PTA / PIA: FDA - OPQ-QMIS - QTR2 - 2025 - FDA4915821

Created Date: 4/9/2025 4:26 PM Last Updated: 4/16/2025 4:48 PM

## General Information

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| **PTA / PIA Name:** | FDA - OPQ-QMIS - QTR2 - 2025 - FDA4915821 | **PTA / PIA ID:** | 2989129 |
| **Component Name:** | FDA - CDER Office of Pharmaceutical Quality - Quality Management Information System | **ATO Boundary Name:** | CDER Regulatory Tracking and Quality Management Systems |
| **Overall Status:** | Complete | **# of Days - Open:** | 7 |
| **Submitter:** | | **Submit Date:** | 4/9/2025 |
| **Next Assessment Date:** | N/A | **Expiration Date:** | 1/1/2100 |
| **Office:** | | **OpDiv:** | FDA |
| **Security Categorization:** | Moderate | | |
| **Make PIA available to Public?:** | Yes | **PIA Required:** | Yes |

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| **General 01:** | Identify the Enterprise Performance Lifecycle Phase of the system. | Operations and Maintenance |
| **General 02:** | Is this a FISMA-Reportable system? | No |
| **General 03:** | Does the system have or is it covered by a Security Authorization to Operate (ATO)? | No |
| **General 04:** | ATO Date or Planned ATO Date. | 10/21/2022 |
| **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

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| **PTA 01:** | Point of Contact (POC) Name | Laura Pogue |
| **PTA 01A:** | POC Title and Organization | Business Owner-Office of the Pharmaceutical Quality (OPQ) |
| **PTA 01B:** | POC Email Address | Laura.Pogue@fda.hhs.gov |
| **PTA 01C:** | POC Phone Number | (301) 539-2155 |
| **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 |

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| **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. | The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) performs an essential public health service by ensuring access to safe and effective drugs. In support of this mission, CDER's Office of Pharmaceutical Quality (OPQ) regulates over the counter and prescription drugs, including biological therapeutics and generic drugs. The Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality, Quality Management Information System (OPQ QMIS) supports OPQ in streamlining and automating its laboratory quality management and business processes to improve and enhance the way the program is managed. Through the implementation of the OPQ QMIS, OPQ is better positioned to maintain the high quality of its testing services to meet the needs of the public, regulated industry, and stakeholders by ensuring the use of good scientific practices and the ethical conduct of its laboratory quality system employees.<br><br>CDER OPQ QMIS allows end users (FDA permanent employees and Direct Contractors) to automate document control, automate management review, and initiate corrective/preventive action. OPQ QMIS serves as a catalyst to harmonize quality management practices agency wide and reduce lifecycle costs. Additionally, OPQ QMIS ensures that FDA decision-based processes are transparent, traceable, and reportable as mandated by Center for Drug Evaluation and Research (CDER).<br><br>The system utilizes FDA’s authentication credentials (username and password) along with the user’s identification badge (PIV) to log users into the system via FDA single sign-on system (SSO).<br><br>Users who do not have an account in OPQ-QMIS are able to access stored documents using a guest access process without providing PII. Guest access requires supervisor (Administrator) approval. Guest access does not require PII and limits the user’s access to a read-only view of documents, based on a need to know, that do not contain PII, and are in a protected PDF format. |

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| **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. | CDER OPQ-QMIS collects and maintains personally identifiable information (PII) of FDA permanent employees and Direct Contractors who use the system. PII includes names, user credentials (username and password), user identification numbers, and business e-mail addresses.<br><br>Non-PII collected and maintained in the system includes internal standard operating procedures (SOPs); policies and other directives governing ways the agency does business; documents and maintenance data for active document lists; master lists; reports; correspondence such as agency-wide announcements and memoranda; quality control records related to internal work products; internal audit reports; management reviews; corrective and preventive action documentation; and, complaints and feedback related to the quality of work products, processes and services provided by the FDA.<br><br>Information is stored on a temporary basis in accordance with National Archives and Records Administration regulations. |
| **PTA 05A:** | Are user credentials used to access the system? | Yes |
| **PTA 05B:** | Please identify the type of user credentials used to access the system. | HHS User Credentials<br>HHS/OpDiv PIV Card<br>HHS Username<br>Password |

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| **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. | CDER OPQ-QMIS is a web-based software program that automates quality management processes. FDA personnel use the software program for managing their local quality processes and automating notification routes through Microsoft Outlook. OPQ-QMIS provides end users with one source that is pre-configured and provides easy access to all standard operating procedures (SOPs), forms, and other quality documents and records at the local level and throughout OPQ. The quality control process includes document control, complaint/corrective/preventive action (CAPA) management, internal audits, management review, improvements, and quality records management.<br><br>OPQ-QMIS collects and maintains the names, business email address, user identification number and user credentials (username and password) of system users.<br><br>CDER OPQ-QMIS collects and maintains document control change requests, corrective actions, preventive actions, work-related feedback and complaints, audit reports, management reviews, and record control information. Complaints entered in OPQ-QMIS are strictly related to the quality issues of CDER /FDA work products and processes, and do not include complaints regarding personnel issues.<br><br>The data in OPQ-QMIS is not shared with or accessible through any other system. |
| **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). | http://opq-qmis.fda.gov/mc/index.cfm#/hubs/my-mastercontrol |
| **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 FDA CDER OPQ-QMIS system is an internal only system used by FDA employees and Direct Contractors. CDER OPQ authorized personnel use the application to automate its laboratory quality management and business processes to improve and enhance the way the program is managed. FDA employees and Direct Contractors have access to the application. Users access the application using FDA's authentication credentials (username and password) along with the user's identification badge (PIV) to log users into the system via FDA single sign-on system (SSO). |
| **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 |

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| **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

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| **PIA 22:** | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | Biographical Information<br>Name<br>User Credentials<br>Contact Information<br>Email Address (Business)<br>Other<br>Other |
| **PIA 22A:** | Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list. | user identification number; username and password. |
| **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. | 500 – 4,999 |
| **PIA 25:** | For what primary purpose is the PII used? | PII is used to create user accounts and task notifications. Tasks include the work which may be assigned to employees for completing a review of a document, completing a form in the system, or completing training. |
| **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. | 5 U.S.C. 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<br>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. | There are no forms associated with this collection, and all system users are internal FDA personnel. |
| **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 |

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| **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. | Users cannot opt out of the collection or use of their PII. It is required to establish user accounts and to authenticate system access. Users who do not have an account in OPQ-QMIS are able to access stored documents using a guest access process without providing PII. Guest access requires supervisor (Administrator) approval and does not require guest users to provide PII. |
| **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. | The OPQ Quality Program communicates with users through regularly provided e-mails, online notices and forms, and/or newsletters. If there is any change to the system, or if the use or collection of user PII changes, users will be notified of that change through those avenues. However, no such changes are anticipated. |
| **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. | Individuals who suspect their PII has been inappropriately obtained may contact FDA's Employee Resource Information Center (ERIC Helpdesk), FDA's Privacy Office, FDA's Cybersecurity and Infrastructure Operations Coordinator Center (CIOCC). Users may contact FDA offices via email, phone and standard mail (all methods listed on fda.gov and the agency's intranet).<br><br>In the event of a suspected incident or data breach, FDA personnel must report without delay to FDA's CIOCC. |
| **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. | Users provide PII voluntarily. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting.<br><br>Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance. OPQ will perform annual reviews to evaluate user access. Data discrepancies identified during system use are addressed when discovered. |
| **PIA 38:** | Identify who will have access to the PII in the system. | Users<br><br>Administrators<br><br>Developers<br><br>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 |

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| **PIA 39:** | Provide the reason why each of the groups identified in 38 needs access to PII. | Users: Users can only access their own PII.<br><br>Administrators: Administrators (including the help desk/apps desk) create user accounts using the supplied PII and review user access rights. Some Administrators are Direct Contractors.<br><br>Contractors: Direct Contractors access accounts/PII to troubleshoot issues with the system.<br><br>Developers: For development and system maintenance. Some developers are Direct Contractors. |
| **PIA 40:** | Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII. | CDER OPQ-QMIS users can only access their own PII while Administrators and Developers have access to PII limited to that necessary to perform their job duties. All OPQ-QMIS users are provided Role Based Access control (RBAC) with least privilege (only the necessary rights to their job functions) access. New OPQ-QMIS users are required to have their supervisor approval to ensure the level of access needed for the particular user. |
| **PIA 41:** | 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. | The CDER OPQ-QMIS team will utilize a user access management account procedure in place to create and modify accounts for OPQ-QMIS. This procedure assigns access rights to users based on the employee job function (administrators, supervisors, users). The standard system user can access only their own PII (the user ID). |
| **PIA 42:** | 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. | All system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on federal laws, policies, and regulations relating to privacy and data confidentiality, integrity and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure).<br><br>The FDA Office of Digital Transformation (ODT) verifies that training has been successfully completed and maintains a record of certificates of training on all<br>FDA employees and Direct Contractors. |
| **PIA 43:** | Describe the training system users receive above and beyond general security and privacy awareness training. | Access to CDER OPQ-QMIS is granted only after an individual has completed system training. OPQ-QMIS use training and guidance materials that are available on the CDER OPQ SharePoint page. |
| **PIA 44:** | 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). | Electronic Records Retention-FDA Programmatic Records Control Schedules: 8420 (NARA No. NC 1-88-07-2; Program Management files), 8123 (NARA No. N1-088-06-3; Administrative Correspondence), and 4913 (NARA No. N1-088-08-3; Employee Training Records). Records are retained temporarily in accordance with the above retention schedules. |

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| **PIA 45:** | Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response. | There are several controls in place for the securing of PII within CDER OPQ-QMIS. The administrative controls include system users completing an access request form and an access review/approval process. The technical controls include firewalls, virtual private networks (VPNs), encryption, and intrusion detection systems. The physical controls are comprised of guarded facilities, gated access to these facilities, security barriers, and locked doors. |

## Review and Comments

### OpDiv Privacy Analyst Review

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| **Privacy Analyst Review Decision:** | Approved | **Privacy Analyst Review Date:** | 4/9/2025 |
| **Privacy Analyst Review Comments:** | | **# of Days - PA Review:** | 0 |

### SOP Review

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| **SOP Review Decision:** | Approved | **SOP Review Date:** | 4/9/2025 |
| **SOP Review Comments:** | The PIA is experiencing an Archer error with Question #3 of the general information Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?”<br><br>The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 11/21/2022.<br><br>At this time, we are unable to update Archer to reflect the correct answer “Yes.”<br><br>The FDA Archer Team is aware of this occurrence and is working on a solution. | **# of Days - SOP Review:** | 0 |

### Agency Privacy Analyst Review

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| **Agency Privacy Analyst Review Decision:** | Approved | **Agency Privacy Analyst Review Date:** | 4/16/2025 |
| **Agency Privacy Analyst Review Comments:** | Reviewer: Shanai Shobowale<br><br>4/16/2025 This PIA is ready for SAOP review and approval. | **# of Days - APA Review:** | 7 |

### SAOP Review

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| **SAOP Review Decision:** | Approved | **SAOP Review Date:** | 4/16/2025 |
| **SAOP Review Comments:** | | **# of Days - SAOP Review:** | 0 |

### SAOP Signature

| Date | User | Type | Name | Original Value | New Value |
|---|---|---|---|---|---|
| 4/16/2025 1:15 PM | 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 | 4/11/2025 | 4/10/2025 Per FDA Email:<br><br>Please note the PIA is experiencing an Archer error when reporting the response for Question #3 of the general information section.<br><br>Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?”<br><br>• The FDA instance of Archer is automatically entering the answer “*No*,” which is incorrect. The ATO date is *11/21/2022*.<br>• Currently, we are unable to update Archer to reflect the correct answer “Yes.”<br>The FDA Archer Team is aware of this occurrence and is working on a solution. | |