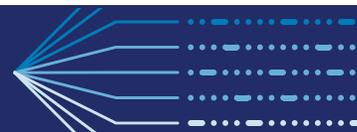




Over-the-Counter Drugs Modernizing Communications Between CDER and Industry

**Athena Shry, Project Manager, Office of Business Informatics
Office of Strategic Programs, CDER**

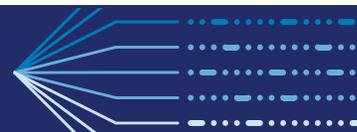
December 4, 2023



Who has bought an Over the Counter product?

- It is estimated that here in the United States, on average there are 2.9 billion trips taken annually to purchase an OTC product
- U.S. consumers make 26 trips a year to purchase OTC products. They only visit doctors, on average, three times a year.
- The average household will spend approximately \$338 per year on OTC drugs.

<https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics>



Over-The-Counter Monographs

- The OTC drug review was established to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972
- The monographs are 'recipe books' that establishes the conditions, under which an OTC drug is generally recognized as safe and effective (GRASE)
 - Their benefits outweigh their risks
 - The potential for misuse and abuse is low
 - Consumer can use them for self-diagnosed conditions
 - They can be adequately labeled
 - Health practitioners are not needed for the safe and effective use of the product



Over-the-Counter Monograph User Fee Agreement (OMUFA) & OTC Monograph Order Request (OMOR)

Industry Initiates Action



Infrastructure

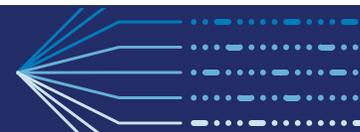
- Build a basic infrastructure (IT and training) to meet the goals of monograph reform

Communication

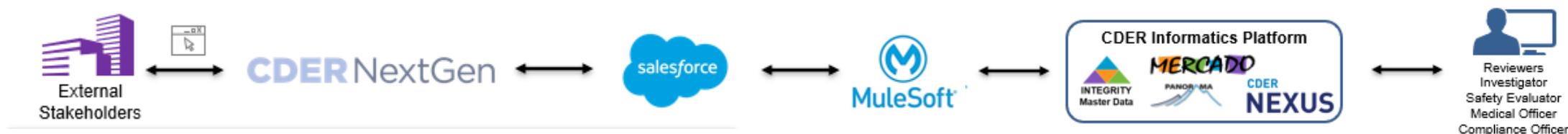
- Enhance communication and transparency

Tracking

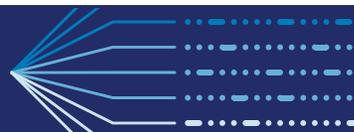
- Develop and incorporate measures to track successes and Agency accountability



CDER NextGen Portal Overview



- ✓ Singular Point of entry for industry
- ✓ Accessibility provided at no cost to industry
- ✓ Leverage Salesforce for enhanced user interface and robust capabilities



Portal OMOR Submission Builder

CDER NextGen
Portal

MGF 402985 - OMOR

SUBMISSION BUILDER

- i Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Submission Information

Requestor Information

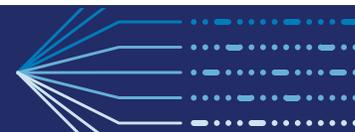
Organization Name	Agent Organization	Address Line 1	Address Line 2	City	State	Co
Tfmcc, LLC		61 Civey Blvd		Bixby	MO	US

Point of Contact Information

Please enter the Point of Contact Information for this OMOR i

This is the Point of Contact as entered when the MGF was created

Salutation <input type="text" value="Select an Option"/>	Job Title <input type="text"/>	Credentials <input type="text"/>
First Name <input type="text" value="Athena"/>	Middle Name <input type="text"/>	Last Name <input type="text" value="Shry"/>
Address Line 1 <input type="text" value="1 Main Street"/>	Address Line 2 <input type="text"/>	City <input type="text" value="Laurel"/>
Country <input type="text"/>	State <input type="text"/>	Postal Code <input type="text"/>



Portal OMOR Submission Builder (cont'd)

CDER NextGen Portal

MGF 402985 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries**
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?
The Help Center is available to answer all of your Over-the-Counter Monograph related questions.

Module 2: Summaries

Summary Documents

Upload contents of your Module 2: Summaries

- + 2.1 Table of Contents
- + 2.2 Introduction to the Summary Documents
- + 2.3 Quality Overall Summary
- + 2.4 Nonclinical Overview
- + 2.5 Clinical Overview
- + 2.6 Nonclinical Written and Tabulated Summaries
- + 2.7 Clinical Summary

Previous Save and Close Save Next

MGF 402985 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?
The Help Center is available to answer all of your Over-the-Counter Monograph related questions.

Module 2: Summaries

Summary Documents

Upload contents of your Module 2: Summaries

2.3 Quality Overall Summary

Please upload unique file names and refrain from uploading files with the same names.

- 2.3.I Introduction
- 2.3.S Drug Substance
- 2.3.P Drug Product
- 2.3.A Appendices
- 2.3.R Regional Information

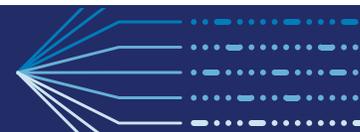
2.3.I Introduction

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as \/:?*" < > | are not allowed.

Upload Files Or drop files

Cancel Save

Previous Save and Close Save Next



Portal OTC Activity Log

CDER NextGen Portal Home Help Notifications User

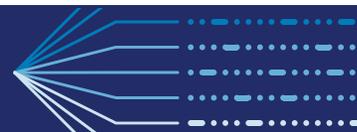
Over-the-Counter Monograph

MGF - 402331

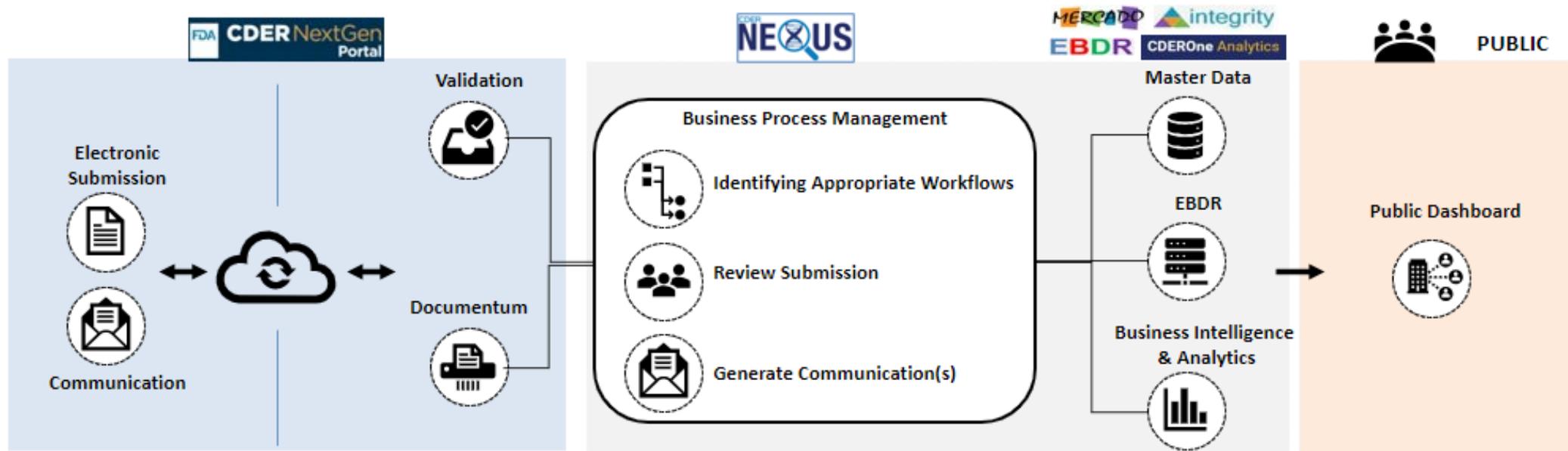
Activity Log Actions

ACTIVITY	SENDER	LAST UPDATED	
Information Request Response [12544] (SDN-3)	Uyen Truong	9/7/2023, 04:25 PM	▼
Information Request Response [12544] (SDN-2)	Uyen Truong	9/7/2023, 04:12 PM	▼
Advice/Information Request Letter [12544]	FDA	8/21/2023, 04:42 PM	▼
OMOR (SDN-1)	Uyen Truong	8/21/2023, 03:18 PM	▼
Pre-Assignment Request	Uyen Truong	8/21/2023, 01:55 PM	▼

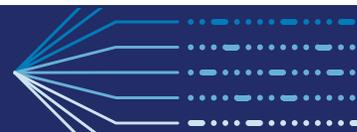
[Go Back](#)



OTC Flow of Information



<https://dps.fda.gov/omuf>



Summary Of Benefits



Efficiency: All information regarding meeting requests, OMORS and other correspondences are stored in one place. Requestors can view all transactions at any time.



Timeliness: Electronic Meeting Requests, OMORs, and Amendments can be delivered immediately. FDA communications including Advice/ Information Requests are also delivered immediately.



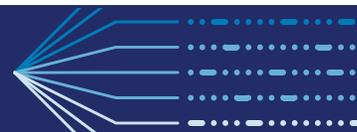
Automation: Requestors can log in, initiate a submission, and receive an automated confirmation of a transaction. FDA also received automated confirmation of new submissions and assignments.



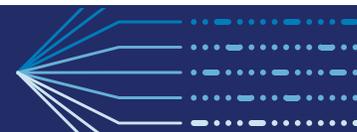
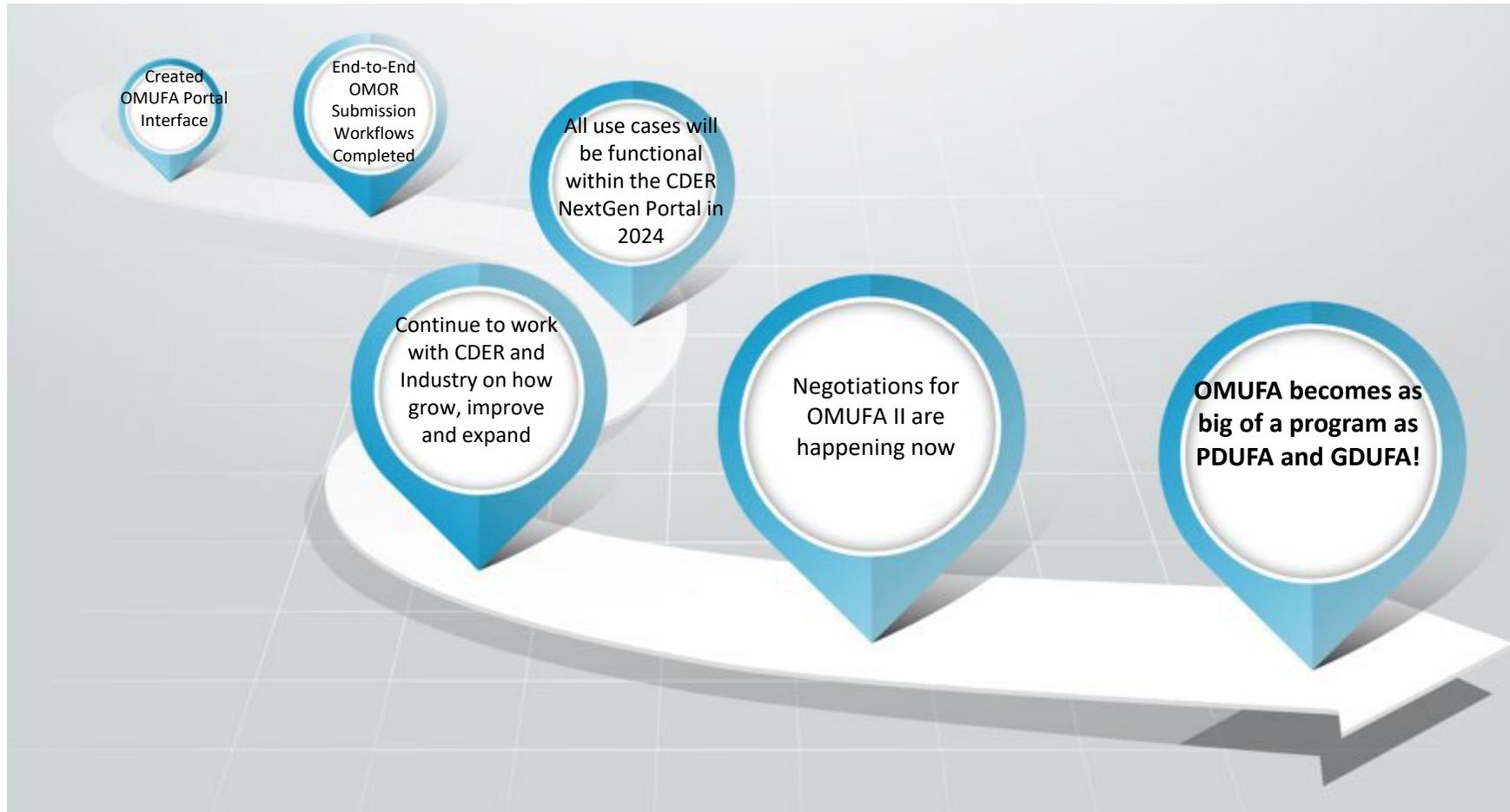
Knowledge Management: Data is created, captured, received and stored in structured format



Instruction: References guides, and step-by-step instructions are available at any time. Helpful hints and resource information is also available throughout the Portal screens



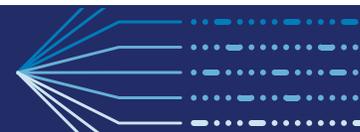
The Future of OMUFA





Questions?

Thank you!





**We are on break
and will
reconvene
shortly.**