PROCEDURES

Office of Business Informatics

CDER Electronic Record Keeping Systems

Table of Contents

PURPOSE

This MAPP documents CDER's Electronic Records Keeping Systems (ERKS) and outlines the policies and procedures for its governance. This includes the following:

- Definition of a Record and ERKS
- Identification of the various systems within CDER that holds the ERKS
- Listing of the ERKS attributes for the identified CDER systems

BACKGROUND

CDER is improving its informatics infrastructure by consolidating data management, business process management and business intelligence. Because of these improvements, legacy systems will be retired, and a modern informatics platform will be established, serving as the new ERKS.

During this transition, it is critical to document what the ERKS is at any given point in time. Per 36 CFR 1236.10, What Records Management Controls Must Agencies Establish for Records in Electronic Information Systems, this is part of the controls necessary to protect the reliability, authenticity, integrity, usability, content, context and structure of the Federal records contained within the ERKS so they can provide adequate and proper documentation of Agency business for as long as the information is needed, (i.e., per their approved retention period in the FDA and CDER records control schedules). In turn, the ERKS helps to fulfill CDER's records management obligations under 44 U.S.C. 3301, Records Management by Federal Agencies.

An **Electronic Records Keeping System** (ERKS) is the authoritative data source for a given data element or piece of information within an information management system. This definition, although consistent with the Freedom of Information and Privacy Act, is specific to CDER's information technology strategy and infrastructure.

RESPONSIBILITIES

CDER OBI / Program Management Office (PMO)

- Documents the ERKS
- Provides guidance for the use of ERKS for various systems' implementation
- Maintains and updates the ERKS for CDER
- Performs regular quality assurance checks.

PROCEDURES

1. The Electronic Records Keeping Systems table is validated and updated annually.
2. Updates to the Electronic Records Keeping Systems table are communicated regularly via OBI's standard procedures.
3. The ongoing updates to the ERKS table are in alignment with CDER MAPPs, FDA Staff Manual Guides, and FDA and CDER Records Control Schedules.

Quality Assurance: Comprehensive procedures, which perform ongoing data quality checks, to ensure the ERKS is up to date.

Conflict Resolution: Key stakeholders will take reasonable steps to reach alignment on unresolved issues. The principles of CDER MAPP 4151.8, *Equal Voice*, and MAPP 4151.2, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director* will be employed to resolve issues, as appropriate.

REFERENCES

1. OMB, Circular A-130, Revised. Management of Federal Information Resources.
2. Clinger – Cohen Act, 40 USC 1401 et seq., 1996.
3. FDA, 2013. Staff Manual Guide 1270.2, Office of Strategic Programs.
4. FDA, 2004. Staff Manual Guide 2010.3. FDA Data Standards Council.
5. FDA, 2004. Staff Manual Guide 3210.2. IT Investment Management.
6. FDA, 2004. Staff Manual Guide 3210.3. IT Project Management Policy.
7. FDA, 2004. Staff Manual Guide 3230.2. Enterprise Architecture Policy.
8. FDA, 2007. Staff Manual Guide 3251.1. Information Resource Management – Information Technology Security.

9. FDA, 2008. Staff Manual Guide 3291.1 Records Management Policy
10. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component.
11. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2, Rev. 1, Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director.
12. FDA, 2013, Center for Drug Evaluation and Research, MAPP 7600.8, Rev. 1, CDER Informatics Governance Process.
13. FDA, 2013, Center for Drug Evaluation and Research, MAPP 7600.10, CDER Master Data Management.
14. 44 U.S.C. 2901, Records Management by the Archivist of the United States.
15. 44 U.S.C 3301, Records Management by Federal Agencies.
16. 36 CFR 1236, Electronic Records Management.
17. 36 CFR 1236.10, What Records Management Controls Must Agencies Establish for Records in Electronic Information Systems.

DEFINITIONS

Electronic Records Keeping Systems: The authoritative data source for a given data element or piece of information within an information management system. (Per 36 CFR 1236.2, an electronic information system is a "system that contains and provides access to computerized Federal records and other information.").

Record: **An item (or) a collection of data. This also** represents a single, implicitly structured data item in a table. Also per 44 U.S.C. 3301 – Records Management By Federal Agencies (The Federal Records Act), "includes all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them",

Records Management: The planning, controlling, directing, organizing, training, promoting, and other managerial activities related to the creation, maintenance and use, and disposition of records to achieve adequate and proper documentation of Federal policies and transactions and ensure effective and economical management of agency operations. (44 U.S.C. 2901)

Master Data: Master Data is a centralized, single source of business data used across multiple systems, and applications processes. Master data may include data about product, sponsor, application, or facility.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
09/24/2014	n/a	Initial issuance.
6/10/2018	n/a	Administrative Change: Added Attachment 1
8/9/21	n/a	Administrative change: Replaced all references of System of Record (SOR) with Electronic Record Keeping System (ERKS), as per NARA name change.
8/24/21	n/a	MAPP Recertified, per Mary Ann Slack memorandum.
11/26/21	n/a	Administrative Change: Added Documentum – RM Client to Attachment 1.
2/2/2022	n/a	Administrative Change: Added OPQ-QMIS to Attachment 1.

ATTACHMENT 1 – ELECTRONIC RECORDS KEEPING SYSTEMS TABLE

This list reflects those ERKSs most commonly used for CDER records. CDER records may be stored in other FDA and select HHS ERKSs (e.g., HHS Learning Management System), as appropriate.

CDER records must not be maintained in shared drives, SharePoint, portable media, Microsoft Outlook, or personal drives without expressed permission by the CDER Assistant Records Liaison Officer (ARLO).

Electronic Records Keeping Systems (ERKS)	System Description	Data Elements and Information	Sample Records
Document Archiving, Reporting & Regulatory Tracking System (DARRTS)	Tracks incoming submissions and outgoing communications and documents for regulatory review (INDs, BLAs, NDAs, ANDAs, DMFs, MAs, Safety Reports, Meeting requests, etc.)	Metadata for Applications Submissions and Supporting documents	Congressional reporting, Performance reporting
Documentum - AIMS	Maintains Work Products performed by Agency administrative support staff	Work Products	Controlled correspondences, external communications
Documentum – CMS (Compliance Management System)	Tracks individual compliance actions and related documentation	Work Products	Inspection reports, compliance actions
Documentum - ECMS	Stores business documents (varies by office)	Work Products	Work products, varying by office **Note:** For those CDER records that do not already have a ERKS specified, it is recommended that they be stored in the Documentum **ECMS FDA Records Management (FDA-RM) repository** which is DoD 5015.2 compliant (a software standard for records management). The default Documentum ECMS Central

			repository does not meet these standards and should not be used for record retention.
Documentum – RM Client	Stores business documents (varies by office)	Work Products	Work products, varying by office **Note:** For those CDER records that do not already have a ERKS specified, it is recommended that they be stored in the Documentum **Records Management Client (RM Client) repository** which is DoD 5015.2 compliant (a software standard for records management). The default Documentum ECMS Central repository does not meet these standards and should not be used for record retention.
Electronic Document Room (EDR)	Maintains electronic regulatory review submissions (INDs, BLAs, NDAs, ANDAs, DMFs, MAs, Safety Reports, Meeting requests, etc.)	Electronic submissions	Incoming CDER electronic submissions, Applications, Supplements, Master files, Annual reports
FAERS	Manages consumer, health care professional, and industry submitted adverse event reports for CDER and CBER regulated products	Electronic Adverse Event Data	Post-marketing adverse event reports, management reports
CDER Informatics Platform – Integrity	Provides unified, accurate, and up-to-date data records that facilitate consistency across the Platform and enable automated content population, cross-referencing, and reporting	Master Data	***Facility:*** Manufacturing Facilities, Clinical Sites, Third party logistics providers, Compounding sites, Wholesale distributors ***Product***: Domestic & Foreign Prescription drugs, Over the counter drugs (OTC), Unapproved drugs, Compounded drugs, Ingredients (Active & Inactive) ***Sponsor:*** New Drug Application holder, Generic Drug Application holder, Drug Master File

CDER Informatics Platform - Mercado	Provides an integrated data warehouse for regulatory data with powerful analytics tools, which allows for flexible querying, reporting, and analysis	Regulatory Reporting and Analytics	Pharmaceutical quality reporting
CDER Informatics Platform - Panorama	Provides end-to-end process templates with built-in document management and routing and custom views for each Office, allowing cross-discipline teams to work, collaborate, and report in one place in real time	Workflow Metadata Work Products	Review/Inspection Status & Outcome, Assignments, Warning letters Application/Supplement/Final labeling/Quality Reviews, Responses to citizen petitions/Congressional inquiries, Approval letters, Sponsor communications
CDER Office of Pharmaceutical Quality (OPQ) Quality Management Information System (QMIS)	Provides users a digital quality management system that automates document-based processes, allowing for streamline/automation of task assignment/routing, scheduling, escalation, tracking, follow-up, review, and approval	Workflow Metadata Work Products	Pharmaceutical quality reporting