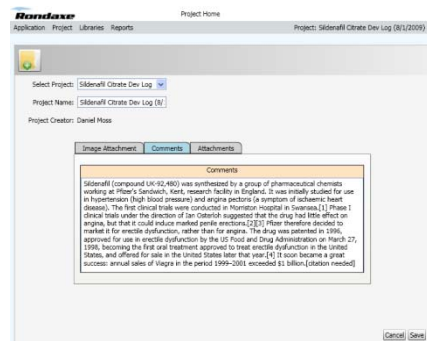


Rondaxe

Development Log 2.0 - How to Guide

Rondaxe Development Log is a software application that allows you to manage all aspects of a drug development project. The software allows the user to collect data and organize into interactive data display screens and reports. This allows a single source where data can be stored and managed in an intelligent way. It will allow users to dynamically interact with data in new ways.



This document is intended to provide an outline of the functionality and overview of instructions and includes additional information on new functionality that has been added.



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General Guideline for Using

In order to populate the Development Log, the following guidelines are useful guide to follow in order to efficiently build the database.

1. Begin by populating the libraries with the basic information for your project: Materials (raw, starting, intermediates, API), Vendors & Impurities.
2. Build Processes.
3. Build Synthetic Routes
4. Build Material Specifications
5. Populate Batches & Results

Remember to SAVE   your work at regular intervals and when moving between pages/tabs. This will avoid any inadvertent loss of your work.

General Navigation

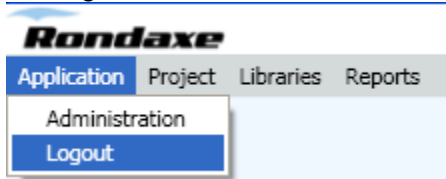
User the Main Menu Bar to move within the application



The navy color highlights the menu item that you are on. Note the project name is always indicated on the right side of the menu bar.



To Log Out follow the Menu Path: [Application](#)> Log Out.





Icons

The following Icons are common within the application

Attach File	
Add / Remove Files	
Add Milestone	
Create a New Project	
Comments	
Create New Entry/Process	
Delete	
Export Table	
Open Attachment/File	
Paste from Clipboard	
Save	
Select a Date	
View / Zoom	

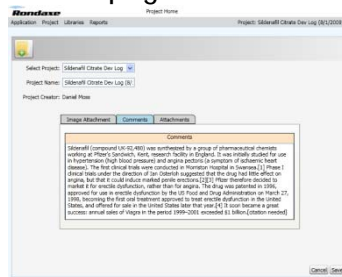


Logging In

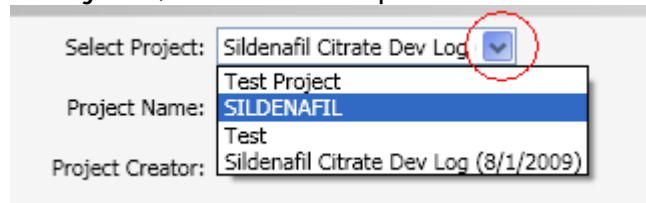
Point your browser to the link for Development Log
Enter your name, password, and client.

Client:
Username:
Password:

Application brings you to the front page of the last Project you worked on.



To switch between Projects, select the drop down menu.

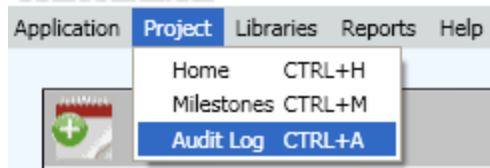


Your administrator will have access to create new projects in the application.
To navigate between different projects select from the drop down menu and
the application will navigate to the selected project.



Audit Log

The Audit Log allows you to see changes that have been made in the system.



User can select all changes or else filter results by area and click FILTER. This report can be exported to excel if required.

Rondaxe Audit Log

Application Project Libraries Reports Help Project: Sildenafil Citrate Dev Log (8/1/2009)

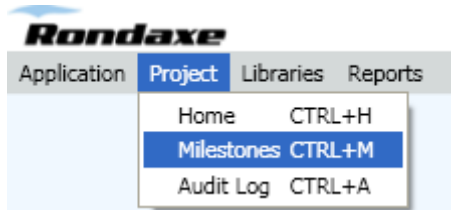
Filter By Source: Vendors [Filter] [Export]

Log Source	Log Item	Log Time	Action Type	Login Nam	Last Name	First Name
Vendors	Vendot 21	7/30/2009 2:01:43 PM	Vendor Modified	dmoss	Moss	Daniel
Vendors	Sigma Aldrich	7/30/2009 2:06:26 PM	Vendor Added	dmoss	Moss	Daniel
Vendors	Sigma Aldrich	7/30/2009 2:06:37 PM	Vendor Modified	dmoss	Moss	Daniel
Vendors	Sigma Aldrich	7/31/2009 4:03:39 PM	Vendor Modified	dmoss	Moss	Daniel







Milestones Information

Click on the Milestones Info tab to see Milestone information for the project.




Use Add New Milestone button to add 

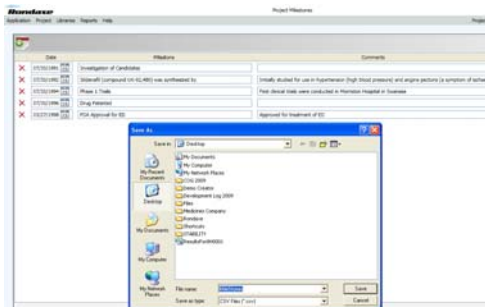
	Date	Milestone	
	07/30/1991 	Investigation of Candidates	
	07/30/1992 	Sildenafil (compound UK-92,480) was synthesized by	Initially

Add date information, Milestone Title, Description, attach relevant files etc.

To Edit a milestone select the line, make any adjustments and SAVE.

To delete a milestone, select the delete icon for that milestone.

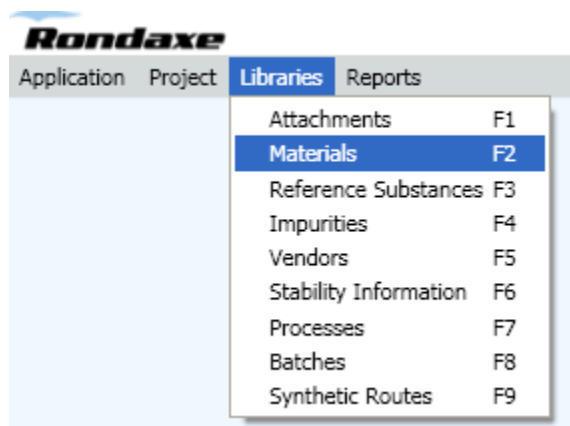
To Export the list to an excel worksheet click the Excel icon  and you will see a dialogue box to open or save the exported file.





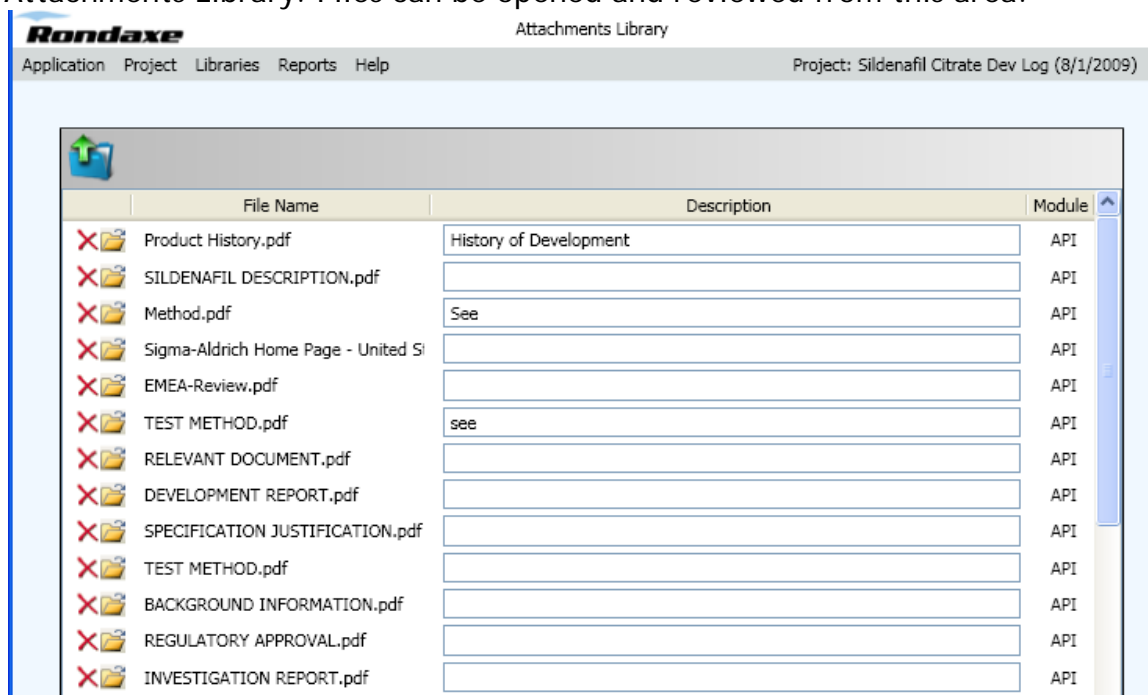
Libraries

The Development Log data libraries are where the user will build the foundation data for the entire application. Access this from the main menu bar.



Attachments Library

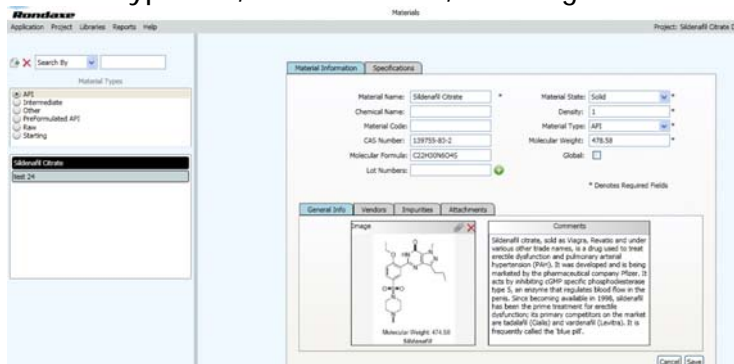
All attachments associated with particular projects can be found directly in the Attachments Library. Files can be opened and reviewed from this area.





Materials

The Materials Library displays all the material in a project. The materials are displayed by material type API, Intermediate, Starting Material etc.

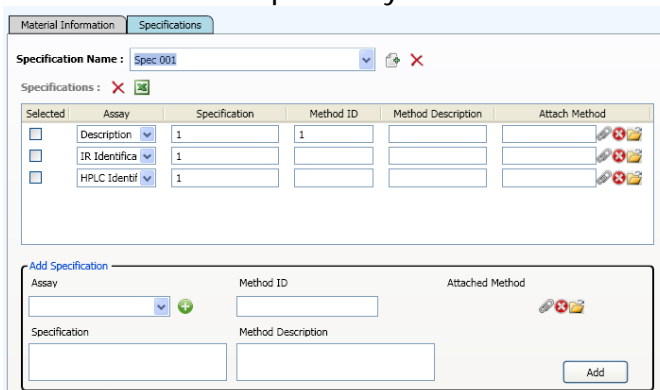


User can create new Material by clicking the Add New button. Complete information such as Name, Molecular Weight, and Density etc. Save to complete.

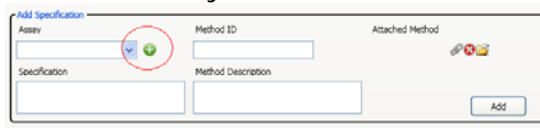
Note the material type selection is important for the application to build synthetic routes. Users are required to select Material Type before a material can be saved.

Material Specifications

Material Specifications can be set up for any material.



Assays can be set up and New Assays can be created. Click New. Add



Set Specifications for a particular Assay.
Attach appropriate documents.



Reference Substances

The Reference Substances Library allows the user to record information on any reference substances for a specific project. User can save information such as Name, Reference Substance Type, Material Type, Batch Number, Purity as well as any other image or text information.

Reference Substance Name:	<input type="text" value="Sildenafil Citrate"/>	Purity:	<input type="text" value="0.00"/>
Reference Substance Number:	<input type="text" value="00001111"/>	Lot Number:	<input type="text" value="8A0001"/>
Chemical Name:	<input type="text"/>		
Reference Substance Type:	<input type="text" value="Reference Material"/>	Global:	<input type="checkbox"/>
Reference Material Type:	<input type="text" value="API"/>		

Image

Molecular Weight: 474.5
2-1001 (API)



Impurities

The Impurities Library allows users to save information on impurities for a project. Name, Molecular Weight, Image, Comments and any Documents required can be associated and saved.

Impurity Name:

Molecular Weight:

Global:

Image Attachment | **Comments** | Attachments

Comments

The US Food and Drug Administration last week posted the final version of its Guidance for Industry, ANDAs: Impurities in Drug Substances. The document provides agency recommendations for establishing acceptance criteria for impurities in drug substances. It also provides recommendations on the chemistry, manufacturing, and controls (CMC) information to include the reporting, identification



Vendors

The Vendors Library allows the user to store information on vendors. Note that Vendor information is global (will show in all projects for a client) - this avoids the requirement to input repeat information. Name, Address, Contact, Audit information can be input and saved. In addition the user can associate materials to a vendor to produce a list of all materials sourced from a particular vendor.

Company Name:	BASF	Contact:	Bob Smith
Address Line 1:	100 Campus Drive	Contact Email:	bsmith@basf.usa.com
Address Line 2:	Suite 1000	Contact Phone:	201 895 2323
City:	Florham Park	Contact Fax:	201 895 2323
State:	New Jersey	Last Audit Date:	06/22/2009
Country:	United States Of America	Next Audit Date:	06/24/2009
ZipCode:	08818		

Associated Materials	Comments	Attachments
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Material	CAS Number	Chemical Name	Type	Molecular Weight	Density
Toluene	108-88-3	Toluene		92.14	0.8669
SOCI2	7719-09-7	Thionyl Chloride		118.97	1
NMP	109-01-3	n methyl piperazin		100.19	
Potassium tert-but	865-47-4]	865-47-4]		112.21	1
TEA	121-44-8	Triethylamine		101.19	1
tert-Butanol	75-65-0	2-methyl-2-propar		74.12	0.78
Sildenafil	139755-83-2	1-[4-ethoxy-3-(6,7		474.6	1



Stability Information

The Stability Information Library allows the user to record information from Stability Studies within the application. Stability Name, Protocol #, Document # can be saved. User can associate specific materials and lot numbers with the study. All relevant information can be entered in the Study Objectives, Performance Conditions area.

Stability Study Criteria can be added by adding

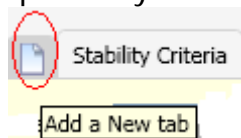
Assay can be set up by clicking add new.

New Assays can be created. Click New

Set Specifications for a particular Assay.

Attach appropriate documents

Results can be recorded at time points by clicking.





NOTE YOU NEED TO SAVE THE STABILITY STUDY, EXIT and REOPEN BEFORE YOU CAN ENTER RESULTS.

Stability Criteria 1 MONTH x 3 MONTH x 6 MONTHS BATCH 4 x

Interval: 6 MONTHS BATCH 4 Date: 08/12/2009 15

Assay	Test	Method ID	Method Description	Attach Method	Results	Out Of Specification
Water by KF	less than 5%	1e	test		10%	<input type="radio"/>
Assay & Imp	complies to sta	1e	test		NOT COMPLETE!	<input checked="" type="radio"/>

Cancel Results Save Results

Remember to Save Results and Save the Stability Information as information is entered.



Batches

The Batches Library allows the user to record specific manufacturing information for a lot of materials.

Batch Information
Result

Batch/Lot ID:

Process:

Process Version:

Output Material:

Date:

Site:

Quantity Output:

Molecular Yield (m%):

Weight Yield (w/w%):

Identity Test 1:

Purity (HPLC AUC):

Yield (Corr for purity):

Test 4:

Test 5:

Materials In
Attachments
Comments

Material Name	Lot #(s)		Quantity	Units	Vendor/Source
(13) Pyrazolecarboxamide	8F0003	+	<input type="text" value="120"/>	<input type="text" value="Kg"/>	+
HCl (30%)		+	<input type="text" value="4"/>	<input type="text" value="Kg"/>	+
Hexanes		+	<input type="text" value="100"/>	<input type="text" value="Kg"/>	+
C18 Silica Gel	2004-010203	+	<input type="text" value="5"/>	<input type="text" value="Kg"/>	+

[Custom Labels](#)

Results can be saved for a particular lot. Select the Specification that the lot was tested against, enter results and Save. Out of Spec results can be flagged.

Batch Information
Result

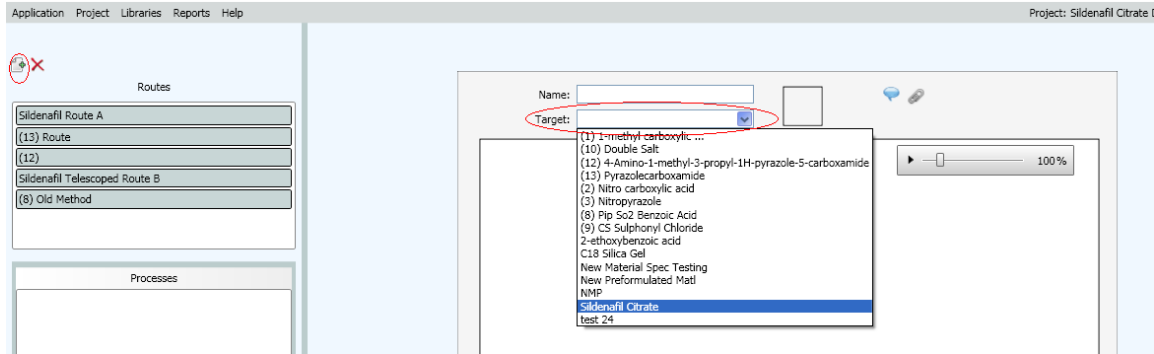
Specification Name :

Assay	Specification	Method ID	Method Descripti	Attach Method	Results	Out Of Specification
Water by KF	Test for water				<input type="text" value="BLUE"/>	<input type="radio"/>

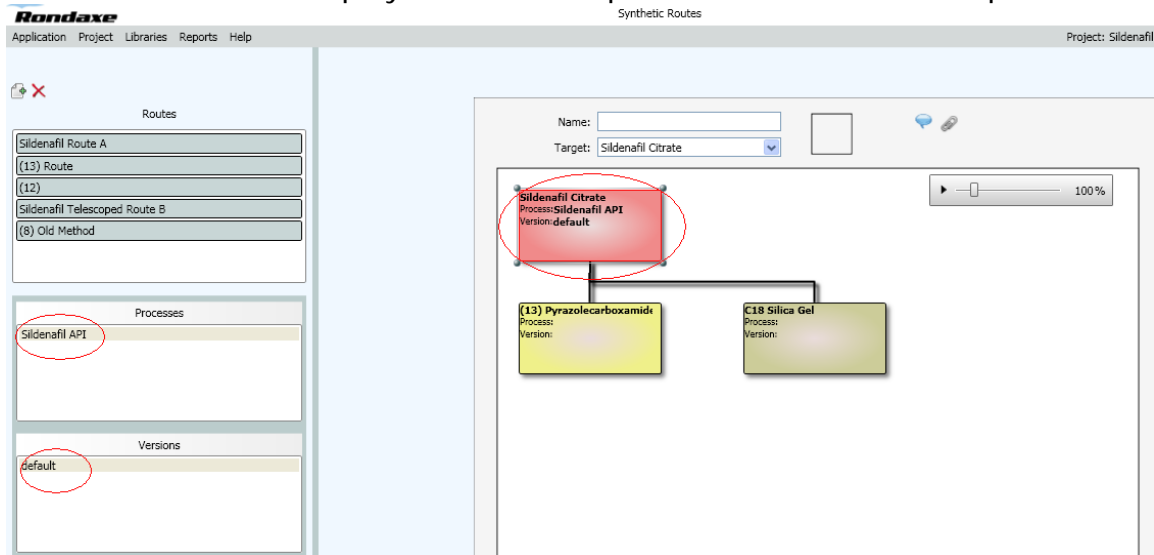


Synthetic Routes

Synthetic Routes allows the user to view the process information in one page. Build the Route as follows. Select the Target material.

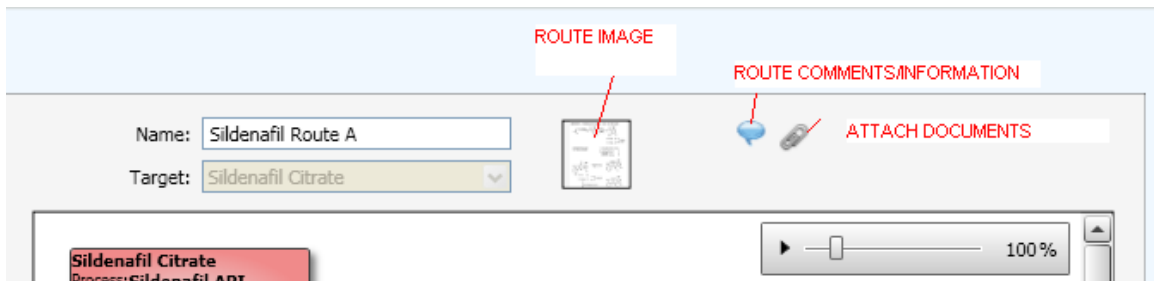


Click on the node to display the available processes in the left hand pane.



Click on the process required and version. Continue until the route is completed. Save.

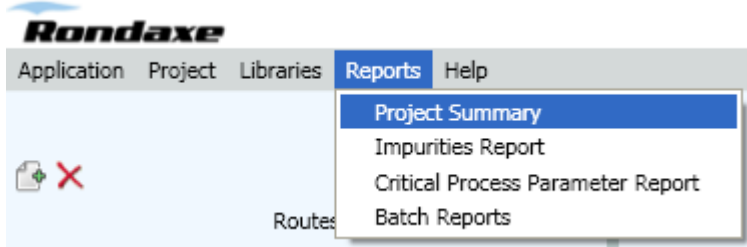
Attach Image and Documents or Comments. Click on each area and Save when completed.





Reports

The Application comes with the following reports.



Project Summary - Summary of Milestones information

Impurities Report - Report detailing all Impurities by Material and information in the application.

Critical Process Parameters - Report (by process) of the Critical Process Parameters that have been entered in the application.

Batch Reports (2) - Two reports have been created in the application.

Material Lot Usage

For a specific Material/Lot Number Combination this Report shows all Batches which had the selected Material/Lot Number as Input Material on the Bill of Materials

Batch Tracking Report

For a specific Material/Lot Number Combination this Report displays a hierarchical history of all Materials/Lot Number/Bill of Materials used in manufacture.

Batch Reports

Material Lot Usage Batch Tracking Report

Material Name Select Batch/Lot