

EasyMatch QC-ER is HunterLab's electronic records version of our EasyMatch QC software intended to support clients with the need to implement FDA 21 CFR Part 11.

Here are requirements to be discussed with the client IT department prior to installation of EZMQC-ER version 4.85 and higher.

A local or network computer should be installed with one of the following Microsoft operating systems following the guidelines for CFR Part 11 compliance.

- Windows 7 Professional and Ultimate editions for 32 or 64-bit operation
- Windows 8 or 8.1 Professional and Ultimate editions for 64-bit operation
- Windows 10 64 bit Professional and Ultimate editions

Here are further steps to be taken by client IT prior to installation of EasyMatch QC-ER software:

1. A System Administrator for the client company with privileges to install software must be present to install EasyMatch QC-ER software. Alternatively, the client company can provide the HunterLab representative with temporary privileges as a member of the Administrators Group for the PC with privileges to install the software.
2. The primary purpose of the System Administrator is to create and populate the QCERAdmins and QCERUsers groups as well as install EasyMatch QC-ER on the client's network or local computer. The System Administrator does not have to be a member of the "QCERAdmins" or QCERUsers" groups who operate EasyMatch QC-ER software.
3. Installation of the EZMQC-ER software can be implemented using the Pre-Installation Wizard in 3 ways:
 - **Network PC installation** with members of the network QCERAdmins and QCERUsers groups having network logins only.
 - **Local installation on a stand-alone PC** with members of the local QCERAdmins and QCERUsers groups having local logins only.
 - **Local PC installation with members of the local QCERAdmins and QCERUsers groups having local or network logins.**
4. Prior to installation, the System Administrator must create two (2) groups – "QCERAdmins" and "QCERUsers":
 - On the network for a network PC installation.
 - On the local PC if the EZMQC-ER operators will be using a stand-alone local PC and local logins.
 - On the local PC if the EZMQC-ER operators will have both local and network on a local PC.

All users operating EZMQC-ER software must be a member on one of these two groups.

- The names of both groups can be defined by the client. Our group names do not have to be used but are recommended for clarity.
- "QCERAdmins" is a standard user group with full privileges to operate all features in EasyMatch QC-ER software.
- "QCERUsers" is a standard user group with more restricted privileges for operation of EZMQC-ER.
- While HunterLab has defined the default privilege set for each group, this is configurable by a member of the "QCERAdmins" group in EZMQC-ER under Options/System Configuration/Access Privileges.
- There must be only one designated "QCERAdmins" group but there can be several "QCERUsers" groups, and they can come from more than one network domain.

- For purposes of verifying and testing the EZMQC-ER installation, at least one test member, for example "QERAdmin1" and "QCERUser1", must be assigned to each group.

Installation following the IQ/OQ/PQ procedures will require sign off at multiple steps by someone designated as a compliance officer with the company. Alternatively, this can be a member of the Administrators Group for the computer, a lab manager or the HunterLab representative.

A printer (network or local) should be attached to the PC to make hard copy reports during the installation.

A hardcopy of the EZMQC-ER Validation and Compliance Notebook (digital copy also available on CD) is supplied with the system but the client company should print out a copy of the software user's manual from the EasyMatch QC-ER CD for reference.