GeneMarker®, GeneMarker®HID and ChimerMarker® are unique genotyping software programs that are designed to provide genetic researchers with a "biologist friendly" genotyping tool. The programs' linked-navigation and intuitive layout make them easy to use, while the accuracy, speed, and extensive collection of post-genotypic applications make them powerful data analysis and research tools.

SoftGenetics takes a risk-based approach to testing its software, prioritizing the critical user and functional requirements defined in its user manuals to ensure the reliable and consistent approach to data analysis. We take pride in the quality of our software, and we take reasonable steps to uphold the accuracy of the results it produces.

The ultimate goal of the SoftGenetics platform is to provide labs the ability to effectively analyze DNA data within GxP environments. **As such, SoftGenetics understands the criticality of incorporating 21 CFR part 11 controls into our software and as a result, have successfully developed and implanted various controls to meet customer expectations including, but not limited to:**

- User Administration and e-Signatures (e.g. 21 CFR part 11.100.a, 21 CFR part 11.200.a.1):
    - Bespoke usernames and passwords
    - Allows users to change their password;
    - User management must be backed up by the lab manager
    - The software exports reports of analysis results. These reports are available for the laboratory to sign using the lab's own e-signature process.
- Access Rights (e.g. 21 CFR part 11.10.g, 21 CFR part 11.10.d, 21 CFR part 11.10.f):
    - Lab manager assigns access rights per each user type
    - Only authorized individuals have access to the analysis software when implemented by the Lab manager
    - Access rights include denying user the ability to change the validated lab SOP analysis templates
- Audit Trails (e.g. 21 CFR part 11.10.b, 21 CFR part 11.10.c, 21 CFR part 11.10.e):
    - User management records all changes / edits to the analysis results
    - Audit trail records all edits to analysis results, including reversal of edit to analysis results
    - Documents of edit history can be exported for review.

Although we understand the criticality of 21 CFR part 11, we currently do not offer a validated instance of the software which meets the validation requirements of 21 CFR part 11.10.a. We have taken this approach for the following reasons:

- The system itself has **NO** direct impact to patient safety, product quality or data integrity and as a result SoftGenetics has classified the system as low risk.
- Additionally, when reviewing the risk against the new FDA (CSA) guidance, the intended use of the system is **NOT** part of production or quality system processes.

As a result of these two factors, SoftGenetics does not, itself, validate the software. However, we have successfully supported many customers who have chosen to undertake validation activities themselves based on their own internal Computer System Validation policies and procedures.

Executive Overview:
When user management is fully implemented on each computer, the software provides an audit trail and documentation of any edits to the analysis results and the verified user ID of the individual logged into the software at the time the report was saved. The pdf reports have an optional header that contains information including the institution name and user ID of the analyst. The user management history provides a login report of user ID, date, time for each log in and forced log out. Each analysis project history contains a log of all analyst edits to the analysis results and analyst comments. The reports can be viewed in the user interface or backed up as a pdf document. The software does not have certified e-signature capability. PDF reports are exported from our software and the laboratory applies their specific e-signature process.