Applications Note

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HunterLab Instruments in the Pharmaceuticals Industry

Complying with FDA Documentation Regulations

HunterLab instruments, particularly the ColorQuest XE, LabScan XE, UltraScan PRO, and UltraScan VIS, are gaining popularity for the color measurement of tablets and powders (in reflectance) and liquid solutions (in transmittance) associated with the pharmaceuticals industry. When an American pharmaceutical company purchases new measuring equipment of any type (liquid and gas chromatographs, for example, in addition to color measurement instruments), they must give special consideration to the documentation requirements of the United States Food and Drug Administration (FDA). These requirements will vary from company to company, as each pharmaceutical company is responsible for defining and maintaining its own documentation requirements list. Some areas to consider and their HunterLab solutions are discussed in the sections below, and a checklist of items that may be required is provided on the last page. Since HunterLab also sells to a number of industries that do not require such extensive documentation, it is not automatically included or its cost bundled into system prices. Therefore, some additional fees may be involved.

Note: If your pharmaceutical company is not in the United States, you may still be required to adhere to FDA regulations for products that will be sold in the United States.

Electronic Recordkeeping and Signatures

In late 1996 the FDA changed its Compliance Policy Guide to allow (but not require) electronic records and signatures. These regulations can be found in 21 CFR 11, available on the World Wide Web at www.fda.gov. This change means that the pharmaceuticals industry is now shifting toward using electronic (i.e., software-maintained) signatures and storage of information, rather than paperwork. In the case of instrumental measurements, it is generally required that every reading ever made with the instrument be named and permanently stored electronically, alteration of the data be disallowed, and that accountability (i.e., which operator makes each measurement) be tracked.

For HunterLab instruments, the software used will usually be EasyMatch QC, and a special version of this package, called EasyMatch QC-ER, may be purchased that addresses all of the technical requirements of 21 CFR 11. Included with the software is a Validation and Compliance Notebook that helps you configure the technical (computer and software) parts of the system, as well as makes suggestions on how to handle the procedural requirements so that the system will be 21 CFR 11 compliant.

Older HunterLab systems may be running Universal Software, which allows log-in and tracking of operators and provides for permanent data storage. However, the software in its standard format does allow measurements to be altered (by administrators) and deleted (by operators or administrators). If this is a concern, the CMR 2681 version of Universal Software may be purchased. This special version blocks all users from altering or deleting measurements, and modifies some of the other software permissions.

Qualification of Instrument and Measurement Method

Installation Qualification, Operation Qualification, and Performance Qualification (IQ/OQ/PQ) protocols are normally required for a new instrument to document that the instrument has been installed properly, meets its performance specifications, and is able to reliably measure typical samples using the chosen measurement method. Some pharmaceutical companies can create their own protocols using information given in the instrument user's manual and their own company template. Others will need to obtain protocols from HunterLab. For those customers that purchase EasyMatch QC-ER, IQ and OQ templates, as well as suggestions on how to draft PQ documentation, are included in the Validation and Compliance Notebook.

For users of other systems, IQ/OQ/PQ protocols may be purchased from HunterLab. Because each company's documentation requirements are different and there are many potential measurement applications for each instrument, protocols provided by HunterLab are personalized to each customer and preparation time is billed on an hourly basis.

Protocols supplied by HunterLab (both separately-purchased personalized protocols and those provided in the EasyMatch QC-ER Validation and Compliance Notebook) normally contain the following types of information:

- A cover sheet referencing your instrument and software type, the company name and address, and relevant approval signatures for the protocols.

IQ

- Purpose of the IQ
- Overview of the system, including any options purchased
- The system's operational features and its intended use
- A list of required reference documents
- Step-by-step installation procedures for the software and hardware with sign-off areas for successful completion
- A statement of qualification.

OQ

- Purpose of the OQ
- Operational diagnostics procedures, such as a wavelength accuracy test, short-term repeatability test, and mid-range reflectance (green tile) check with sign-off areas for successful completion
- A statement of qualification.

PQ

- Purpose of the PQ

- Check of instrument's performance using the method and accessories that will normally be used for measuring samples with a sign-off area for successful completion
- A statement of qualification.

Training

Training of operators on instrument and software use and maintenance is required by many companies and documentation of the training is often maintained.

Basic instrument and software training is normally provided at no charge by your sales representative when the instrument is first installed. If you require a training sign-off sheet or other documentation concerning the training or trainer, you will need to speak with your sales representative in advance of the instrument installation to ensure that your needs will be met. Extensive directed training will involve an additional fee above the purchase price of the instrument. If training of new personnel is required in the future, it may also be purchased through HunterLab's Technical Services Department. Certificates for operators that successfully complete the training can be provided with fee-paid training.

Preventive Maintenance and Continuing Instrument Verification

Documentation of instrument and standards maintenance is often required. HunterLab's Service Department offers a preventive maintenance program whereby once a year a trained service technician will inspect and test your instrument, check and adjust mechanical and electro-mechanical parts, replace lamps and air filters as needed, as well as clean the optical components. Documentation of the service performed is provided in a service report which you may then keep for your records. For an additional fee, you may also purchase a Calibration Verification Report, which documents the exact results the technician obtained while performing diagnostics.

Instruments may also be sent to HunterLab for service and/or recalibration of instrument tiles. After instrument service at HunterLab (or for a newly manufactured instrument), a Certificate of Calibration may be purchased indicating the instrument's readings on a complete set of colored BCRA tiles both before and after service.

Other Documentation

You may want to include the following documents in your files concerning your HunterLab instrument:

- The software and hardware user's manual (included with the instrument purchase)
- Validation and Compliance Notebook (included with EasyMatch QC-ER only)
- Any CMR addenda that apply to your system (included with the CMR purchase)
- Documentation concerning your computer system (included with your computer purchase)
- Tile Data Sheet (included with the instrument purchase)
- Certificate of Traceability for the instrument white tile (included with your instrument purchase)
- Printouts from any diagnostic tests performed, such as in the OQ and PQ protocols
- HunterLab's ISO 9001 certificate (can be obtained from www.hunterlab.com).

Checklist

Prior to purchasing your HunterLab instrument that will be used for measuring pharmaceuticals, consider whether the following items are required for your FDA documentation. You may then work with your sales representative to obtain the items that you need. The symbol "$$" indicates that an additional cost above and beyond the system purchase price may be associated with this item if you choose to obtain it from HunterLab.

- ❑ Basic instrument and software training
- ❑ Calibration Verification Report ($$)
- ❑ Certificate of Calibration ($$)
- ❑ Certificate of Traceability
- ❑ CMR 2681 version of Universal Software for control of data storage, plus its addendum ($$)
- ❑ Computer documentation
- ❑ EasyMatch QC-ER and its Validation and Compliance Notebook ($$)
- ❑ Extensive directed training with certificates for participants ($$)
- ❑ HunterLab ISO 9001 certificate
- ❑ Installation Qualification Protocol ($$)
- ❑ Operation Qualification Protocol ($$)
- ❑ Performance Qualification Protocol ($$)
- ❑ Preventive maintenance with service report ($$)
- ❑ Software and hardware user's manual
- ❑ Tile data sheet
- ❑ Training of new personnel with certificates for participants ($$)
- ❑ Training sign-off sheet.

For Additional Information Contact:

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