

TEMPLATE 4

RFI REQUIREMENTS FOR SAFE-BIOPHARMA-COMPLIANT DIGITAL SIGNATURES

Introduction:

The following requirements should be included in a Request for Information (RFI) where information is needed about the ability of application(s) being considered by <Company Name> to either already be certified compliant with SAFE-BioPharma Standard requirements for digital signatures or the ability of applications being considered to meet the SAFE-BioPharma Standard requirements for digital signatures

Requirements:

1. Does the application have an electronic signature capability such that all electronic signatures executed on digital objects (documents and files) which are intended for <purposes specified by Company> WILL be electronic signatures which employ cryptographic means in order to execute the signature – otherwise known as Digital Signatures?
2. If the application does have a digital signature capability WILL the application's digital signature capability meet the requirements of the SAFE-BioPharma Standards OR has the application been previously certified by SAFE-BioPharma as compliant with SAFE-BioPharma Standards?

NOTE 1: All Public Key credentials used during the execution of an individual's Digital Signature MUST be issued and managed by Certificate Authorities (CAs) which are cross-certified with the SAFE-BioPharma Bridge CA (SBCA) AND certified compliant with EU requirements as stipulated in the current versions of ETSI Standards EN 319 401, EN 319 411 and EN 319 412. CAs which are cross-certified with the SBCA are shown on the SAFE-BioPharma web site noted below. EU qualified CAs are shown in the EU Trust List at <https://ec.europa.eu/digital-agenda/en/eu-trusted-lists-certification-service-providers>

NOTE: The SAFE-BioPharma Standard comprises a series of documents which provide specific technical, policy and practice requirements for identity credentials (both PKI and non-PKI). These documents also include the Operating Rules for members and vendor partners for the two SAFE-BioPharma trust frameworks (PKI and non-PKI). Vendor products and services which have been certified by SAFE-BioPharma as compliant with appropriate SAFE-BioPharma technical requirements are listed on the SAFE-BioPharma website. <http://safe-biopharma.org> SAFE-BioPharma standards may be obtained by contacting SAFE-BioPharma at info@safe-biopharma.org