Stab·e·lity Version 3.0

21 CFR PART 11 FORM

Stab.e.lity is a software application that manages the evaluation of stability data acquired from new drug substances and generates the associated information in compliance with international guidelines for both biological and non-biological products.

Stab.e.lity is a product of:
PharmaLex BelgiumS.A.
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Belgium

This product was managed by the Quality Assurance team of *PharmaLex Belgium S.A.*

Statistics for the validation of analytical procedures are required by the *GxP* (Good Practice guidelines). The software providing those statistics must also respect the applicable regulatory documents. It must be validated (see *STAB3.0-18.V03 Factory Release form* for details on the validation process).

Stab.e.lity and Electronic Records

No electronic data are recorded by *Stab.e.lity* after 30 minutes of inactivity or after log-off. Data necessary for the computations are only saved during user's connection period. No trace of this data is kept once the connection ends. In the same way, reports obtained from the data are not saved. The user can choose to print or download them, but when the session closes, they are deleted from the server. We can therefore consider that *Stab.e.lity* works as a "Typewriter system" (see *21 CFR Part 11 IV. Scope (§ 11.1), paragraph 22)* and that "Electronic records" requirements do not apply to *Stab.e.lity*.

Nevertheless, *Stab.e.lity* implements technical solutions that guarantee the confidentiality and integrity of data exchanged between server and client computers (see *STAB3.0-19.V03 Security and Confidentiality form* for details).

Stab.e.lity and Electronic Signatures

Software does not manage any electronic signature, so the electronic signature requirements of *21 CFR Part 11* does not apply to *Stab.e.lity*.

However, for security reasons *Stab.e.lity* identifies each user by a unique combination of a log-in and a password. For traceability reasons, reports generated by *Stab.e.lity* are labelled with a unique identifier. They also indicate the name of the user responsible for the report and date & time of issuing.

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V02: change of Head Office Address and replacement of CEO by Project Leader/Head of Programming
V03: Change Company name and logo, project leader name and replacement of Qa associate by the System Owner.