



## Introduction to CombiStats Online Q&A session

### **Do we also need to validate CombiStats Online with CombiStats Desktop?**

*No, a successful comparison of results between by the two applications has been carried out at the EDQM.*

### **Is this software validated? If not, it is still appropriate for GLPs/regulatory submissions?**

*The application has been successfully tested on the Chrome and Edge web browsers. As regards statistical validation, the calculation steps of the desktop version have been reproduced in the online version and tested successfully on all examples published in Ph. Eur. general chapter 5.3 and Appendix A of the desktop version user manual, as well as almost all the numerical examples given by D.J. Finney.*

### **Where can we find the documentation of this validation?**

*The EDQM has not provided any documentation concerning the validation of the application.*

### **Will the desktop version be discontinued? If so, when?**

*The desktop version will be available until 31 March 2025 (for those with a licence for 2023-2024).*

### **Is it still possible to open "old" template files (.epm files)?**

*Yes.*

### **Since we have validated some applications (templates) on the desktop version, after importing into the online version, could we consider them already validated too?**

*We recommend that you contact your QA for this. .epm templates created with the desktop version can be uploaded to the online version. Any previously applied protection level is lost but you can define a new protection level when you publish the .epmx template.*

### **Will templates/data be stored online or locally?**

*They will be stored online but not indefinitely. They will be deleted 3 years after the date of creation. Therefore, we recommend you download your files locally on a regular basis or when a study is finalised.*



**Can templates be exported and then imported again at a later date?**

*Yes, it is possible – not just templates but any file (.epax, .epmx, .epcx) – but note that the audit trail is lost when a file is exported.*

**Can we import the templates we use in the desktop version?**

*Yes, all files from desktop versions 5-7 are compatible with the online version.*

**Since we have validated some application on the desktop version, after importing into the online version, could we still consider them validated since the core of the software has not been changed or do we need to revalidate the templates?**

*When importing the templates from the desktop version, the protection level is removed. The user has to set the protection level again (when publishing the template). This may require a new validation from your side.*

**In the desktop version, it was possible to import CombiStats templates to our halus measuring equipment software, and the software was able to transfer the data from halus measurements to this template in order to perform the calculations. Will this be possible with the online version? Or will we have to transfer the halus measurements manually (data integrity GAP)? Is there any interface to transfer the data automatically to the template in the workspace? If so, what would be the required format of this input data?**

*It is not fully clear how the communication between CombiStats Desktop and your equipment was set up. CombiStats Online does not yet have an interface that supports data transfer; however, the files created with CombiStats Desktop 5.0-7.0 can be imported into the online version. Therefore, you can continue to create the files according to your current process and instead of opening them in the desktop version and importing them directly into the online application.*

**Do you anticipate support for Firefox as well?**

*For the moment, only Edge and Chrome have been tested successfully.*

**Which version of Windows is needed to use the online application?**

*There is no requirement to have a particular version of Windows installed, just an internet connection and the Chrome or Edge browser.*

**Could you explain a little more about the residuals plot?**

*Unfortunately, this is beyond the scope of this webinar. However, [the notes for guidance](#) contain some information about the residual plots.*



**Can one select "highest dose first" for one half of the plate and "highest dose last" for the second half of the plate?**

*Do not use Dose entry = Automatic. Doses should be entered manually for this type of configuration.*

**Is there the possibility to perform online digital review and "release"?**

*No. One option may be to apply your certified digital signature to the PDF report (e.g. using the Adobe product suite).*

**At the end of an assay calculations, is it possible to use an electronic signature for the user and for the reviewer?**

*No. One option may be to apply your certified digital signature to the PDF report (e.g. using the Adobe product suite).*

**How many assignees are allowed for an OMCL? Is it just 6? Or more?**

*The default is 50 seats, but the number of seats can be modified (contact [orders@edqm.eu](mailto:orders@edqm.eu)).*

**Can licences be transferred between users? What happens if a user leaves my organisation?**

*You can revoke this user. The seat can then be assigned to another user by the licence manager. You do not need to contact the EDQM to perform this step.*

**Can the number of users for a licence manager be extended, e.g. to 100?**

*Yes, at any time. You just need to send a request via the EDQM store.*

**1 licence = 1 user/workspace?**

*No, one licence gives access to a dedicated workspace for n seats/users. You just have to indicate the number of seats you need when you order CombiStats on the EDQM webstore.*

**600 euros = 1 licence?**

*600 euros = 1 seat/user account. Discounts may be applied according to the number of seats purchased. Visit the [webstore](#) for more information.*



**If you already own an account at EDQM e.g. Ph. Eur., is simple sign-in is sufficient or do you have to register again?**

*If you already have an EDQM account (e.g. for the Ph. Eur.), you still need to register to access CombiStats using your existing account (username and password).*

**Does this have to be applied for separately? How many users are standard?**

*To begin with, the number of seats for your workspace = number of desktop licences you ordered in 2023.*

**So, if I understood correctly, in our case, we only have one licence for the desktop version (registered to a single e-mail address). Can we use this licence to give access to more than one user?**

*With the online version, you can purchase a licence to grant workspace access to your desired number of users.*

**Can we download the software on more than one computer system?**

*Since CombiStats is now an online application, you do not need to download anything to access it. Users just need an account and a supported web browser (Chrome or Edge) to connect to it.*

**Is there any change in the purchase/ordering process for existing users?**

*Yes, with the launch of the new online application, orders can be placed directly on our [webstore](#). For more information see [this video on placing an order](#).*

**For existing users, will renewal reminders continue as before?**

*Each licence is valid for 1 year after the activation date. Each licence manager and assigned user will receive a reminder notification 1 month and 2 weeks prior to the expiration date.*

**How are orders placed? What are the payment options?**

*With the launch of the new online application, orders can be placed directly on our [webstore](#). For more information see [this video on placing an order](#).*



**What should we do to "convert" this one a desktop licence into the online workspace?**

*You will receive a licence key to the online application in the coming days. You will be able to use the new CombiStats alongside the desktop version.*

**Has the manual of the online version been released?**

*The user guide is available on the [CombiStats Online HELP page](#).*

**As with the previous desktop version, will an instruction manual on the use of the CombiStats Online be made available?**

*Yes, to access the user guide and notes for guidance, go to the [CombiStats Online HELP page](#).*

**Is it possible to make changes to the PDF report (e.g. not show the charts)?**

*No, this is not possible.*

**Could you please share the example PDF report with the presentation at the end of the training?**

*Yes, we will share the examples.*

**Regarding access: is it possible to link access to the workspace with the active directory of our organisation? Or do we have to create new users, specific for the online app?**

*It is not possible to link the access to your AD. You will need to create an individual access for each user to log in to CombiStats.*