QUICK START GUIDE: SHELF-LIFE COMPUTATION MODULE

Access and Login

Transval is accessible by web via the following hyperlink**:** **https://www.arlenda.com/log/** and clicking on the corresponding **Demo Version** or on the corresponding **Production Version** link.

Enter the **User ID** and **Password** in the fields provided and click on the **Login** button. If the **User ID** and **Password** combination are valid, the **Homepage** will be displayed.

Three modules are available:

- ▶ Shelf-life Computation
- ▶ Accelerated Testing
- ▶ Commercial (OOT – OOS)

Click the Shelf-life Computation link, this option should be used for the downloadable **Long-term shelf-life** sample **Excel** data file (longterm.xls) that is available on the **Arlenda** website (https://www.arlenda.com/documents). The **Project description** page is displayed.

Step 1: Project description

The following sections will be presented:

- ▶ 1. Project description
- ▶ 2. Data introduction

Data introduction

Data can be entered in two ways: manually or automatically, using a pre-filled **Excel** template file (also available on the **Project description** page). We will use the latter in this guide.

Click on the **Browse** button to select the file, followed by **Upload**. This will auto-fill the data text are of the page with the data contained within the pre-filled **Excel** template file. The other fields are not completed.

Fill those with the same values as their names (i.e. enter Product Name for the **Product Name**).

Click **Next** to advance to the **Data visualization** screen.

Step 2: Data visualization

Two tables are presented:

- ▶ Summary
- ▶ Data

The first one contains a summary of the data entered by the user.

The second lists all the values entered by the user.

Click **Next** to advance to the **Parameters determination** screen.

Step 3: Parameters determination

The following sections will be presented:

- ▶ 1. Statistical models,
- ▶ 2. Statistical parameters,
- ▶ 3. Shelf-life graph parameters,
- ▶ 4. Application of the ICH recommendation for he computation of the shelf-life,
- ▶ 5. Report parameters.

Enter a **Lower specification limit** of 90.

In the third section, fill the text fields with the same values as their names (i.e. enter Title for the **Title**).

Click **Next** to advance to the **Model selection** screen.

Step 4: Model selection

A table presenting the Shelf-life and the P-Value will be presented, the aim of which is simply to serve as an aid in assisting you in your choice of model. The name of each model is a hyperlink pointing towards a graph displaying all the batches behaviour for that method. Click on the hyperlink to view the figure.

When you have determined which model you will use select the radio button associated with that model in the **Selected Model** column.

When you have made your selection, click **Next** to advance to the **Get report** screen.

Step 5: Get report

Format and Comment-Entry

The available report format are:

- ▶ WordML
- ▶ Non-secured (eCTD) PDF
- ▶ Secured PDF

The reports can be downloaded by clicking on the icon available towards "Secured PDF".

Only the Secured PDF format is available in demo version.

Report Download

When any comments have been introduced, click on the **Get Report** button. The complete User Guide is available by clicking on User's Guide option in the Left-Menu.