


General Information			
PTA / PIA Name:	FDA - FSM - QTR2 - 2025 - FDA4918496	PTA / PIA ID:	3170608
Component Name:	FDA - OC Flash Smart Manufacturing	ATO Boundary Name:	OC Flash Smart Manufacturing
Overall Status:	Complete 	# of Days - Open:	23
Submitter:		Submit Date:	4/22/2025
Next Assessment Date:	N/A	Expiration Date:	1/1/2100
Office:		OpDiv:	FDA
Security Categorization:	Moderate		
Make PIA available to Public?:	No	PIA Required:	Yes
General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?		Yes
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		Yes
General 04:	ATO Date or Planned ATO Date.		11/30/2023
General 05:	Is the system or electronic information collection, agency or contractor operated?		Agency
History Log:	View History Log		

Privacy Threshold Analysis			
Privacy Threshold Analysis			
PTA 01:	Point of Contact (POC) Name		POC #1 Name: Kirstie Snodderly
PTA 01A:	POC Title and Organization		POC Title: System Owner: POC Organization: FDA/OC/OCS/ORES
PTA 01B:	POC Email Address		Kirstie.Snodderly@fda.hhs.gov
PTA 01C:	POC Phone Number		3017968467
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.		New

PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	<p>The purposes of the Office of the Commissioner (OC) Flash Smart Manufacturing (FSM) system are: 1) demonstrating the modeling and simulation toolbox for regulated manufacturers, building experience for regulators, reviewers, and inspectors; 2) providing scientists a platform to research the types of tools and metrics used in industry to, in turn, assess and develop improved metrics and regulatory science questions to ask during review. This system supports the Food and Drug Administration's (FDA) work to identify areas for innovation in manufacturing, foster the adoption of advanced manufacturing, and facility increased domestic manufacturing of critical medical products.</p> <p>System users are all internal to FDA. The system is accessed through the FDA network, and the system is hosted in the FDA Ashburn Data Center.</p>
PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	<p>The types of information collected into the system are FDA employee first names, FDA employee last names, center name, and FDA employee work e-mail addresses.</p> <p>Information is stored in accordance with general records retention schedule.</p>
PTA 05A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system.
PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	FDA Active Directory (AD)
PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	The information about OC FSM users is collected and/or maintained to support FDA advanced manufacturing, modeling and simulation, and research activities. First names, last names, and email addresses are needed to assign resources and deliver confirmation notifications.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	<p>Preproduction URL: https://ocet-flash.preprod.fda.gov/</p> <p>Production URL: https://ocet-flash.fda.gov/</p>
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No

PTA 09:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The purpose of the website is to provide scientists a platform to research and assess the types of tools and metrics used in industry to support of FDA's work to identify areas for innovation in manufacturing, foster the adoption of advanced manufacturing, and facility increased domestic manufacturing of critical medical products. Website users are FDA employees and Direct Contractors that access the website via the HHS intranet by single sign-on.
PTA 10:	Does the website have a posted privacy notice?	Yes
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA 12:	Does the website use web measurement and customization technology?	No
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name Contact Information Email Address (Business) Other Other
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	Center name.
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	<100
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose of assigning resources and to deliver confirmation notifications in the OC FSM system to support FDA advanced manufacturing, modeling and simulation, and research activities.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.

PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are: 5 U.S.C. 301 which permits agency heads to create the usual and expected infrastructure necessary for the organization to accomplish its purposes and mission; and the Food Drug and Cosmetic Act (FD&C), 21 USC § 301.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Government Sources Within the OPDIV
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	The OMB information collection is not required because this system/component does not collect information using an information collection request as defined by the Paperwork Reduction Act.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	There is no option to object to or opt-out of the information collection because the PII consisting of name and contact information is necessary for FDA to manage resourcing. Users can choose not to provide their PII, however, they will not be given access to the system. This may impact the FDA-related work that they are required to do per their job duties.
PIA 35:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). If they cannot be notified or have their consent obtained, explain why.	No such changes are planned or anticipated. In the event a major change occurs to the system is made, notice language will be added to a webpage.
PIA 36:	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	The processes in place to resolve an individual's concerns when their PII has been inappropriately obtained, used or disclosed include: an email OCET-Flash-Smart-Manufacturing-Innovation-Team@fda.hhs.gov from the user or the supervisor of the user with the concern. FDA employees may also contact the Employee Resources and Information Center (ERIC), FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), and the FDA Privacy Office.

PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	<p>The process in place for periodic reviews of PII to ensure the data integrity is to validate all data limit data access and permissions, perform regular access audits, and ensure that the system periodically backs up the data in its storage locations through annual review through FDA Authorization to Operate (ATO) assessment, and regular review by the Business Owner.</p> <p>The process in place for periodic reviews of PII to ensure data availability is using role-based access control to provide users with all data necessary to perform their individual work. It is also ensured through annual review through FDA ATO assessment, and regular review by the Business Owner.</p> <p>The process in place for periodic reviews of PII to ensure data relevancy is regularly removing user information for those who no longer need access to the system. Relevancy is also ensured through annual review through FDA ATO assessment, and regular review by the Business Owner.</p> <p>Accuracy of PII is ensured by design of system and related processes to solicit or collect only the PII necessary for the system’s purpose and supporting functionality. Accuracy is also ensured through annual review through FDA ATO assessment, and regular review by through Business Owner.</p>
PIA 38:	Identify who will have access to the PII in the system.	Administrators Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	<p>Administrators require access to PII about users to: perform systems operations and maintenance only. Administrators are FDA Employees and Direct Contractors.</p> <p>Contractors: FDA Direct Contractors are administrators.</p>
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The administrative procedures in place to determine which system users may access PII are: An FDA employee supervisor and OC Flash Smart Manufacturing systems administrators determine role-based access needs.

<p>PIA 41:</p>	<p>Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.</p>	<p>The following technical methods are in place to allow those with access to PII to only access the minimum amount of information necessary to perform the job:</p> <p>Access to the system is restricted based on the business needs of the user to ensure minimum necessary access only. An FDA employee supervisor and OC Flash Smart Manufacturing systems administrators determine role-based access needs.</p>
<p>PIA 42:</p>	<p>Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.</p>	<p>All users for system are required to complete the following training and awareness programs to make them aware of protecting PII: annual security and privacy awareness training and role-based training for IT administrators.</p>
<p>PIA 43:</p>	<p>Describe the training system users receive above and beyond general security and privacy awareness training.</p>	<p>System administrators also receive the following additional training: role-based training for IT administrators.</p>
<p>PIA 44:</p>	<p>Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).</p>	<p>Records are managed in accordance with National Archives and Records Administration (NARA) Records schedule is N1-088-04-005, Item 1.2. Research Projects. Disposition: TEMPORARY. Cutoff at end of the calendar year in which the project is completed. Transfer paper records 3 years after cutoff to FRC. Destroy or delete records 30 years after cutoff.</p>
<p>PIA 45:</p>	<p>Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.</p>	<p>FDA secures PII in the system using the following administrative controls: via FDA employee supervisor review, implementation of Need to Know and Minimum Necessary principles when awarding access, and others.</p> <p>FDA secures PII in the system using the following technical controls: via user identification, firewalls, encryption, smart cards, and public key infrastructure (PKI).</p> <p>FDA secures PII in the system using the following physical controls: all system servers are located at facilities protected by guards, locked facility doors, and climate controls.</p> <p>Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.</p>

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	Privacy Analyst Review Date:	4/22/2025
Privacy Analyst Review Comments:		# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	4/22/2025
SOP Review Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	# of Days - SOP Review:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	5/15/2025
Agency Privacy Analyst Review Comments:	5/15/2025 This PIA was approved outside the tool on 5/1/2025. The PIA has now synced in Archer.	# of Days - APA Review:	23

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	5/15/2025
SAOP Review Comments:		# of Days - SAOP Review:	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
5/15/2025 7:41 AM	BLAND, CRYSTAL	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	5/15/2025	5/15/2025 This PIA was approved outside the tool on 5/1/2025. The PIA has now synced in Archer.	OC Flash Smart Manufacturing_Updated 5-1-2025_Approved.pdf