



Pfizer Regulatory Quality Assurance

Audit Certificate

I, the undersigned, confirm and certify that the following investigator site audit activities were performed.

Study C4591001

Two (2) investigator site audits were performed between 17-Jun-2021 and 02-Sep-2021 for Study C4591001.					
Investigator Name	Center Number	Country	Dates of Audit	Type of Audit	Name of Auditor
Rupp, Richard Earl	1142	United States	21 Jun 2021 to 24 Jun 2021	Routine	Cutler, Robert
Rodriguez, Hector A	1156	United States	26 Jul 2021 to 30 Jul 2021	Routine	Jilla, Abilash

Approver:

Cecilia Gabarain
Senior Director, Regulatory Quality Assurance

090177e198cfa491\Approved\Approved On: 08-Dec-2021 11:09 (GMT)

Robert N Cutler

7997eefb-6feb-4dbc-a232-c15936633467

REASON: I attest to the accuracy
and integrity of this document.

09 Nov 2021 14:20:012-0500

090177e198cfa491\Approved\Approved Qn: 08-Dec-2021 11:09 (GMT)

Cecilia Gabarain

6809829b-f9ec-4ac9-bc23-e28cfa721dc

REASON: I approve this
document.

09 Nov 2021 14:59:023-0500



Validation Report

1 ✓

Subject CN	TAIGLE LLC
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=TAIGLE LLC,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	19482482486555712400772614192179934953
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time	09 Nov 2021 14:59:023-0500

- ✓ The Certificate chain was successfully built to a Trusted Root Certificate.
- ✓ The Signer's identity is valid.
- ✓ The Document has not been modified since the signature was applied.

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FDA-CBER-2022-5812-0500299



Audit Trail Report

Document Name C4591001_Audit_Cert_09_Nov_21.pdf
Document ID b0287ef5-0954-425a-8b83-0a621b96c796

Time Stamp	User	Action	Details
09 Nov 2021 14:16:057-0500	(b) (6) UU D : (b) (6) Email (b) (6) IP Address : (b) (6)	Started	The custodian composed the ePak succesfully. Subject: C4591001_Audit_Cert_09_Nov_21 ePak UUID: e2a8d6b1-47a6-453e-b0c4-f500508de662
09 Nov 2021 14:16:057-0500	Robert N Cutler UU D : 7997eefb-6feb-4dbc-a232-c15936633467 Email : robert.cutler@pfizer.com	RequestSent	Sign request sent to ePak recipient.
09 Nov 2021 14:19:054-0500	Robert N Cutler UU D : 7997eefb-6feb-4dbc-a232-c15936633467 Email : robert.cutler@pfizer.com IP Address : 148.168.96.26	DocumentViewed	Document viewed by signer.
09 Nov 2021 14:20:012-0500	Robert N Cutler UU D : 7997eefb-6feb-4dbc-a232-c15936633467 Email : robert.cutler@pfizer.com IP Address : 148.168.96.26	SignerTagFilled	The signer filled Time Stamp. Value: 09 Nov 2021 14:20:012-0500
09 Nov 2021 14:20:012-0500	Robert N Cutler UU D : 7997eefb-6feb-4dbc-a232-c15936633467 Email : robert.cutler@pfizer.com IP Address : 148.168.96.26	Signed	The recipient signed the document with no comments. Comments: None Reason: None Consent: I understand that my Electronic Signature is Equivalent to my Handwritten Signature and is therefore legally binding. My Electronic Signature will remain unique to me, and under no circumstance I am allowed to disclose my password to any individual which may allow unauthorized access to system. I understand that I am accountable and responsible for all actions associated with my Electronic Signature.
09 Nov 2021 14:20:012-0500	(b) (6) UU D (b) (6) Email (b) (6)	EPakStateChanged	The ePak progressed to the next workflow state .
09 Nov 2021 14:20:012-0500	Cecilia Beatriz Gabarain UU D : 6809829b-f9ec-4ac9-bc23-e28cfba721dc Email : ceciliabeatriz.gabarain@pfizer.com	RequestSent	Sign request sent to ePak recipient.
09 Nov 2021 14:58:012-0500	Cecilia Beatriz Gabarain UU D : 6809829b-f9ec-4ac9-bc23-e28cfba721dc Email : ceciliabeatriz.gabarain@pfizer.com IP Address : 148.168.40.123	DocumentViewed	Document viewed by signer.
09 Nov 2021 14:59:023-0500	Cecilia Beatriz Gabarain UU D : 6809829b-f9ec-4ac9-bc23-e28cfba721dc Email : ceciliabeatriz.gabarain@pfizer.com IP Address : 148.168.40.123	SignerTagFilled	The signer filled Time Stamp. Value: 09 Nov 2021 14:59:023-0500

090177e198cfa491\Approved\Approved On: 08-Dec-2021 11:09 (GMT)

<p>09 Nov 2021 14:59:023-0500</p>	<p>Cecilia Beatriz Gabarain UU D : 6809829b-f9ec-4ac9-bc23-e28cfba721dc Email : ceciliabeatriz.gabarain@pfizer.com IP Address : 148.168.40.123</p>	<p>Signed</p>	<p>The recipient signed the document with no comments. Comments: None Reason: None Consent: I understand that my Electronic Signature is Equivalent to my Handwritten Signature and is therefore legally binding. My Electronic Signature will remain unique to me, and under no circumstance I am allowed to disclose my password to any individual which may allow unauthorized access to system. I understand that I am accountable and responsible for all actions associated with my Electronic Signature.</p>
<p>09 Nov 2021 14:59:023-0500</p>	<p>(b) (6) UU D (b) (6) Email (b) (6)</p>	<p>Completed</p>	<p>The ePak is completed successfully.</p>