In the strictest sense, no Excel sheet could ever be fully 21.11 compliant. CFR Part 21.11 compliance requires a "closed system", with full audit trails and QA supervision. For instrument maintenance and PQ type activities, it is quite possible that no commercially available software meets that standard. The oversight role lies with your Quality Assurance and your SOP's and internal review systems. Even when instrument manufacturers do full OQ on a new instrument, their software is not likely 21.11 compliant in the sense that if it is not a part of your qualified QA system, it is not compliant. It can be shown their software to be reliable, in that they qualify and validate it to produce accurate calculations and results – just as our Chemical Solutions PQ kits. You receive a certificate, which your own QA will deal with in terms of meeting your internal SOP's.

It can be shown that the Excel template (program) provided with the Chemical Solutions qualification products calculates results accurately, and that it is controlled, to the extent that you couldn't arbitrarily change it to falsify results making is more acceptable to your QA team. The original data used in your qualification is generated by your 21.11 compliant HPLC software. To be extend this compliance if you feed those peak areas into our program, the results you get are accurate (precision, linearity, etc.), which is done when we qualified the software. The software is protected to the extent that one cannot erroneously type something into a cell and corrupt their calculations or data.

We are confident that our spreadsheet is very strong in this way and a reliable validation report is available that should satisfy most QC departments.

Click *HERE* for PQ Kits for Ordering Information.

Printed from the Chrom Resource Center

Copyright 2024, All Rights Apply

MicroSolv Technology Corporation

9158 Industrial Blvd. NE, Leland, NC 28451

tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com