FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

ORA/CDRH Resources Available to the Medical Device Industry

PRESENTED TO

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SUMMARY

There is a significant amount of information and data made available by FDA to the medical device industry.

- Why does FDA make this information and data available?
- What data does FDA make available?
- How can I obtain this data?
- Where can I go to get my questions answered?

WHY DOES FDA MAKE THIS INFORMATION AND DATA AVAILABLE?

Presidential Memorandums and Directives

- Memorandum on Transparency and Open Government 01/21/2009
  - Push for information transparency
  - Disclose information rapidly in form easy to use
  - Leverage new technologies
  - Open Government Directive from OMB included online, open format, and openness as permitted by law
- Memorandum on Regulatory Compliance 01/18/2011
  - Make regulatory compliance and enforcement activities accessible, downloadable, and searchable online.

FDA's Transparency Initiative

- FDA launched a Transparency Initiative in June 2009
  - Phase I (01/2010)– *FDA Basics*
  - Phase II (05/2010) - *Public Disclosure*
  - Phase III (01/2011) – *Transparency to Regulated Industry*
- Additional efforts and reporting:
  - Report on Good Guidance Practices (12/2011)
  - Transparency Reports on Compliance and Enforcement Activity (10/2011, 01/2012, 04/2014)

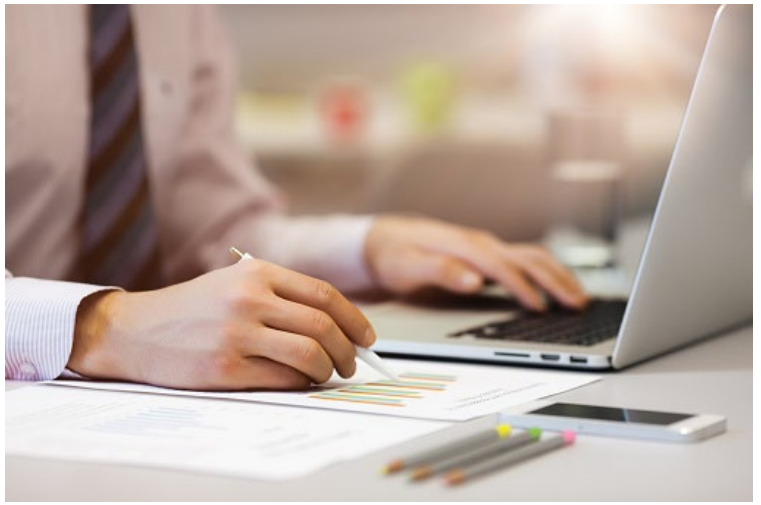
WHAT DATA DOES FDA MAKE AVAILABLE?

Types of Data Available

- Pre-market Data
  - 510(k) Premarket Notifications
  - Premarket Approvals (PMA)
  - De Novo 513(f)(2) Classifications
- Post-market Data
  - Medical Device Reports (MAUDE)
  - Recalls
  - Radiation Emitting Electronic Products Corrective Actions
- Firm/Device Data
  - Registration/Listing
  - Device Classification
  - Total Product Lifecycle
  - UDI Coding
- Regulatory Activity Data
  - Inspections
  - 483 Observations (Citations)
  - Compliance Actions

Quantity of Data

- Device Classifications (~6,700)
- Registration and listing data for medical device firms and their products (~300,000)
- Premarket Approvals (PMAs) and supplements since 1977 (~47,000)
- 510(k) Clearances (~160,000)
- Recalls (~46,000)
- Adverse event reports since 1991 (~14 million)
- UDI Coding (~3,000,000)



Data Limitations

- Only publish certain types of data routinely – does not include all types available by FDA
- Does not include data restricted from disclosure
- There may be certain delays before information is published
- Data should be treated as unvalidated; includes user-submitted and/or manually entered

HOW CAN I OBTAIN THIS DATA?

Methods – Web Search

- **Web searches of databases/dashboards on FDA.gov**
  - Search can be tailored easily using criteria, requires only a web browser
  - Many results include links to other resources
  - Formatting prioritized for human readability and use, including some graphical representations of the data
  - Some allow all or a portion of the data to then be exported for review in other applications

Methods – Downloads & API

- **Download entire datasets**
  - Different formats/processes depending on source, may require certain applications to view properly
  - Larger datasets are broken into more than one file, may require manual or automated combination to make data usable
- **Application Programming Interface (API) calls**
  - Scope of query can be tailored to needs/interest
  - Formatting prioritized for use by applications
  - Requires some knowledge to properly structure and submit requests

Deciding on a Method

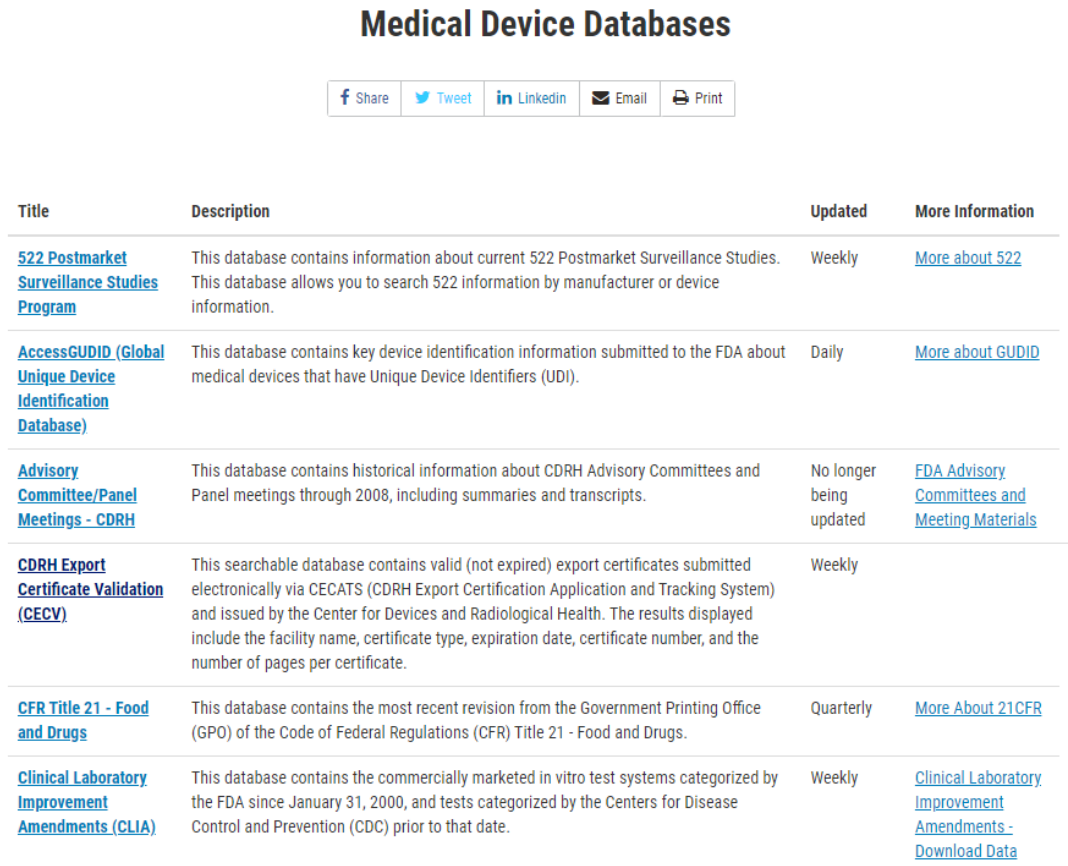
- What type of data are you looking for?
  - NOTE: Some data sets only have one method to obtain the data, others have several.
- Are you looking to return a small or large number of results?
- How complex of a query do you need to get the data you want?
- What will you be doing with the data once you obtain it?

Example JSON Return


```
"results": [
  {
    "cfres_id": "173284",
    "product_res_number": "Z-0053-2020",
    "event_date_initiated": "2019-05-17",
    "event_date_created": "2019-10-07",
    "recall_status": "Terminated",
    "event_date_terminated": "2020-09-24",
    "res_event_number": "82984",
    "product_code": "FOZ",
    "k_numbers": [
      "K900263"
    ],
    "product_description": "Pediatric Two-Lumen Central Venous
Catheterization\nKit with Blue FlexTip ARROWg+ard Blue Catheter, REF AK-
25502\n\nProduct Usage;  Provide short-term (< 30 days) central venous access
for treatment of diseases or conditions requiring central venous access",
    "code_info": "Lot/Batch Numbers: 13F18C0374, 13F18H0580, 13F18D0504,
13F18L0507,  13F18E0380, 13F18L0714, 13F18G0180, 13F18L0936,  13F18G0480",
    "recalling_firm": "Arrow International Inc",
```

FDA.gov's Medical Device Databases

- The list of Medical Device Databases is found at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases



Medical Device Databases

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Title	Description	Updated	More Information
522 Postmarket Surveillance Studies Program	This database contains information about current 522 Postmarket Surveillance Studies. This database allows you to search 522 information by manufacturer or device information.	Weekly	More about 522
AccessGUDID (Global Unique Device Identification Database)	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	More about GUDID
Advisory Committee/Panel Meetings - CDRH	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	FDA Advisory Committees and Meeting Materials
CDRH Export Certificate Validation (CECV)	This searchable database contains valid (not expired) export certificates submitted electronically via CECATS (CDRH Export Certification Application and Tracking System) and issued by the Center for Devices and Radiological Health. The results displayed include the facility name, certificate type, expiration date, certificate number, and the number of pages per certificate.	Weekly	
CFR Title 21 - Food and Drugs	This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.	Quarterly	More About 21CFR
Clinical Laboratory Improvement Amendments (CLIA)	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000, and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.	Weekly	Clinical Laboratory Improvement Amendments - Download Data

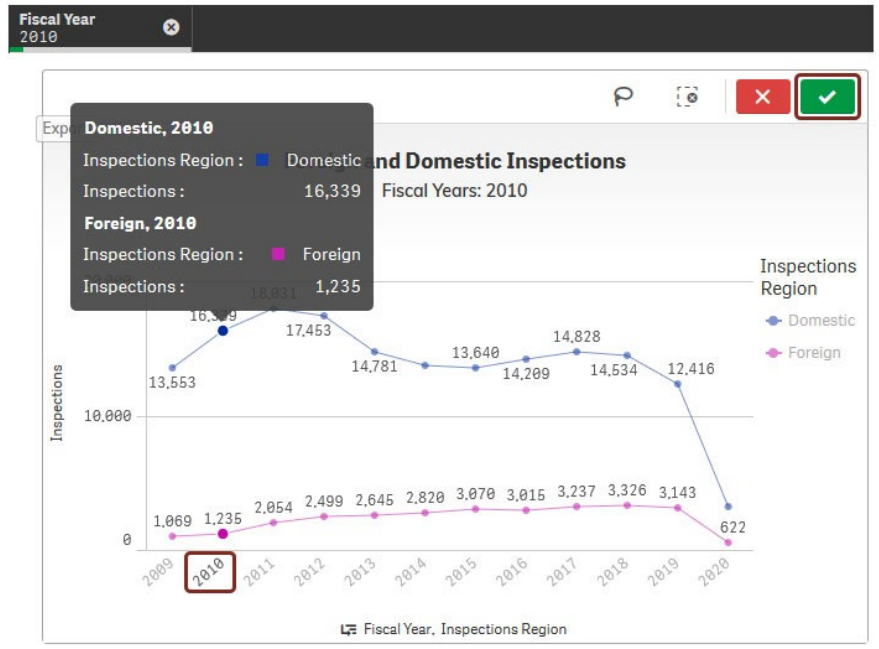
FDA.gov's Medical Device Databases Cont.

- Includes Pre-market, Post-Market, and Firm/Device Data
- Links to resources about the data set and compliance requirements
- Many offer export to CSV for complete dataset or search results

- DEMONSTRATION:
  - 510(k)
  - MAUDE
  - Device Classification
  - TPLC

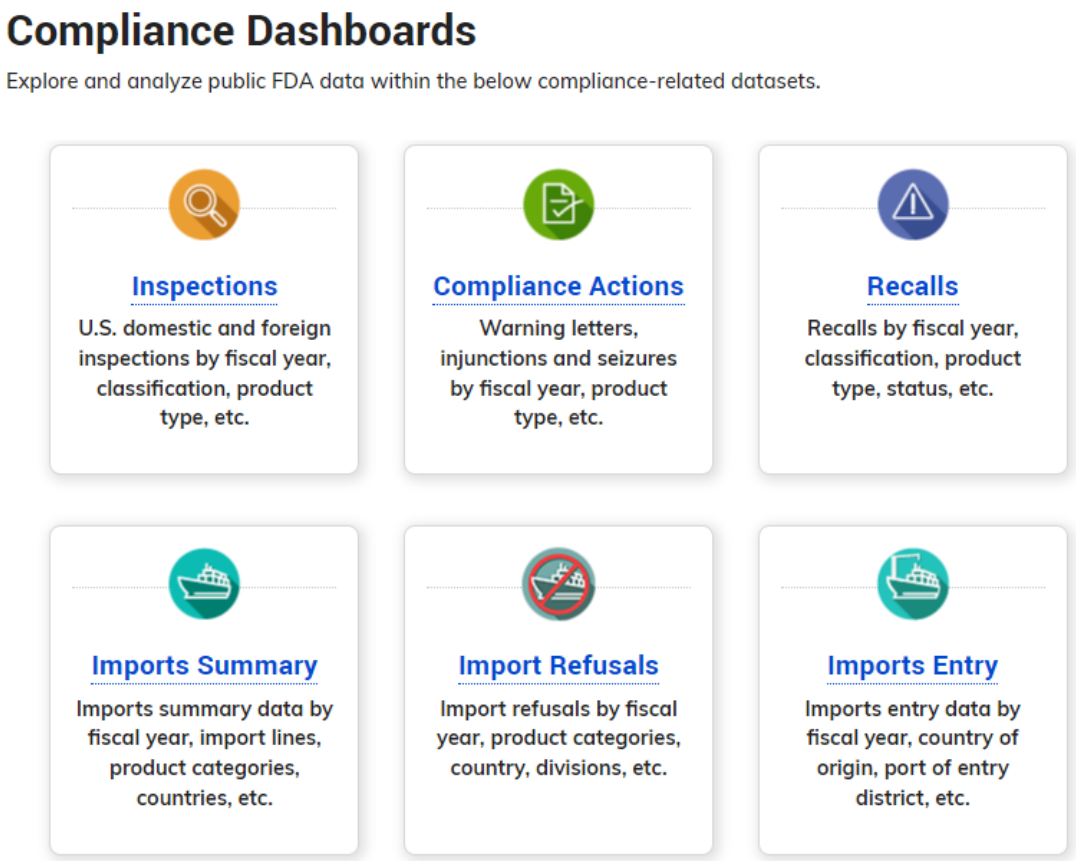
Data Dashboards

- Released 2014, the Data Dashboards afford access to a wide variety of compliance and enforcement data
- The dashboards provide various ways to visualize the data available
- Includes inspection, compliance action, imports and FSMA related dashboards
- Updated over time to add data types



FDA's Compliance Data Dashboards

- List of Compliance Data Dashboards found here: https://datadashboard.fda.gov/ora/cd/index.htm



FDA's Compliance Data Dashboards Cont.

- Dashboards include charts and tables displaying data
- Filters and searching available to help visualize data of interest
- Can download either full dataset, or a subset based on your filters. Data download in XLSX format with column headers.

- DEMONSTRATION
  - Inspections
  - Citations
  - Compliance Actions
  - Recalls

OpenFDA

- Released in 2014 to make it easier for FDA regulatory stakeholders to obtain important datasets
- Can download the complete datasets, or can have applications query via Application Programming Interfaces (APIs)

OpenFDA Download

- The link to download data sets is here: https://open.fda.gov/data/downloads/
- Data in zipped JSON format by endpoint, some may have many files due to size
- A Data Dictionary which defines each of the field names present in the data is provided here: https://open.fda.gov/data/datadictionary

- DEMONSTRATION
  - Recalls

FDA Data Dashboard and OpenFDA APIs

- Allows using structured queries to the server to return information of interest in JSON format
- FDA Data Dashboard https://datadashboard.fda.gov/ora/api/index.htm
- OpenFDA https://open.fda.gov/apis/
- Approximately 8 million API calls to OpenFDA in June 2022 alone!

```
{
    "start" : 1,
    "rows" : 10,
    "sort" : "ProductCode",
    "sortorder" : "ASC",
    "filters" : {
        "FEINumber":[3003378587,1000117386,3008091479]
    },
    "columns" : [
        "FEINumber",
        "FirmName",
        "CountryCode",
        "ProductCode",
        "RefusalDate"
    ]
}
```

WHERE CAN I GO TO GET MY QUESTIONS ANSWERED?

Device Resources

- CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn) provides training on basic FDA regulatory requirements related to the development, manufacture, and distribution of medical devices. Topics include:
  - Basics
  - How to Study and Market Your Device
  - Post-market Activities
  - Unique Device Identification (UDI) System
  - Specialty Technical Topics

Division of Industry and Consumer Education (DICE)

- Contact for regulatory questions from firms and the public, and develops educational resources to help industry understand FDA regulations and policies
- Will respond to question within 3-4 days

Email: DICE@fda.hhs.gov

Phone: 1(800) 638-2041 or (301) 796-7100

9AM-12:30PM, 1:00PM-4:30PM ET

QUESTIONS?

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