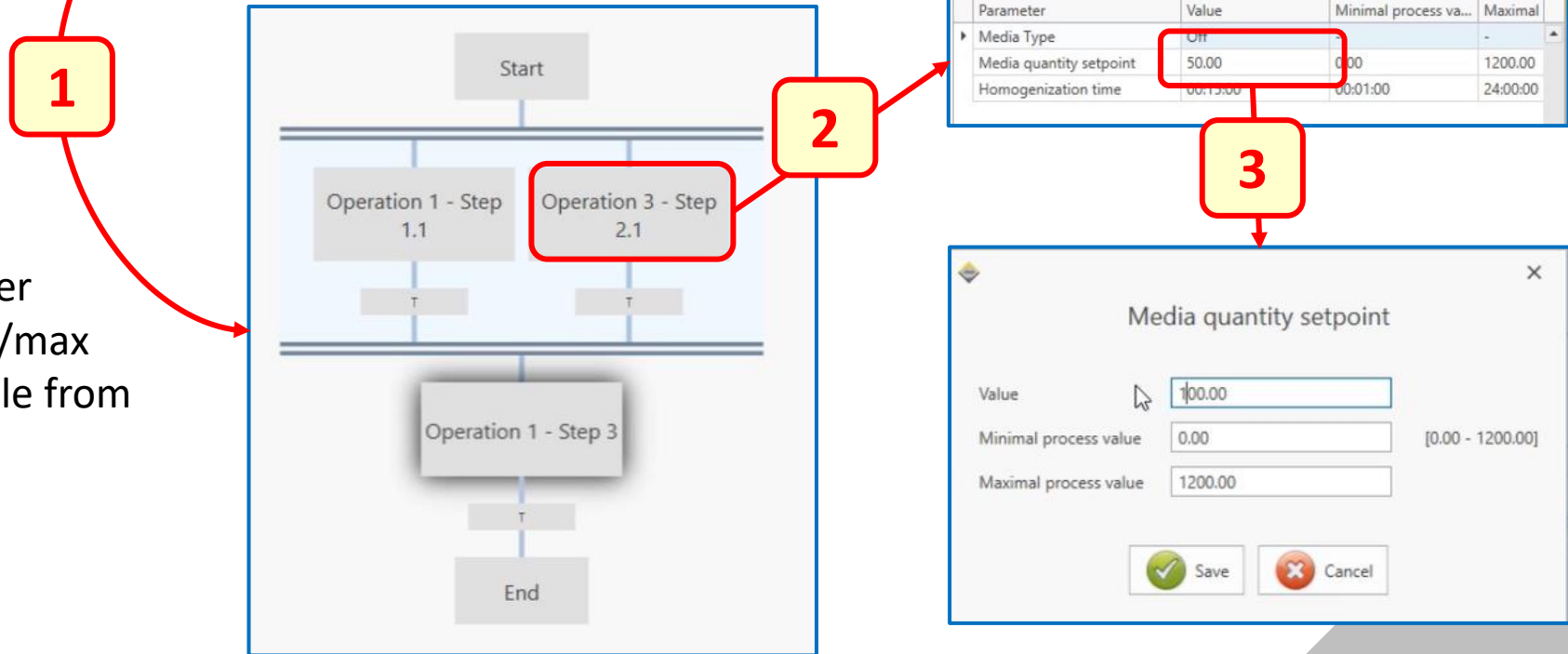
1) Create a SFC that fits your process

(SFC= Sequential Function Chart)

Name	Description	Version	Product name	GMP status
Sample Recipe 1	Sample Description 1	1		In preparation - Deactivated
Sample Recipe 2	Sample Description 2	1		In preparation - Deactivated
Sample Recipe 3	Sample Description 3	1		In preparation - Deactivated

2) Define parameters for every operation that is defined in the SFC


3) The values for every parameter are limited with predefined min/max limits. They can be also selectable from the drop-down list.



# Recipe report example

- Each recipe can be printed to be reviewed and approved





**Local recipe** 11.02.2016  
**MRP -** 09:50:15  
*RecID: 124*

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**Recipe type:** SIPCV\_0407  
**Name:** test\_SIP\_CV0407 **Status:** In preparation-Activated  
**Version:** 1  
**Description:**

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**Operations:**  
SIPCV\_0407

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Selected object : CV0407

Required sterilization temperature : 121,0	°C
Required time of sterilization : 00:01:00	hh:mm:ss
Cooling temperature set point : 65,0	°C





## 2. Module - Reports

After the industrial process is completed, the PDBM reports module comes into play.

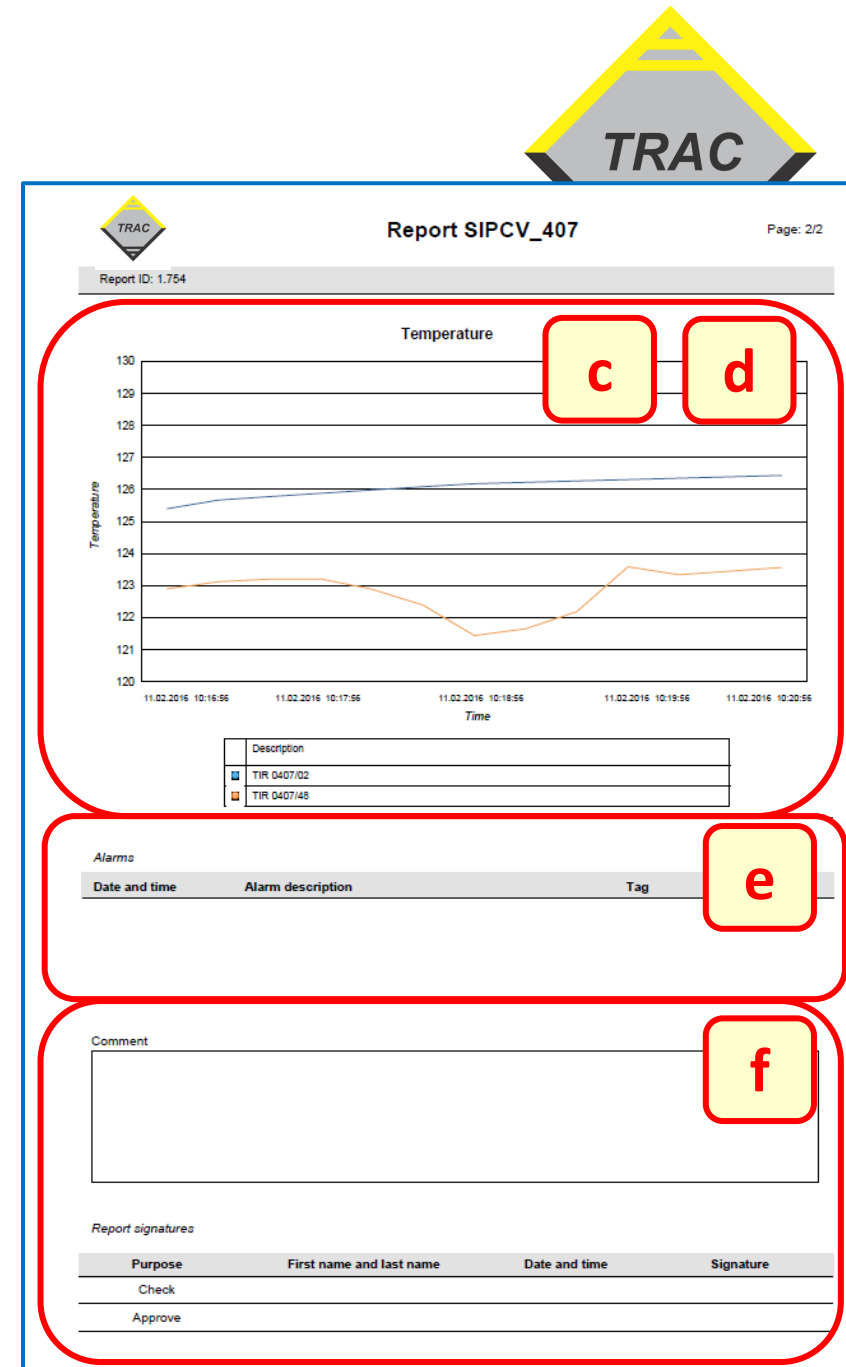
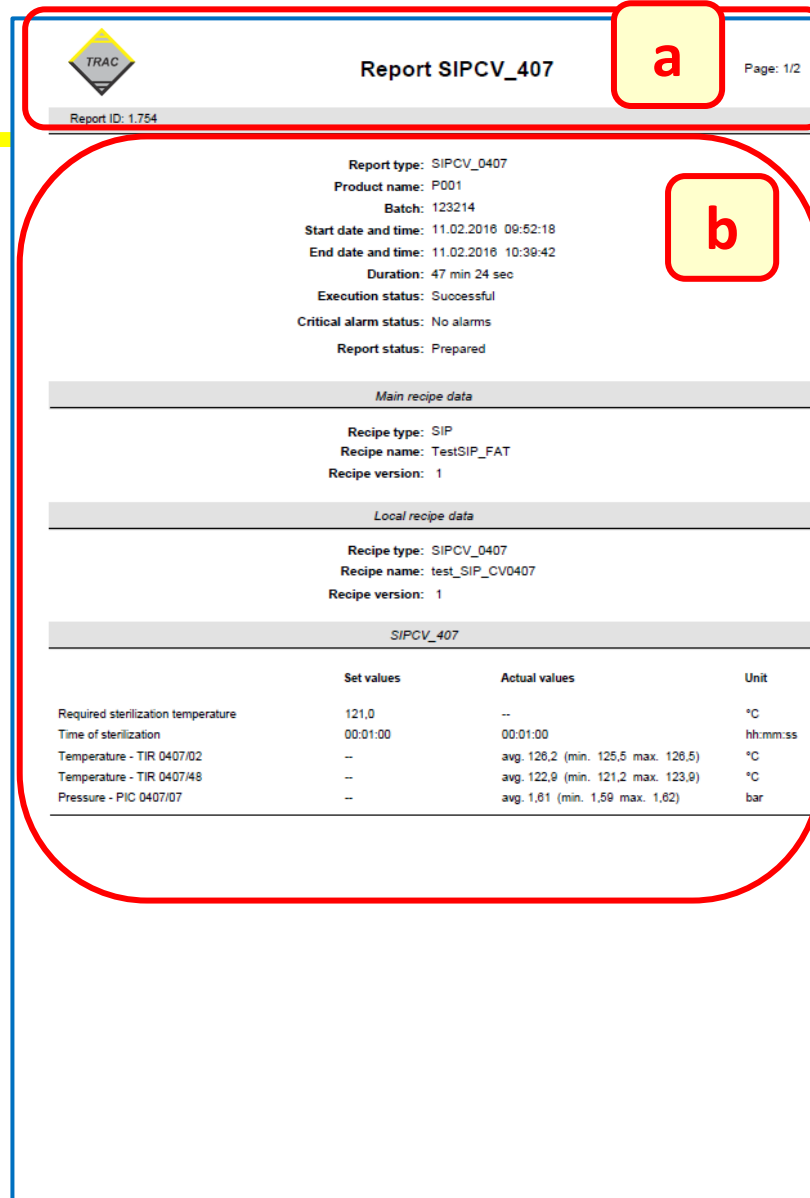
Besides previewing and exporting the reports, the reporting PDBM Reports module gives the user complete freedom to configure the report's look and feel.

Reports are generated based on the data provided by the external production system while the PDBM application ensures report integrity and safe storage in the database.



# Report example

- 1) Create a custom report layout that suits your requirement.
- 2) Report can be composed of the following report segments:
  - a) Header
  - b) Process data body
  - c) Trending data graph
  - d) Trending data table
  - e) Events
  - f) Review area





## 3. Module – Audit Trail

Deeper analysis of the process execution and compliance with regulatory standards.

PDBM Audit Trail module keeps records of anything that is happening within the process.

Various types of events are supported:  
*from* alarms, authentication events and application events  
*to* user defined events that are fully configurable to fit the demands of the external system.



# Audit trail - example



- 1) Filtering data on various parameters
- 2) List of all events in the tabelarical form
- 3) Can be printed on the paper or exported as PDF/XLS

The screenshot shows the TRAC Audit trail interface. The navigation menu on the left has 'Records' selected. The main area has a filter section with checkboxes for 'Occurred after', 'Occurred before', 'Type', 'Source', and 'Username'. Below the filter is a table of audit events. Red callout boxes with numbers 1, 2, and 3 highlight the filter section, the table, and the 'Audit trails' button respectively.

Timestamp	Type	Source	Username	Description
10/08/2020 14:25:24	Event	PDBM	trac	//step /parameter Media quantity setpoint Value - changed from 1000.00 - to 100.00
10/08/2020 14:42:42	Event	PDBM	trac	Access right "PDBM Settings" was added to user group "MAINTENANCE".
10/08/2020 14:42:42	Event	PDBM	trac	Access right "PDBM Settings" was added to user group "SUPERVISOR".
10/08/2020 14:42:19	Event	PDBM	trac	Access right "R1" was added to user group "ADMINISTRATOR".
10/08/2020 14:42:30	Event	PDBM	trac	Access right "R1" was added to user group "OPERATOR".
10/08/2020 14:42:30	Event	PDBM	trac	Access right "R1" was added to user group "SUPERVISOR".
10/08/2020 14:42:19	Event	PDBM	trac	Access right "R1" was added.
10/08/2020 14:40:52	Event	PDBM	trac	Access right "RIGHT 1" was added to user group "ADMINISTRATOR".
10/08/2020 14:41:11	Event	PDBM	trac	Access right "RIGHT 1" was added to user group "OPERATOR".
10/08/2020 14:41:11	Event	PDBM	trac	Access right "RIGHT 1" was added to user group "SUPERVISOR".
10/08/2020 14:40:52	Event	PDBM	trac	Access right "RIGHT 1" was added.
10/08/2020 14:41:49	Event	PDBM	trac	Access right "RIGHT 1" was removed.
10/08/2020 14:44:10	Event	PDBM	trac	App user "TEST" was added.
10/08/2020 14:20:19	Event	PDBM	trac	Data interpretation of parameter with id "2" was changed from "Enumeration" to "De
10/08/2020 14:20:19	Event	PDBM	trac	Length of parameter "Media quantity setpoint" was changed from "15" to "".
10/08/2020 14:15:59	Event	PDBM	trac	Login







## 4. Module – User Management

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In modern industrial sites different users can operate different aspects of the production process.

PDBM User Management module allows the administrator to manage users that can access the PDBM application and organize them into user groups.

Integration with active directory is also supported.



# User management- example



- 1) User groups are defined according to the project requirements
- 2) Each user is assigned to one of the user groups

Users can be

**local** - password verification is done on the local computer

**domain**, where the authentication is done on the domain server.

In both cases the password data transfer and its storage are made in a secure encrypted way.

- 3) The access configuration can be printed on the paper or exported as PDF/XLS

Username	First name	Last name	User group	locked	Email
admin			ADMINISTRATOR	<input type="checkbox"/>	
trac	TracName	TracLastName	ADMINISTRATOR	<input type="checkbox"/>	
operator_local	OperatorName	OperatorLastName	OPERATOR	<input type="checkbox"/>	
supervisor_local	SupervisorName	SupervisorLastName	SUPERVISOR	<input type="checkbox"/>	
maintenance_local	MaintName	MaintLastName	MAINTENANCE	<input type="checkbox"/>	
qa_local	Qa Name	Qa Last Name	QA	<input type="checkbox"/>	info@trac.si
administrator_local	AdminName	AdminLastName	ADMINISTRATOR	<input type="checkbox"/>	





# 5. Module – Access Management

Minimize the risks of data misuse with finely grained control over the access rights and system.

Module supports adding internal and external user-defined access rights resulting in a fully customizable access management solution.

When even stricter access control is required, the PDBM application supports electronic signatures that must be signed before the requested action can be executed.



# Access management- example



1) Every activity or button has its own **Access right property**

This property can be configured selectively to every user group

Valid for PDBM, SCADA and HMI

2) Definition which activities have to be verified with two-layer verification with electronic signature or electronic confirmation

3) The access configuration can be printed on the paper or exported as PDF/XLS

The screenshot displays the 'Access management' section of the TRAC software. The navigation menu on the left includes 'Access rights', 'Access right groups', and 'Electronic signatures' (highlighted with a red box and labeled '2'). The main area shows a table of access rights for various activities across user groups. A 'Preview' button is highlighted with a red box and labeled '3'. A red circle highlights the table content, with a '1' in a red box pointing to it.

Access right	ADMIN...	OPERATOR	SUPE...	MAINTENA...	QA
PDBM					
PDBM Settings	✓	✗	✗	✗	✗
Recipes - : Tab	✓	✗	✗	✗	✗
Recipes - Recipes: Menu	✓	✗	✗	✗	✗
Recipes - Recipes: New	✓	✗	✗	✗	✗
Recipes - Recipes: Edit	✓	✗	✗	✗	✗
Recipes - Recipes: Delete	✓	✗	✗	✗	✗
Recipes - Recipes: Preview	✓	✗	✗	✗	✗
Recipes - Recipes: Copy	✓	✗	✗	✗	✗
Recipes - Recipes: New version	✓	✗	✗	✗	✗
Recipes - Recipes: Can access unapproved a...	✓	✗	✗	✗	✗
Recipes - Recipes: Edit SFC	✓	✗	✗	✗	✗
Recipes - Recipes: Set GMP status	✓	✗	✗	✗	✗
Recipes - Procedural element: Menu	✓	✗	✗	✗	✗
Recipes - Procedural element: New	✓	✗	✗	✗	✗
Recipes - Procedural element: Edit	✓	✗	✗	✗	✗
Recipes - Procedural element: Delete	✓	✗	✗	✗	✗
Recipes - Parameters: Menu	✓	✗	✗	✗	✗





# 6. Module – Configuration

Freedom to configure all aspects of the PDBM

Configuration module gives the user complete freedom to configure PDBM: *from* process-oriented elements such as operations with their parameters, measurement units and sensors *to* user interface elements such as translations of user data and table layouts.





# Play the challenges with PDBM

## PDBM

- Is developed to **address data management challenges**
- **Simplifies complete control** of the process data
- **Helps mitigate the risks** of data management
- **Shortens process time**





# FMAP

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## PDBM

While **operated as part of FMAP platform** which integrates process and analytical equipment into a single platform allowing user to run the whole process through unified and simple interface **top notch service for most demanding users is provided.**

## FMAP

The Flexible Modular Automation Platform (FMAP) is an innovative platform that sets **a new standard for data and process control.**





# About TRAC

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**Thank you for  
placing your  
confidence with  
TRAC**

Our **strategy** is to continuously develop and improve in order to be able to design and develop new automation solutions within different industries.

**We strive** to be recognized within an industry as a unique, reliable developer and trustable solution finder!







# About TRAC

[www.trac.si](http://www.trac.si)

<b><u>1992</u></b> since	<b><u>28+</u></b> countries	<b><u>500+</u></b> finished projects
over 25 years experiences in the pharmaceutical industry	global presence	successful complex and high- tech projects in different areas:

