



STUDYBUILDER LTD.
JOHN ECCLES HOUSE
ROBERT ROBINSON AVENUE
OXFORD OX4 4GP
UNITED KINGDOM
TELEPHONE: +44 (1865) 338 092
FACSIMILE: +44 (1865) 338 100
E-MAIL: UK@STUDYBUILDER.COM
WEB: HTTP://WWW.STUDYBUILDER.COM

INTERNATIONAL

AMERICAS
268 BUSH STREET, SUITE 1123
SAN FRANCISCO CA 94104
UNITED STATES OF AMERICA
E-MAIL: US@STUDYBUILDER.COM

EUROPE/AFRICA
POSTBUS 177
1000 AD AMSTERDAM
THE NETHERLANDS
E-MAIL: NL@STUDYBUILDER.COM

ASIA/PACIFIC
LEVEL 11 PARK WEST BUILDING
6-12-1 NISHI-SHINJUKU
SHINJUKU-KU TOKYO
160-0023 JAPAN.
E-MAIL: JP@STUDYBUILDER.COM

To whom it may concern

Telephone:
Facsimile:
E-mail:

OUR REFERENCE: /3.11.6.5/2004/rcs/1
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Dear Sir,

Further to your request for a document to indicate our quality policy and the compliance of StudyBuilder software with regulations for electronic data collection, please find below our quality policy and regulatory compliance statements.

Quality policy

In our Quality Manual and its implementing procedures, StudyBuilder addresses quality objectives, management's commitment to achieving these objectives, organizational goals, and the expectations and needs of StudyBuilder customers. Improvements to the Quality System are made to enhance the achievement of StudyBuilder strategic objectives.

StudyBuilder ensures that quality is an integral part of the design, development, and delivery of StudyBuilder products and services. The activities governed by the Quality System are identified and documented. These documented procedures are controlled and effectively implemented to ensure that StudyBuilder products meet customer requirements.

StudyBuilder ensures that only materials and products that have passed required inspections and tests are released. Documented procedures specify that the inspection and test status of materials and products is identified during receipt and throughout the material or product life cycle. The material or product status indicates conformance or nonconformance to inspection and test procedures.

Regulatory compliance statement

StudyBuilder software can be used to build systems that are compliant or non-compliant with the intent of the regulations for electronic data collection as specified in FDA 21 CFR Part 11. While StudyBuilder make every effort to ensure that its software implements the technical requirements of a compliant system, it is the sole responsibility of the user of the software to ensure that they configure and operate StudyBuilder software and standard operating procedures in such a way as to be compliant with the appropriate regulations.

If you have any questions, please do not hesitate to contact us.

Yours sincerely,

The StudyBuilder Development Team

enc: None
cc: File 3.11.6.5