

# **Project Managing Drug Assessors Under Generic Drug User Fee Amendment (GDUFA) III Regulations**

**Nuri Tawwab, PharmD, MPH**

LCDR, U.S. Public Health Service

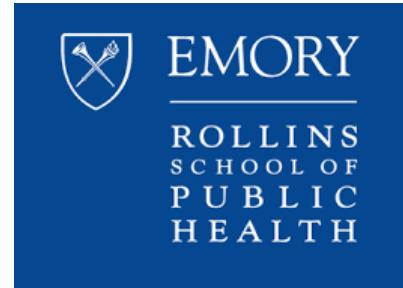
Stakeholder Engagement Team

Division of Prevention Communication and Public Engagement (DPCPE)

Center for Substance Abuse Prevention (CSAP) | Substance Abuse and Mental Health  
Services Administration (SAMHSA)

# LCDR Nuri Tawwab Educational Background

- Pharmacist
  - Hampton University School of Pharmacy
  - Emory University: Rollins School of Public Health
    - Concentration in prevention science



# Career in the Government

- Commissioned officer in the United States Public Health Service
  - Started as a Pharmacist at the Indian Health Service in 2012 in Kayenta, Arizona
    - Junior COSTEP in 2011
    - Senior COSTEP in 2012
  - Transferred to the FDA in 2015 to become a Regulatory Business Process Manager (RBPM) in OPQ
    - The Office of Pharmaceutical Quality's (OPQ) mission is to assure that quality medicines are available for the American public.

# Current Job Role

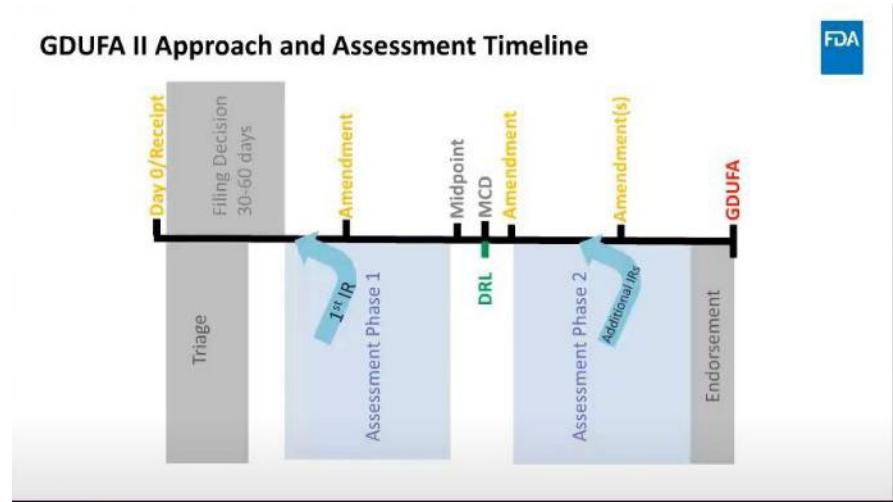
- Regulatory Business Process Manager
  - POC for communication related to drug product quality or facility status information to the drug firms.
    - Information request (IR) letters
    - Discipline review letters (DRL)
  - Manage the lifecycle of drugs via a team-based Integrated Quality Assessment (IQA) model.
    - IQA aligns patient-focused and risk-based drug product quality recommendations. It encompasses
    - new drug applications (NDAs),
    - abbreviated new drug applications (ANDAs)
  - The congressional mandate that we follow when managing these applications or projects is called the Generic Drug User Fee Amendments (GDUFA).

# What is GDUFA 3

- “Generic Drug User Fee Amendments- reauthorized every five years
- The law signed to speed up the delivery of safe and effective drugs to the public improving the predictability of the review process. The amendments are based on agreement from FDA and the generic drug industry.
  - GDUFA 1: 2012
  - GDUFA 2: 2017
  - **GDUFA 3: 2022**
- References
  - [GDUFA commitment letter: GDUFA](https://www.fda.gov/media/82022/download) <https://www.fda.gov/media/82022/download>
  - [GDUFA 2 commitment letter: https://www.fda.gov/media/101052/download?attachment](https://www.fda.gov/media/101052/download?attachment)
  - [GDUFA 3 commitment letter: https://www.fda.gov/media/153631/download?attachment](https://www.fda.gov/media/153631/download?attachment)

# GDUFA 3 Improvements

- There are many improvement from GDUFA 2 and GDUFA 3 to enhance the review process.
  - 10 month assessment
  - Managing correspondence from the firms.
  - Late cycle IRs and Goal date extension
- Time line rules, ex. Filing, 60 days
- Reference
  - GDUFA 3 commitment letter:  
<https://www.fda.gov/media/153631/download?attachment>



# Scope of the Work

1. Applications are triaged to 30 alignment teams by senior RBPMs.

Office	Discipline	Position	AT 1		AT 2	
OPRO		RBPM (BC)	RBPM		RBPM	
		RBPM (BC)	RBPM		RBPM	
		RBPM (BC)	RBPM		RBPM	
OPQA 1/2	Drug Product	SPQA	DIMRPI-B1	AtI	DIMRPI-B1	ATL
			DIMRPI-B1	Assessor	DIMRPI-B1	Assessor
			DIMRPI-B1	Assessor	DIMRPI-B1	Assessor
			DIMRPI-B1	Assessor	DIMRPI-B1	Assessor
			DIMRPI-B1	Assessor	DIMRPI-B1	Assessor
		Primary				
OPMA	Manufacturing	Primary/SPQA	DPMA I	assessor /Senior Pharmaceutical Quality Assessors (SPQA)		
			DPMA I	assessor/SPQA		
			DPMA I	assessor/SPQA		
			DPMA I	assessor/SPQA		
			DPMA I	assessor/SPQA		
			DPMA I	assessor/SPQA		
OPMA	Micro	Primary/SPQA	DPMA I	assessor/SPQA		
			DPMA I	assessor/SPQA		
			DPMA II	assessor/SPQA		
OPQA 1/2/3	Biopharm***	SPQA	DB			
			DB	assessor		
			DB	assessor		
			DB	assessor		
			DB	assessor		
OPQA 3	Drug Substance (DMF)	SPQA	DLAPI	SPQA		
			DLAPI	assessor		
			DLAPI	assessor		
			DLAPI	assessor		
			DLAPI	assessor		
			DLAPI	assessor		
			DLAPI	assessor		

# Scope of the Work

## 1. Tracking sheet

- Coordinating and tracking the workload of assessors.

2	AT 2.0 AT19 and AT20 Workload	Original Assigned Originals Assigned				Total Amendments	TOTAL
3		L-Non-Sterile	L-Sterile	Solids	Total Originals		
4	<b>OLDP</b>						
5	assessor/ATL						
6	assessor/ATL						
7	assessor/ATL						
8	assessor/ATL						
9	assessor/ATL						
0							
1	assessor/ATL						
2	assessor/ATL						
3	assessor/ATL						
4	assessor/ATL						
5	assessor/ATL						
6	<b>OPMA</b>						
7	Assessor/SPQA						
8	Assessor/SPQA						
9	Assessor/SPQA						
10	Assessor/SPQA						
11	Assessor/SPQA						
12	Assessor/SPQA						
13	<b>MICRO</b>						
14	Assessor/SPQA-F						
15	Assessor/SPQA						
16	Assessor/SPQA						
17	<b>Biopharm</b>						
18	Assessor/SPQA						
19	Assessor/SPQA						

# PM Tools for Managing the Lifecycle of Generic Drugs

PANORMA



MERCADO

# Tools for Managing the Lifecycle of Generic Drugs: Panorama

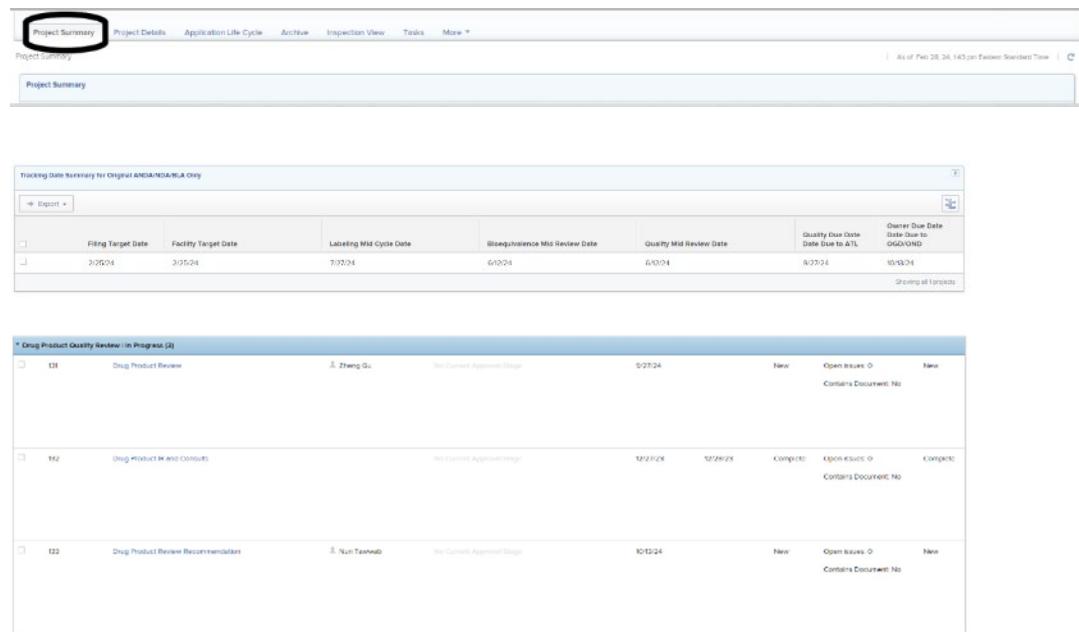
Panorama – a unique tool custom built for FDA which involved mapping all the review and project management tasks and implementation of automated task assignment, tracking, status updates, and communications. This system allows tracking of a given document from the moment it arrives at CDER till its review is completed and outcome filed.



# Panorama

## Project summary page of application

- List the tracking dates of the
  - QDD-1 (MID-cycle review)
  - QDD-2
  - ODD
- Disciplines current status in their review and any open issues
  - Planning and coordinating the review: tracking progress ensuring that the process is completed effectively and that quality standards are met



The screenshot shows the Project Summary page of an application in Panorama. The top navigation bar includes Project Summary, Project Details, Application Life Cycle, Active, Inspection View, Tasks, and More. The Project Summary section displays tracking dates for QDD-1, QDD-2, and ODD. Below this is a table for 'Tracking Date Summary for Original ANDA/NDMA/BLA Only'. The table includes columns for Filing Target Date, Facility Target Date, Labeling Mid-Cycle Date, Bioequivalence Mid-Review Date, Quality Mid-Review Date, Quality Due Date, Date Due to GDUFA/OND, and Owner Due Date. The data shows dates from 3/25/24 to 10/31/24. The bottom section shows a list of 'Drug Product Quality Review (In Progress: 3)'. It includes rows for 121 (Drug Product Review, by Zheng Gu, No Current Approval Stage, 5/27/24, New, Open Issues: 0, Contains Document: No), 122 (Drug Product Review (AND, C), by No Current Approval Stage, 5/27/24, 5/27/24, Complete, Open Issues: 0, Contains Document: No), and 123 (Drug Product Review Recommendation, by NutraHealth, No Current Approval Stage, 10/12/24, New, Open Issues: 0, Contains Document: No).

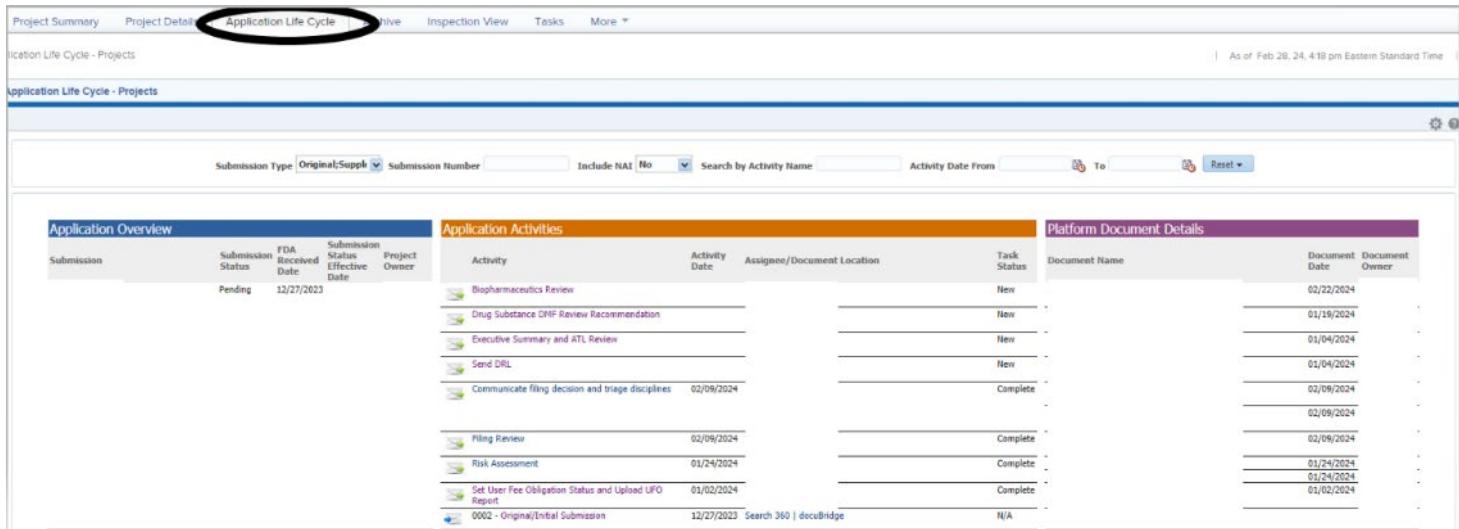
Tracking Date Summary for Original ANDA/NDMA/BLA Only							
Export		Actions					
	Filing Target Date	Facility Target Date	Labeling Mid-Cycle Date	Bioequivalence Mid-Review Date	Quality Mid-Review Date	Quality Due Date Date Due to GDUFA/OND	Owner Due Date
	3/25/24	3/31/24	7/31/24	6/10/24	6/10/24	9/30/24	10/31/24

Drug Product Quality Review (In Progress: 3)							
	Task	Owner	Review Stage	Due Date	Open Issues	Contains Document	Notes
121	Drug Product Review	Zheng Gu	No Current Approval Stage	5/27/24	New	Open Issues: 0	New
122	Drug Product Review (AND, C)	No Current Approval Stage	5/27/24	5/27/24	Complete	Open Issues: 0	Complete
123	Drug Product Review Recommendation	NutraHealth	No Current Approval Stage	10/12/24	New	Open Issues: 0	New

# Panorama

## Application Life Cycle

- History of all submission from the firm (drug company)
- History of communications sent to the firm



The screenshot shows the Panorama application interface for managing drug submissions. The top navigation bar includes 'Project Summary', 'Project Details', **Application Life Cycle** (which is circled in black), 'Archive', 'Inspection View', 'Tasks', and 'More'. A status bar at the top right indicates 'As of Feb 28, 24, 4:18 pm Eastern Standard Time'. The main content area is titled 'Application Life Cycle - Projects' and shows a table of activities. The table has three main sections: 'Application Overview', 'Application Activities', and 'Platform Document Details'.

Application Overview				Application Activities				Platform Document Details		
Submission	Submission Status	FDA Received Date	Submission Status Effective Date	Activity	Activity Date	Assignee/Document Location	Task Status	Document Name	Document Date	Document Owner
	Pending	12/27/2023		Biopharmaceutics Review			New		02/22/2024	
				Drug Substance DMR Review Recommendation			New		01/19/2024	
				Executive Summary and ATL Review			New		01/04/2024	
				Send DRL			New		01/04/2024	
				Communicate filing decision and triage disciplines	02/09/2024		Complete		02/09/2024	
				Piling Review	02/09/2024		Complete		02/09/2024	
				Risk Assessment	01/24/2024		Complete		01/24/2024	
				Set User Fee Obligation Status and Upload UFO Report	01/02/2024		Complete		01/24/2024	
				0002 - Original/Initial Submission	12/27/2023	Search 360   docuBridge	N/A		01/02/2024	

# Panorama

- **Dashboard**
  - List of all the drug applications currently being worked on.
    - Updated in Realtime.
    - Those completed and under review
- **Work Request**
  - Applications that require an action from me
  - Different from the dashboard as it allows you to find applications like supplements that you are managing that may not show up on the dashboard as these application or managed differently.

# Panorama

## Documentation importance in Panorama

- Review status updates
- Anticipated miss goal dates



OPQ RBPM	Quality Review Note	Quality Percent Complete
<input type="checkbox"/>	01/04/2023: triaged, QDD-1 is 06/12/2024. QDD-1: 6/12/24 QDD-2: 9/27/24 ODD: 10/13/24 Goal Date: 10/27/2024	<div style="width: 39.36%;">39.36%</div>

Showing all 1 tasks

# Tools for Managing the Lifecycle of Generic Drugs: Mercado

- Mercado (Reporting): Real-time, automated reporting that enables project managers and leaders to better allocate resources and understand performance relative to public and Congressional commitments.
- Mercado (Search): A “Google-like” search web application that allows users to easily access data across multiple business domains to facilitate drug application reviews.



# Mercado

## Assigning assessor to applications

- Used in addition to our excel tracking sheet
- View assessor current amount of application compared to counter parts.
- Compare goal date assessor to determine which assessor to assign.



# Lessons Learned

- Managing meetings with stakeholders
  - Collecting list of names and positions before the meeting
  - Having an agenda for the meeting
  - Asking for the firm to send in minutes at the end the meeting
- Communicating with authorized agents on 356-H
  - Make sure all communication is sent through the representative or U.S. agent list specifically on the 356-H.
  - Asking that all scientific information is submitted through CDER eCTD to keep track
- Timing of email notifications from drug firms
  - Asking to acknowledge all communication
  - Making calendar invites for assessors

# Questions?

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# Thank You!