Compliance Validation Software Module
For the Octet System

Key Features

- Password-protected user accounts
- Secure date- and time-stamped audit trail
- Electronic signatures
- Verification of electronic records

ForteBio's Compliance Validation Module for the Octet System provides the tools to comply with the FDA guidelines for 21 CFR part 11. Key features include security, data validation and audit trail capabilities with data generated on the Octet System. The compliance validation module should be used in conjunction with your internal standard operating procedures and policies to satisfy the compliance requirements.

SPECIAL NOTE:

Installation of the Compliance Validation Module on the Octet System does not ensure compliance with the FDA's 21 CFR part 11 guidelines. It is the user's responsibility to establish and follow policies and standard operating procedures that satisfy compliance requirements.

USER ACCOUNT MANAGEMENT

The Octet Compliance Validation Modules provides the capability to create and manage user accounts. The accounts are managed by a system administrator that is designated at the time of installation. The system administrator has the following capabilites:

- Account creation
- Disabling an account
- Changing or resetting a password

Changing Users

The current user is autmatically logged off when a new user logs onto the system.

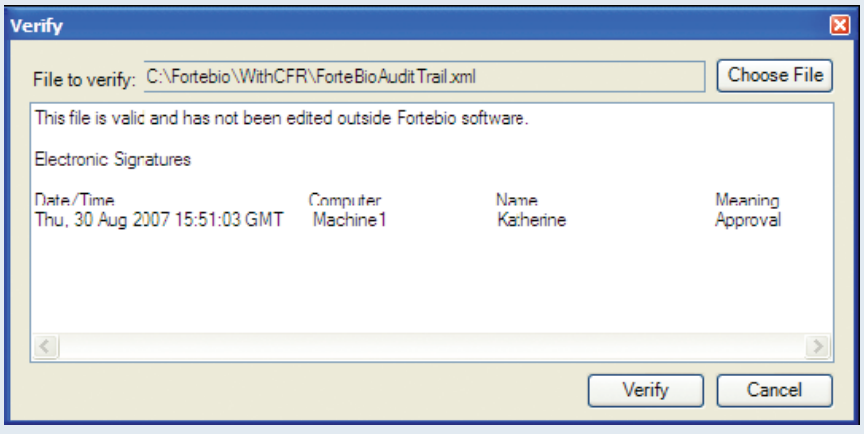

FIGURE 1: Verification dialog box from the Compliance Validation software module

AUDIT TRAIL

The Octet Compliance Validation Module generates an audit trail that includes date and time stamp records for the following functions on the Octet System:

- User log on or log off
- A method file is opened or saved
- An experiment is run or stopped
- The Octet instrument is reset
- A report is saved
- The temperature is set
- The shaker is stopped

The audit trail file (ForteBioAuditTrail.xml) is maintained in the Octet Application directory. This file can be viewed, printed or validated.

ELECTRONIC SIGNATURES

The Octet Compliance Validation enables authorized users to electronically sign an experimental method file (.fmf), results (.frd), or an audit trail and indicate the meaning or intent of the signature. In addition to electronic signatures, the software modules provides the means to verify that results or methods have not been edited.

EQUIPMENT QUALIFICATION (IQ/OQ)

Under the FDA guidelines for 21 CFR part 11 compliance, companies are required to certify and validate instruments. The Octet Installation Qualification (IQ) and Operational Qualification (OQ) manual provides the procedures to document and verify that the correct Octet System was ordered, delivered and installed according to ForteBio specifications. ForteBio offers Octet customers the documentation and services needed to assure successful validation of the Octet System. They can be ordered separately or as a complete package.

MATERIALS REQUIRED:

- Octet Q or QK instrument
- Octet Software 4.0 or later installed

ORDERING INFORMATION

Octet Software Compliance Validation Modules	
Part No.	**Description**
50-5009	Octet Q Compliance Validation Module
50-5010	Octet QK Compliance Validation Module

Qualification Manuals & Services*	
41-0062	Octet IQ/OQ Documentation Manual
90-9003	Octet IQ/OQ validation service
90-9004	Complete Octet Validation Package. Includes: • Compliance Validation Software Module (1) • Octet IQ/OQ Documentation Manual (1) • Service, Octet IQ/OQ validation (1)

**Availble November 2007.*

fortéBIO™

ForteBio, Inc.
1360 Willow Road, Suite 201
Menlo Park, CA 94025

t: 888.OCTET-QK *or* 650.322.1360
f: 650.322.1370
web: www.fortebio.com

0056-01 | P/N PB-1017 Rev A