ELECTRONIC SIGNATURE ACKNOWLEDGEMENT FORM

LEGAL NAME *(**please PRINT name clearly**)*	**DATE** *(e.g., May 10, 2009)*
Operating Unit (OPU) *(e.g. BIPI, BI USA)*	**DEPARTMENT** *(e.g.,R&D. IT, Sales – If Field Sales, please include district number)*

INTRODUCTION: On August 20, 1997, the FDA Final Rule of 21 CFR Part 11-Electronic Records; Electronic Signatures became effective. It describes the requirements for use of Electronic Records and Electronic Signatures in a regulated environment. Pursuant to the ruling the Board of Managing Directors of Boehringer Ingelheim International GmbH submitted a letter to the FDA on September 12, 2001 certifying that "all electronic signatures executed to electronic records required by predicate rules in Boehringer Ingelheim systems, used on or after September 12, 2001 as found in the Federal Food and Drug Administration regulations, are intended to be the legally binding equivalent of traditional handwritten signatures."

SCOPE: This Acknowledgement Form applies to electronic signatures executed for regulatory documents defined under FDA 21 CFR Part 11.

AGREEMENT: By signing this Electronic Signature Acknowledgment Form, I agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.

By signing below, I accept the conditions of this agreement.

Signature _____ Date _____

Witness Signature (must be at least eighteen years of age) _____ Date _____

Witness (printed name) _____

Please return this completed form to:

Global GxP LMS Team
Boehringer Ingelheim Pharmaceuticals Inc
900 Ridgebury Rd
Ridgefield, CT 06877

Direct questions to the Service Desk at x54600 or externally 203-798-4600 or 800-344-4095 x54600

Information Regarding Electronic Signature
The Electronic Records & Signature Rule - 21 CFR Part 11

What is 21 CFR Part 11?

- An FDA regulation describing the criteria under which the FDA will accept electronic records and electronic signatures as the equivalent to paper records and handwritten signatures.
- It applies to all computerized systems that create or use electronic records and electronic signatures to fulfill or support FDA regulated processes (such as GMP, GLP).

What is an ELECTRONIC RECORD?

- Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

What is an ELECTRONIC SIGNATURE?

- A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

What are the characteristics of an ELECTRONIC SIGNATURE?

- Signed electronic records must indicate:
    - Printed full name of signer
    - Date / time when signature was executed
    - Signature meaning (review, approval, Student recorded, etc.)

What do you need to record an ELECTRONIC SIGNATURE?

- a unique combination of UserID + Password or UserID + PIN
- Unique to one individual
- Not re-used or re-assigned to anyone else
  NOTE! Be cautious not to confuse System logon with E-Signature execution!
    - Both require UserID + Password/PIN
    - E-signature has pop up box that states you are about to execute an electronic signature

How does Part 11 affect you?

- Casual sharing of ID codes and passwords not acceptable
- E-record falsification is as serious as paper record falsification
- Group password is valid for read only access

- Your contributions
    - Only access systems that you have been trained to use
    - Enter UserID and Password before performing functions
    - Adhere to system procedures
    - Sign the Electronic Signature Acknowledgement Form
    - Understand what you are signing when you execute an electronic signature.

For more information on BIPI's E-signature policy, visit WebBI >Policies,Procedures,SOPs,Guidelines & Manuals>BIPI>BIPI Policies