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**1.0 Purpose**

This procedure describes the system for documenting and verifying signatures, electronic signatures, and initials of persons who document/sign off on work performed in the Biopharmaceutical Development Program (BDP) (to include forms and logbooks).

**2.0 Scope**

This procedure applies to every individual who signs Good Manufacturing Practices (GMP) documents and/or applies electronic signatures in any software program. This includes BDP personnel and its consultants/contractors, Facilities Maintenance and Engineering (FME) (as appropriate), and other US government personnel, but excludes vendors.

**3.0 Overview**

FDA has issued regulations (21 CFR 11) for the control of electronic records, electronic signatures, and handwritten signatures executed to electronic records, to permit the widest possible use of electronic technology compatible with FDA’s responsibility to protect public health. [Guidance for Industry: Part 11, Electronic Records; Electronic Signatures-Scope and Application, Aug 2003].

As part of the controls over electronic signatures, organizations must establish and adhere to written policies that hold individuals accountable and responsible for actions initiated under their electronic signature in order to deter record and signature falsification [21CFR11.10(j)]. In addition, before allowing electronic signature, an organization shall verify the identity of the individual [21 CFR 11.100(b)], and users of an electronic signature must certify that their electronic signature is the legally binding equivalent of traditional handwritten signatures [21CFR11.100(c)].



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A Personal Identity Verification (PIV) card is a United States federal smart card issued to federal employees and contractors to grant access to federal facilities and information systems. The PIV system is based on secure and reliable forms of identity credentials issued by the US Federal government. Homeland Security Presidential Directive-12 (HSPD-12) established the requirements for the common identification standard for identity credentials issued by US Federal departments and agencies. HSPD-12 directed the development of Federal Information Processing Standards (FIPS 201) to define a common identity credential. PIV cards can only be issued after an extensive identity proofing and registration process has been completed. This process includes at a minimum a complete federal background investigation, capturing of biometrics data (such as fingerprinting), appearing in-person at least once, and providing two forms of identity source documents in original form. Each PIV card is personalized with identity information for whom the card is issued and provides three factor authentication (a PIV authentication certificate, a personal identification number or PIN, and a biometric). Automated systems can use the electronically stored data on the card to conduct automated identity verification. Additional details on the PIV process can be found by referencing the current version of the FIPS PUB 201.

#### 4.0 Authority and Responsibility

- 4.1 The Director, Regulatory Compliance has the authority to define this procedure and is responsible for the implementation of this procedure.
- 4.2 BDP staff, NCI BRB staff, and FME Management are responsible completing Form 21406-01 and including it in a MasterControl task.
- 4.3 BDP BQA monitors open MasterControl tasks and verifies the proper completion of the task.
- 4.4 Managers and Supervisors are responsible for generating and collecting forms from any consultants/contractors used.
- 4.5 BQA is responsible for quality oversight of this operation.

#### 5.0 Procedure

- 5.1 The identity of the employee is verified by Human Resources (HR) upon acceptance of an offer of employment through comparison to the individual's driver's license or other official photo ID.
- 5.2 US Government employees and its contractors that are issued PIV cards have completed a personal identity verification process (refer to the overview section of this SOP). US Government issued PIV cards may be used by US government employees and its contractors to sign documents electronically/digitally. This, and signatures within validated software are the only forms of electronic signature accepted by BDP.
- 5.3 **Form 21406-01** must be completed by employees or other US government staff that will provide signatures on GMP documents.
  - 5.3.1 Employees should electronically open **Form 21406-01** and apply their electronic/digital signature to the electronic signature line on **Form 21406-01** using their PIV card.



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- 5.3.1.1 To apply an electronic/digital signature, click on the “electronic signature” line box. A window will open, and you should choose the digital ID to sign the form. This needs to be the ID assigned to your PIV card. It will say “Issued by: HHS-FPKI-Intermediate-CA-E1 Expires:\_\_\_\_\_”. Note the digital ID must not be expired.
  - 5.3.1.2 Select “continue”. Another window will open with the appearance of your electronic signature. Select “sign”. No changes should be made to the appearance of the signature.
  - 5.3.1.3 Save the form to your personal network folder or desktop when requested. If your PIV card is not already inserted in the computer, you may get a message to insert your PIV card before you save.
  - 5.3.1.4 Next a window will open for you to type in your PIV card PIN number. Select “OK” when done.
  - 5.3.1.5 Print the form and document all signatures and initials that they use on BDP documents on Form 21406-01.
  - 5.3.1.6 Scan the form and upload it into the training task in MasterControl. Follow instructions in the task to add the form.
  - 5.3.1.7 Provide the original form to BQAD to archive.
- 5.4 After receipt of a completed **Form 21406-01**, BQAD files the completed form in the personnel signature file.
  - 5.5 Employees must complete **Form 21406-01** every two years or if the name and/or initials of an individual changes through marriage or divorce.
  - 5.6 Consultants/Contractors  
Form 21406-01 is created for all consultants/contractors responsible for signing BDP GMP documents. The hard copy of the form is included in their training file.

## **6.0 References and Related Documents**

- 6.1 Federal Information Processing Standards Publication (FIPS PUB) 201; Personal Identity Verification (PIV) of Federal Employees and Contractors; US Department of Commerce, National Institute of Standards and Technology
- 6.2 **FORM 21406-01** *Signature File and Electronic Signature Equivalency statement*

