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

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Stakeholder Engagement Team

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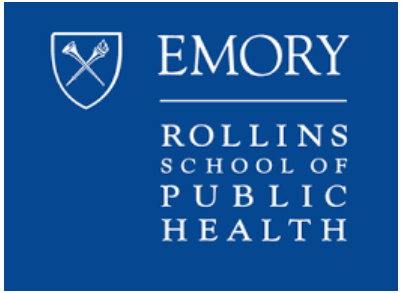
LCDR Nuri Tawwab Educational Background

- 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

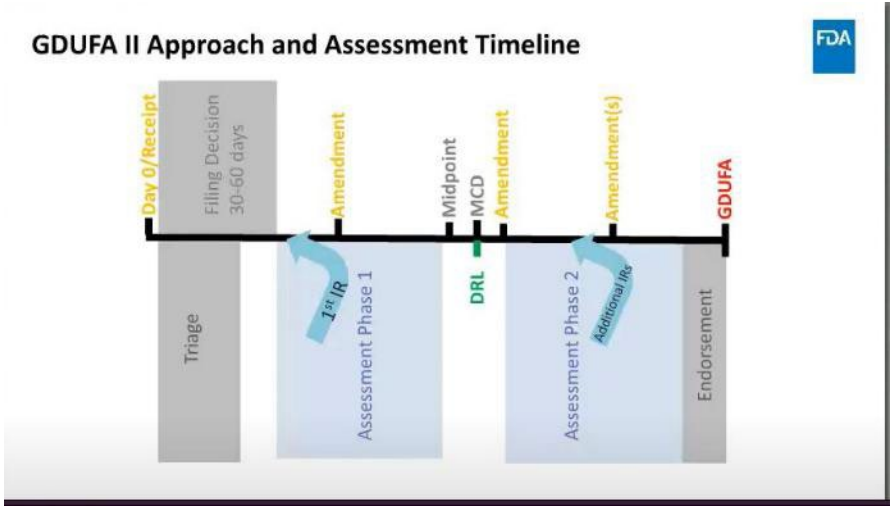
- Regulatory Business Process Manager
  - POC for communication related to drug product quality or facility status information to the drug firms.
    - Information request (IR) letters
    - Discipline review letters (DRL)
  - Manage the lifecycle of drugs via a team-based Integrated Quality Assessment (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
  - GDUFA 2 commitment letter: https://www.fda.gov/media/101052/download?attachment
  - GDUFA 3 commitment letter: 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		
			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.

	AT 2.0 AT19 and AT20 Workload	Original Assigned / 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						
	assessor/ATL						
	OPMA						
	Assessor/SPQA						
	Assessor/SPQA						
	~~Assessor/SPQA~~						
	Assessor/SPQA						
	Assessor/SPQA						
	Assessor/SPQA						
	MICRO						
	~~Assessor/SPQA r~~						
	Assessor/SPQA						
	Assessor/SPQA						
	Biopharm						
	Assessor/SPQA						
	Assessor/SPQA						

PM Tools for Managing the Lifecycle of Generic Drugs

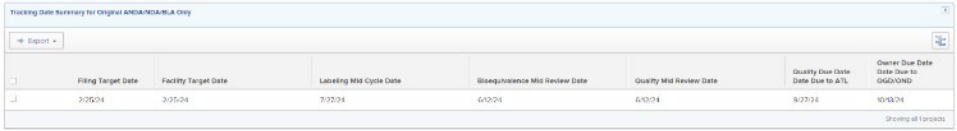
Tools for Managing the Lifecycle of Generic Drugs: Panorama

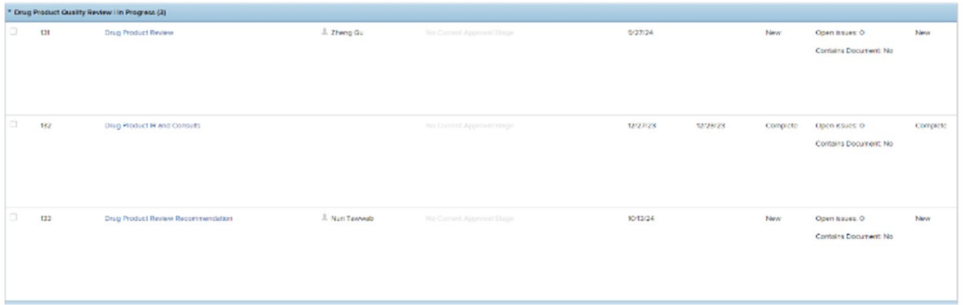
Panorama – a unique tool custom built for FDA which involved mapping all the review and project management tasks and implementation of automated task assignment, tracking, status updates, and communications. This system allows tracking of a given document from the moment it arrives at CDER till its review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

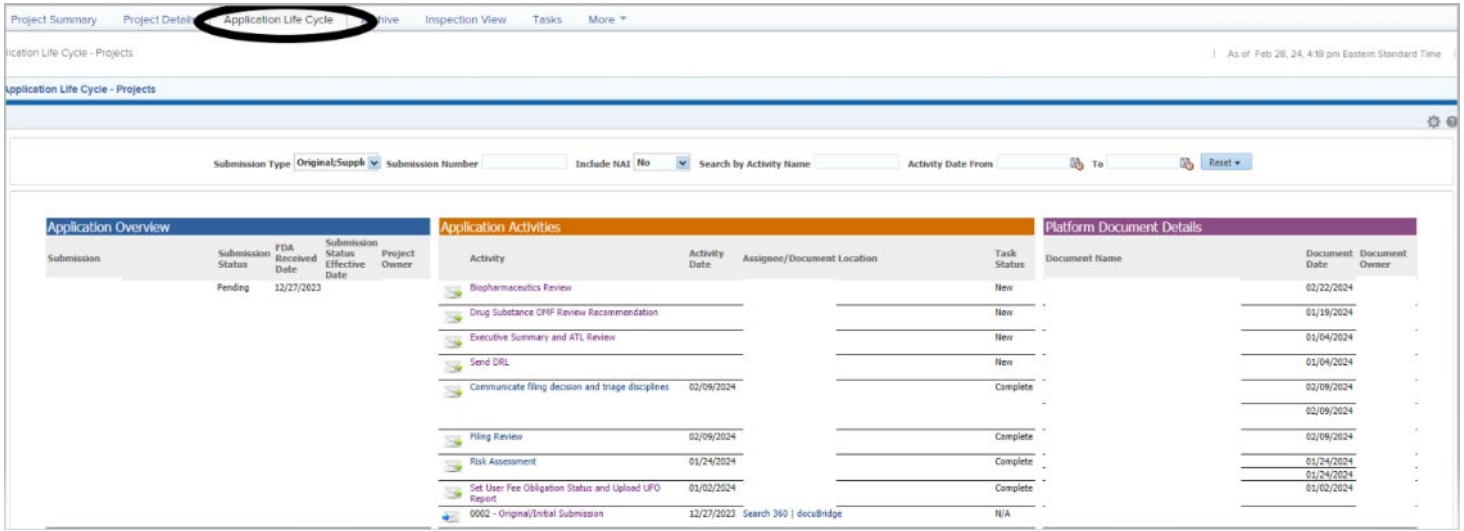




Panorama

Application Life Cycle

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



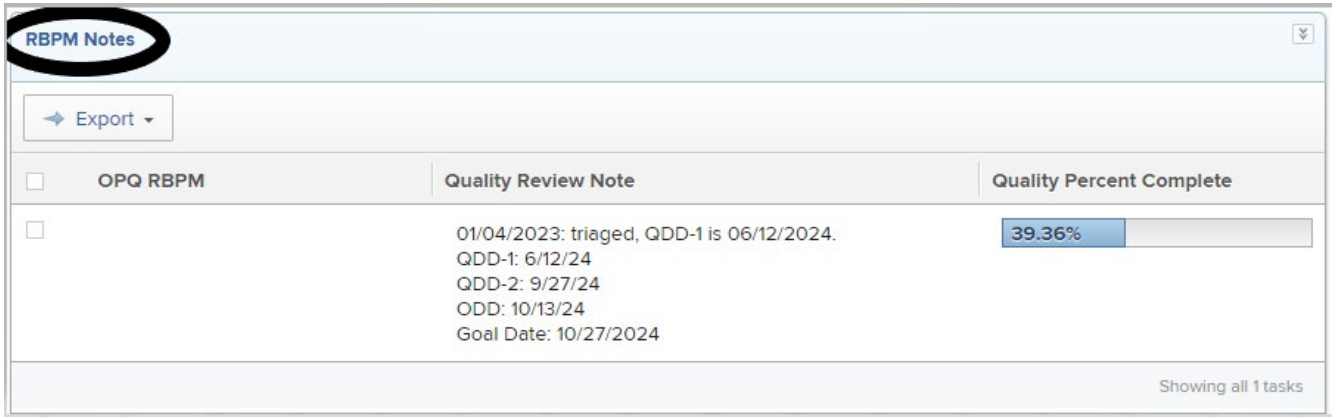
Panorama

- **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



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!