

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

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LCDR, U.S. Public Health Service

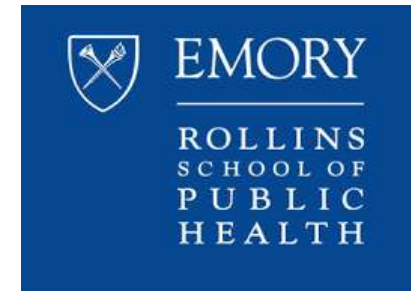
Stakeholder Engagement Team

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

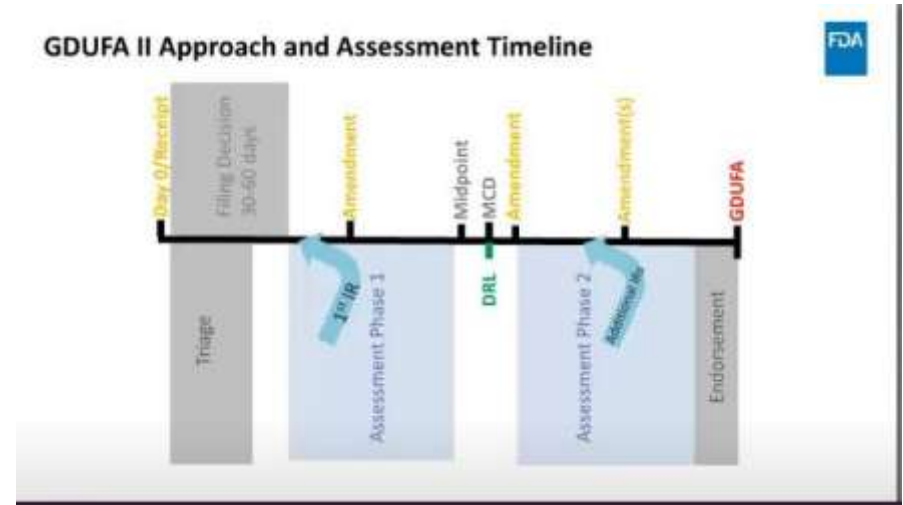
- Regulatory Business Process Manager
 - POC for communication related to drug product quality or facility status information to the drug firms.
 - Information request (IR) letters
 - Discipline review letters (DRL)
 - Manage the lifecycle of drugs via a team-based Integrated Quality Assessment (IQA) 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. Application are triaged to 30 alignment teams by senior RBPMs.

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

		Original Assigned						
	AT 2.0 AT19 and AT20 Workload	Originals Assigned						
		L-Non-Sterile	L-Sterile	Solids	Total Originals	Total Amendments	TOTAL	
	OLDP							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	assessor/ATL							
	OPMA							
	Assessor/SPQA							
	Assessor/SPQA							
	Assessor/SPQA							
	Assessor/SPQA							
	Assessor/SPQA							
	Assessor/SPQA							
	MICRO							
	Assessor/SPQA							
	Assessor/SPQA							
	Assessor/SPQA							
	Biopharm							
	Assessor/SPQA							
	Assessor/SPQA							

PM Tools for Managing the Lifecycle of Generic Drugs



Tools for Managing the Lifecycle of Generic Drugs: Panorama

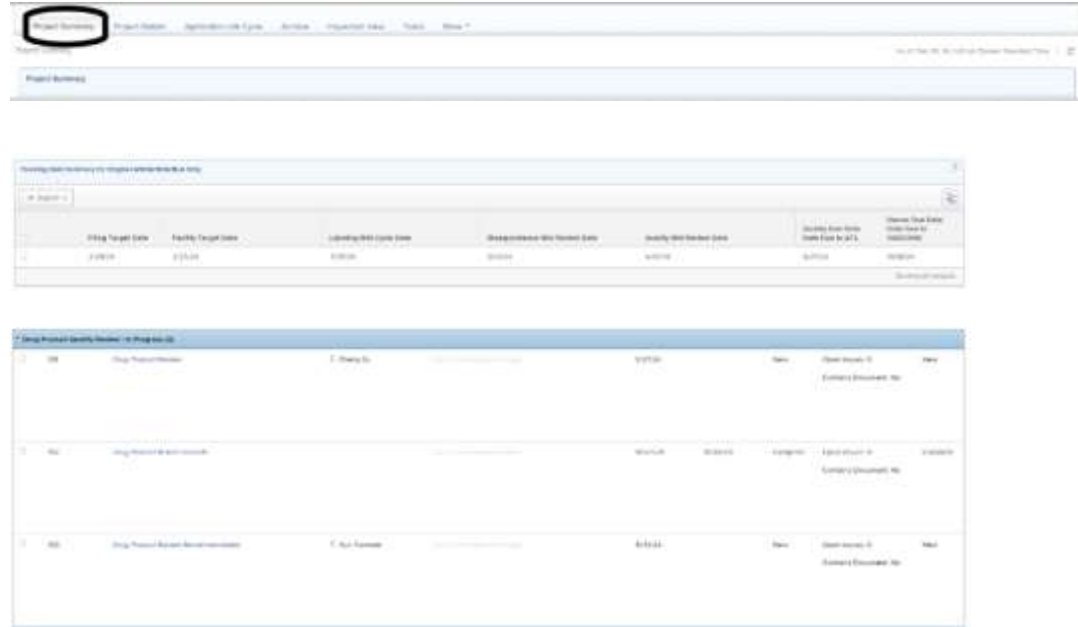
Panorama – a unique tool custom built for FDA which involved mapping all the review and project management tasks and implementation of automated task assignment, tracking, status updates, and communications. This system allows tracking of a given document from the moment it arrives at CDER till its review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



QDD-1 Target Date	QDD-2 Target Date	QDD-3 Target Date	QDD-4 Target Date	QDD-5 Target Date	QDD-6 Target Date	QDD-7 Target Date	QDD-8 Target Date	QDD-9 Target Date	QDD-10 Target Date
2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18

QDD-1 Target Date	QDD-2 Target Date	QDD-3 Target Date	QDD-4 Target Date	QDD-5 Target Date	QDD-6 Target Date	QDD-7 Target Date	QDD-8 Target Date	QDD-9 Target Date	QDD-10 Target Date
2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18	2/28/18

Panorama

Application Life Cycle

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

The screenshot displays the 'Application Life Cycle' section of the Panorama software. The top navigation bar includes tabs for 'Project Summary', 'Project Details', 'Application Life Cycle' (which is circled), 'Archive', 'Inspection View', 'Tasks', and 'More'. Below the navigation bar, the page title is 'Application Life Cycle - Projects'. The main content area features a search bar with filters for 'Submission Type' (set to 'Original/Suppl'), 'Submission Number', 'Include RIA' (set to 'No'), 'Search by Activity Name', 'Activity Date From', and 'To'. Below the search bar, there are 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	Project Owner	Activity	Activity Date	Assignee/Document Location	Task Status	Document Name	Document Date	Document Owner
	Pending	12/27/2023			Biopharmaceutics Review			New		02/02/2024	
					Drug Substance GRP Review Recommendation			New		01/16/2024	
					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	
					Filing 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 docs@hedge	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

RBPM Notes		
Export		
<input type="checkbox"/> 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	39.36%
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!