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1 Introduction

1.1 Organization Overview

This document is organized into seven main sections.

- **Section One (Introduction)** discusses the background, scope, and organization.

- **Section Two (Getting Started)** contains instructions on connecting to the system, logging on, requesting accounts, and navigation from the home page.

- **Section Three (Settings for All Users)** provides information on system wide settings available to all POCA user roles.

- **Section Four (Advanced Settings for Business and System Admin. Users)** describes information on system wide settings available to System Administrators and Business Administrators users.

- **Section Five (Advanced Settings – System Administrators)** provides information on system wide settings accessible to the System Administrators user group.

- **Section Six (Advanced Settings – Business Administrators)** provides information on system wide settings accessible to the Business Administrators user group.

- **Section Seven (Drug Name Searches – All Users)** provides information about how to perform drug name searches.

1.2 Background

A vital part of the Food and Drug Administration (FDA) and Center for Drug Evaluation and Research (CDER)’s mission is to develop new standards to prevent medication errors due to proprietary name confusion. The Office of Surveillance and Epidemiology (OSE), Division of Medication Errors Prevention and Analysis (DMEPA) contributes to this effort by evaluating all proprietary names submitted to CDER for similarity to other marketed names. In December 1999, the Institute of Medicine (IOM) Report recommended testing of proposed proprietary names to prevent confusion and medication errors with existing drug names. The Quality Interagency Coordinating Task Force (QuIC) reporting to the President in February 2000 endorsed the IOM recommendation.

In response to these reports, FDA devoted greater resources to the area of drug name confusion analysis. Proprietary name confusion may stem from the manner in which a name is pronounced or scripted. The Phonetic and Orthographic Computer Analysis System (POCA) is a web application developed to determine written (orthographic) and spoken (phonetic) similarities between proposed drug names.
1.3 Document Scope

This User Guide provides information about all of the features in the application. It is not a technical developer’s manual, nor does it provide in-depth information on the database or operating systems.

This document was written for the FDA and refers to three types of users, namely Safety Evaluator, Business Administrator, and System Administrator. The scope of their access to the system is as described below.

**Safety Evaluator User Group**
Access Level includes:
- Conduct Searches
- Retrieve Archived Searches
- Personal settings

Settings for safety evaluators include as per the screen below:

![Figure 1: Settings Page for Safety Evaluators](image)

**Business Administrator User Group**
Access Level includes:
- Conduct Searches
- Retrieve Archived Searches
- Personal Settings
- Manually Add Drug Names To Database
- View and Delete Drug Names from Database
- Add/Edit Users
- Add/Edit News Items
- UAR Report
- Change Password Policies
- Edit Account Request and Feedback Email Addresses
Settings for business administrators include as per the screen below:

![Figure 2: Settings Page for Business Administrators](image)

**System Administrator User Group**

Access Level includes:

- Conduct Searches
- Retrieve Archived Search
- Personal Settings
- Datasources Maintenance
- Add/Edit Users
- Add/Edit News Items
- UAR Report
- Change Password Policies
- Edit Account Request and Feedback Email Addresses

Settings for System Administrators include as per the screen below:
Figure 3: Settings Page for System Administrators
2 Getting Started

To access POCA, open your web browser (Internet Explorer, Chrome, Firefox or any other browser). Internet Explorer is opened by double clicking on the IE browser icon on your desktop or by selecting Start, Programs, and Internet Explorer from the start menu. In the address bar of your web browser, type the universal resource locator (URL) for POCA as http://poca.pub.com/. The Login screen will appear as shown below.

![Login Screen](image)

Disclaimer
This is a Federal computer system and is the property of the United States Government. It is for authorized use only. Users (authorized or unauthorized) have no explicit or implicit expectation of privacy.

Any or all use of this system and all files on this system may be intercepted, monitored, recorded, copied, audited, inspected, and disclosed to authorized site, Food and Drug Administration, and law enforcement personnel, as well as authorized officials of other agencies, both domestic and foreign. By using this system, the user consents to such interception, monitoring, recording, copying, auditing, inspection, and disclosure at the discretion of authorized site or Food and Drug Administration personnel.

Unauthorized or improper use of this system may result in administrative disciplinary action and civil and criminal penalties. By using this system you indicate your awareness of and consent to these terms and conditions of use.

Figure 4: Login Screen

You will need a user account to access POCA. If an account has been created for you, enter your user ID and password and click the Login button.

2.1 Resetting Your Password

If you do not remember your password, click the “Reset Password” link. The Reset Password screen, shown below, will be displayed.
Figure 5: Reset Password Screen

Type your username and click “Submit.” POCA will assign a temporary password to your account and send you an automated e-mail message with the temporary password. It is recommended that you change your password upon first login after the password is reset.

2.2 Changing Your Password

If you wish to change your password, click on the “Change Password” link on the POCA login page. The Change Password screen will be displayed, as seen below.

Figure 6: Change Password Screen

Enter your current login credentials in the text boxes labeled “User ID” and “Old Password” to allow POCA to verify your identity. Enter your desired password into the textboxes labeled “New Password” and “Confirm New Password,” and click the “Submit” button. If the current login information you entered is incorrect, your passwords do not match, or your new password does not comply with POCA password requirements, you will be asked to correct your inputs.
2.3 Requesting an Account

If you do not have a POCA account, you may request the POCA account by clicking on the “Request Account” link on the login screen. The Request an Account screen will be displayed.

![Request an Account Screen](image)

Enter your name and email address in the text boxes provided, and click the “Submit” button. An email will be sent to a POCA administrator stating that a POCA account is being requested for you. The POCA administrator will add your account to POCA with the Safety Evaluator user role unless a different role is requested. You will receive POCA email with your user ID and temporary password after your account is created. At that point, you may log in by typing [http://poca.pub.com](http://poca.pub.com) in your browser. Upon successful log in, the home page is displayed.

2.4 Home Page and Navigation

The home page is the main control panel for the system. From the homepage users can access all of the functionality of the system. Specific sections of the home screen and their purpose are described below.

![Home page](image)
2.4.1 Navigation Bar
At the top right hand portion of the home page you will find a navigation bar with links for accessing major parts of the POCA application, such as the Home page, Search page and Settings page. The navigation bar has other links such as Comments, Help and Logout. This navigation bar is accessible on all POCA pages.

2.4.2 New Search/Retrieve Archived Search Bar
Another option to navigate to the search page is the “New Search” link located at the top of the home page, below the FDA banner.

The New Search link is available for all users. This will allow you to search for a drug name.

The Retrieve Archive Search link is available for all users. Clicking the link will display a search page that can be used to search for previously conducted searches.

2.4.3 News
News and announcements are displayed for all users. To view more information about the news item, the user can click on the news title.

2.4.4 Drug Name Search
Drug Name Search is displayed for all users. The User can perform Orthographic, Phonetic or Text searches for any drug name with in the selected data sources. More about how to use the Drug Name Search feature is described in section 7.
2.4.5 Single Name Direct Search

The single name direct search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and Comparator Drug Names. After entering those 2 drug names and pressing the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed for those 2 drug names as illustrated in Figure 11 below.

2.4.6 Multiple Name Direct Search

The Multiple Direct Search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and multiple Comparator Drug Names. Click on "Open Direct Search Page" under the “Multiple Name Direct Search” section.
A new page will appear with Candidate Drug and Comparator Drugs text fields. To use this search function, follow the instructions below:

- Enter a name in the Candidate Drug text field
- Enter multiple drug names in the Comparator Drugs text field, each separated by commas. Click on the “information” button - that will display popup message about Comparator Drugs text field format.
- Click the Submit button once all names have been entered in the text fields.

After clicking on the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed as illustrated in Figure 12 below.

**Figure 12: Multiple Name Direct Search page**

### 2.4.7 Manually Add Drug Name to Database

This functionality is available to business administrator users only. It allows users to add drug name manually to “Name Entered by Safety Evaluator” data source. Please see Section 6.1 for more information.
3 Settings for All Users

All personal settings for your POCA account can be accessed from Your Settings section on the Settings screen. To access the Your Settings screen, click on the “Settings” link found in the navigation bar. Each role will see different functionality in Settings page as described in section 1.3.

The following settings are available to all users.

3.1 Change Your Password

Users can change his or her account password by clicking the “Change your password” option under Your Settings. See section 2.2 for more details on Changing the password.

3.2 Set your Returned Results Threshold

Users can set the threshold for returned results by clicking the “Set your returned results Threshold” option under Your Settings.

The threshold is the percentage match required for a result to be returned by the search
engine. For example: If the threshold is set to 50%, only results with a match percentage of 50% or higher will appear in the result set.

3.3 **Set Your Number of Results per Page**

POCA allows users to set the default number of results displayed per page by clicking on the “Set Your Number of Results per Page” link under *Your Settings*. When a user conducts a search, the default number of results will be displayed per page. If there are more results returned than the default number of results, the user will have the ability to scroll through the pages of results.

Enter the number of results to return per page per module: 20

Submit

*Figure 15: Number of results per page*
4 Settings for Business and System Administrator Users

Business Administrators and System Administrators user groups have the same advanced settings except for their level of access to ‘Datasource/Records’. The table below shows the level of access for each type of administrator under Datasource/Records:

<table>
<thead>
<tr>
<th>Administrator User Group</th>
<th>Datasources/Records Level of Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Administrator</td>
<td>Datasource Maintenance</td>
</tr>
<tr>
<td></td>
<td>Modify Datasource Name</td>
</tr>
<tr>
<td>Business Administrator</td>
<td>Delete Drug Name</td>
</tr>
<tr>
<td></td>
<td>View SE Drug Names</td>
</tr>
</tbody>
</table>

The following settings are available to all business and system administrator users.

4.1 Add/Edit a User

To add or edit a user profile, click the “Add/Edit a User” link under Advanced Settings on the Settings page. To access the Advanced Settings screen, click on the “Settings” link found in the navigation bar. The User Administration page will be displayed as shown below.

![User Administration Page](image)

To add a new user profile, fill out the form that appears under the Add a new user heading. All input fields available on the form are described in the table below.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition/Description</th>
<th>Field Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User Name</strong></td>
<td>Enter a username for the new account. The username will be used by the user to log in to POCA. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>First Name</strong></td>
<td>Enter the first name of the user. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>Last Name</strong></td>
<td>Enter the last name of the user. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td>Enter the email address of the user, and be sure to check for typos. It is important to type this field correctly. The application will use this field to send electronic notifications to the user. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>User Group</strong></td>
<td>Select from the list if the user is a Safety Evaluator, Business Administrator or System Administrator.</td>
<td><strong>Pick list</strong></td>
</tr>
</tbody>
</table>

When editing a user profile, please note that there are two pick lists for existing user profiles, one for enabled accounts, and another for disabled accounts. You can choose an account to edit by selecting from either list the username corresponding to the user profile you wish to edit, and clicking the “Edit User” button. Once a user is selected for editing, the **Edit User** form, seeded with all available information, will display. An example of the **Edit User** form following the selection of username **arka.biswas1** for editing appears as below.

**Edit User**

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Name:</td>
<td>arka.biswas1</td>
</tr>
<tr>
<td>First Name:</td>
<td>Arka</td>
</tr>
<tr>
<td>Last Name:</td>
<td>Biswas</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:arka.biswas@fda.hhs.gov">arka.biswas@fda.hhs.gov</a></td>
</tr>
<tr>
<td>User Group:</td>
<td>Business Administrator User Group</td>
</tr>
</tbody>
</table>

![Figure 17: Edit User Screen](image)

The **Edit User** form allows the editing of the First Name, Last Name, Email, and User Group associated with a user. When you are done editing these fields, click “Update User” to submit these changes to the POCA database.

In addition, the **Edit User** form for the enabled user account can be used to disable user accounts. To disable the enabled user account, simply click the “Disable User” button on
the Edit User page. A disabled account cannot be used to log in to POCA, but all data associated with the disabled user will be preserved.

Similarly, the Edit User form for the disabled user account can be used to enable user accounts. To enable the disabled user account, simply click the “Enable User” button on the Edit User page.

4.2 Add/Edit News Items

News Items display on the home page of the POCA system under News section. Existing news items can be edited, and additional news items can be created by clicking the “Add/Edit News Items” link in the list of Advanced Settings on the Settings screen. To add a news item, populate the Headline, News Teaser, News Item, and Expire Date fields in the form that appears below, and click the “Submit/Update” button. Click “Reset” to clear the form.

![Add/Edit News Item page](image)

Figure 18: Add/Edit News Item page

The fields on this form are described below table.

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition/Description</th>
<th>Field Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Headline</strong></td>
<td>This is the title that will identify the news item. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>News Teaser</strong></td>
<td>Text entered here will appear below the headline on the home and login pages. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td><strong>News Item</strong></td>
<td>This is the main text of the news item. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>expire Date</strong></td>
<td>Expire date determines when a news item will no longer be displayed on the home and login screens. Enter a date in the format MM-DD-YYYY. This field is required.</td>
<td><strong>Edit</strong></td>
</tr>
</tbody>
</table>

To edit an existing news item, select a news item in the drop down list at the top of the screen, and click the ‘Get News Item’ button. Edit the information that appears in the form, and click “Submit/Update” when you are satisfied with the information you entered.

![Figure 19: Edit a New Item](image)

### 4.3 User Access Report (UAR Report)

Administrator users can view a list of all users, enabled users and disabled users with their full name, e-mail addresses, status, and user group assignment from this feature. You can export the user’s list into a Microsoft Excel by clicking on the ‘Export to Excel’ button. You also can filter user’s list for a specific time frame.
4.4 Change the Password Policies

The POCA system supports the capability to configure the password policies. These policies will be enforced for user passwords characteristics such as length of the password, number of failed login attempts, etc. This page, as shown below, will be displayed by clicking the “Change the Password Policies” link in the list of Advanced Settings on the Settings screen.

![Change the Password Policies Screen](image)

Enter proper values in the respective text boxes. Click “Submit” to store your changes to the POCA database.
4.5 Edit Account Request Email Address

When a user account is requested, an automatically generated email is sent to the account request email address stored in the POCA database. This email address can be changed using the “Edit Account Request Email Address” link in Settings page. It will display the page as shown below.

![Figure 22: Edit Account Request Email Screen](image)

To have POCA send account requests to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.

4.6 Edit Feedback Email Address

When a user fills out and submits the Comments and Feedback form, POCA will send an automatically generated email to the Feedback Email Address stored in the database. This email address can be changed using the “Edit Feedback Email Address” link in Settings page. It will display the page as shown below.

![Figure 23: Edit Feedback Email Address Screen](image)

To have POCA send feedback and comments to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.
5 Advanced Settings – System Administrators

5.1 Datasource Maintenance

For members of the System Administrators group, the POCA system supports capability to identify, load, refresh, and delete data sources from the POCA database. The data access process begins with the Datasource Maintenance screen, which can be accessed by clicking the “Datasource Maintenance” link in the Advanced Settings section of the Settings page.

Select the datasource type, enter the date of the data in the format “MM-DD-YYYY”, and check if you wish to load or refresh the data source. Click the “Next” button, and follow the directions provided.

5.2 Modify Datasource Names

To rename datasource in POCA database and also to add new datasources click on the “Modify Datasource Names” link in the Advanced Settings section of the Settings page. You will see below page in the following screen. Select the "Edit" button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the "Update" button to successfully update the data.
6 Advanced Settings – Business Administrators

6.1 Manually Add Drug Name to Database

In Home Page, “Manually Add Name to Database” section is only available to Business Administrator users. This field allows Business Administrators to add proposed proprietary names to the POCA database which updates the data source entitled 'Name Entered by Safety Evaluator'. Each proposed proprietary name assigned to a safety evaluator should be entered into the POCA database by a business administrator. This enables all safety evaluators to search the 'Name Entered by Safety Evaluator' data source to find other proposed names submitted to the Agency for review which may have orthographic or phonetic similarity to the proposed name they are assigned to evaluate.

If the name is entered manually in error or spelled it incorrectly, please delete the incorrect entry (see section 6.2) and re-enter the correct name once the incorrect name is deleted.

![Manually Add Name to Database](image)

Figure 26: Manually Add Name to Database

6.2 Delete Drug Name

To delete a drug name from the POCA database, click the “Delete Drug Name” link under Advanced Settings in Settings page. The first screen in the Delete a Record wizard, shown below, allows you to search for a drug record in the POCA database. Enter the name of the drug you wish to delete in the text box provided and click the “Search” button. In the sample below, we searched for the name lipitor.

![Delete a Record Screen](image)

Figure 27: Delete a Record Screen (1 of 2)

Our search returns a list of records composed of drug names and their associated data sources, as shown in the screen capture below.
Find the record you wish to delete and mark it for deletion by clicking the radio button to the left of the drug name. Click the “Delete” button. At the “Delete Confirmation” page, press the “Yes” button to remove the record from the POCA database or “No” button to not remove the record from the POCA database.

6.3 View SE Drug Names

To view the drugs entered by safety evaluators, click on the “View SE Drug Names” link under Advanced Settings in Settings page. In the following screen, select the date range from the drop down and you will see the drug names, similar to the figure below.
7 Drug Name Searches - All Users

7.1 Search Algorithms

The POCA system has three search modules, namely orthographic, phonetic, and text.

The orthographic search module is implemented using an ALINE algorithm modified for orthographic purposes. The orthographic search engine does not accept wild cards, as the algorithm takes each part of a written name into account when matching against names stored in the POCA database. Orthographic search algorithm is updated in POCA 4.0 to take more confuse pairs matrix into account. The update has been tested thoroughly by FDA team.

The phonetic search module is implemented using an ALINE algorithm for phonetic matching. The phonetic search engine does not accept wild cards because each sound of a name is taken into account when matching against names in the POCA database. The phonetic search engine ignores the numeric and special characters in the drug name.

The combined score is calculated as the average of the orthographic and phonetic scores.

Note that both the orthographic and phonetic search engines ignore numeric and special characters included in drug names. For example, the orthographic and phonetic similarity score for ‘Drug-2’ and ‘Drug-25’ will be 100%. See the below screen shots for examples.

The text search module is implemented using comparison methods for text matching built in to the Oracle 11g Database Management System. Several wildcards are available for the text search engine.

The percent sign (%) is a wildcard character that will match any sequence of consecutive characters.
For example:
Search Term: flo\%in
Results: floucin, floxin

The underscore character (_) is a wildcard that will match any single character.
For example:
Search Term: flo_in
Results: floxin

Wildcard characters can be used in conjunction with each other for matching a wider variety of patterns.
For example:
Search Term: fl\%x__
Results: flexin, flexon, floxin, fluanxol, flavocoxid

In the above example, both types of wild cards were used. A ‘\%’ character was used to match any sequence of characters after the ‘l’ character and before the ‘x’ character in the search term. Two underscore characters (‘_’) were used to match any two (2) characters at the end of a name.

7.2 Accessing the Search

The “Drug Name Search” section in Home page provides easy interface to conduct searches in POCA. The Search page can also be accessed by clicking the “Search” link in the Navigation Bar or by clicking the “New Search” link in the Options Bar.

The “Direct Search” functionality is available to all users under “Direct Search” section in Home page as well as in Search page. This feature provides user the ability to do direct search between Candidate Drug and Comparator Drug. After entering those 2 drug names and pressing Submit button, the Combined, Phonetic and Orthographic score search results will be displayed for those 2 drug names.

7.3 Search View

The “Drug Name Search” view allows users to search the POCA drug databases for a drug name using a combination of Orthographic, Phonetic, and Text algorithms. The Drug Name Search is accessible directly from the Home page, or by clicking on the “Search” link in the header.

By default, orthographic and phonetic searches will run. However, you may also choose by checking or unchecking any one or any combination of the orthographic, phonetic and text searches. When performing a text search, the underscore ‘_’ character may be used to match any single character or the percentage ‘%’ character may be used to match any string of characters.
By default, the drug name search will run against the Drugs At FDA, RxNorm and Name Entered by Safety Evaluator datasources. You may choose by checking or unchecking any combination of the datasources you wish to include in your search.

Enter the drug name to search in the “Search” Textbox and click on “Submit” button or press “Enter” key. The “Reset” button is provided to bring the “Drug Name Search” view in the default selection of Search Text, Search Type and Datasources.

The search results will be calculated and filtered with the scores that are equal to and greater then “user’s results threshold” value. The “Search Results” page will be displayed with the table of results with pagination and “Export to Excel” button.

### 7.4 Search Results

The *Search Results* page displays the results of every search. It displays a table containing drug names that matched the search criteria for every search module specified in the search.

Note that if the phonetic and orthographic search types are specified for the search, the results will display in a table that contains tabs which will allow users to display scores for each search type separately for the ‘combined’ results, ‘phonetic’ results, and ‘orthographic’ results. There is also a tab that allows user to display all three types of search results on one page. An overview of the result tabs is illustrated in Figure 28 below. It shows the *Search Results* page displaying the results of a search for *lipitor* using the orthographic and phonetic search types.
For Text search type, the Search Results page will display the Text tab with the table of exact text match.

All table columns on the Search Results page can be sorted by clicking on the column header.

If you would like to see additional information about any names returned by the search, simply click on the drug name of concern. “Product Details” page will be displayed in new window or new tab with all product details about the drug name stored in the POCA database, including the data sources. The Product Details page will be similar to the screen below. Please be aware that some results identified from RxNorm will not contain all information in Product Details page.
7.5 Export To Excel

The ‘Export To Excel’ button displayed above the search results table. It can be clicked to transfer search results into an Excel Spreadsheet. This feature will export the combined scores, the phonetic scores, and the orthographic scores, as well as any product information from the product details into the Excel spreadsheet.

Also, please note that when the tab for combined search results is selected and the results are exported to Excel, then the Excel spreadsheet will contain the combined, phonetic, and orthographic scores for all of the combined results.
When you click on the ‘Export to Excel’ button, a pop up window appears at the bottom of the screen asking if you want to open or save your search results. If you click on the dropdown arrow next to the ‘Save’ tab, then a menu appears for you to select from either ‘Save’, ‘Save as’, or ‘Save and Open’. Select ‘Save as’ and the data will be saved in a file with a ‘.xls’ extension appearing after the file name. This format will allow you to easily edit the information in your spreadsheet. If you choose only to open the spreadsheet, be aware that when you decide to save it, you will need to click on the ‘File’ tab in the upper left hand corner of toolbar, select ‘Save as’ and from the dropdown menu, choose the version of Excel with the file extension, ‘.xls’.