

# Mid-Review Cycle Meetings for Complex Products

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# Learning Objectives

Goals of the Mid-Review Cycle Meeting

What this Means to Industry & FDA

Overall Impact

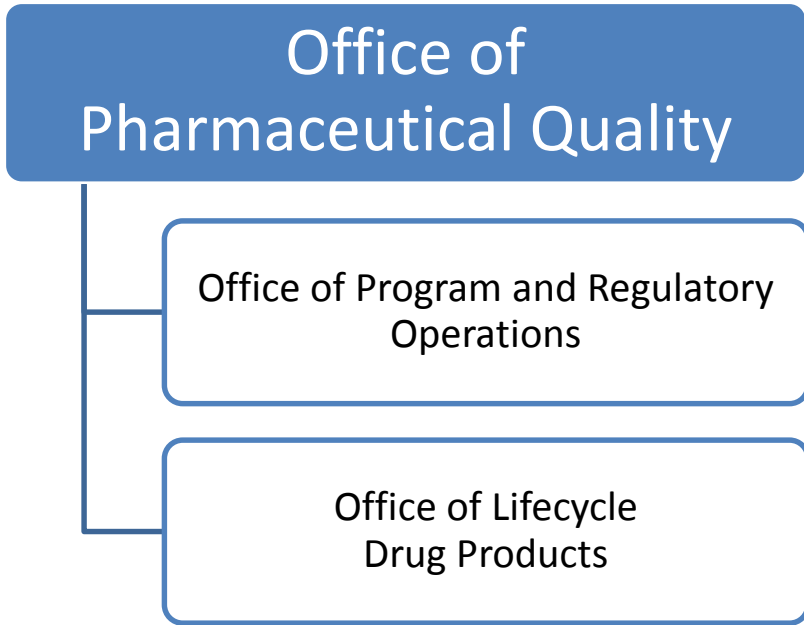
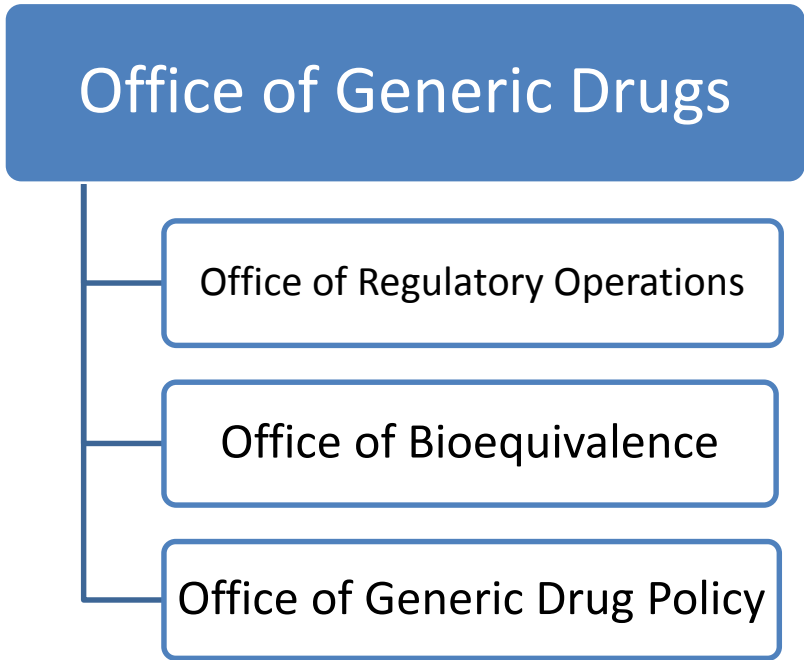
Industry & FDA Responsibilities

How Industry Can Assist

# Commitment Letter Language

- Section [III. F. 2. a.]: As set forth in guidance issued pursuant to Section III(A)(1), the Project Manager and other appropriate members of the FDA review team **will call the applicant to provide the applicant with an update on the status of the review of their application.** An agenda will be sent to the applicant prior to the mid-review-cycle meeting. The Project Manager will coordinate the specific date and time of the telephone call with the applicant. (emphasis added)

# Work Group Organization



# What is New?

## GDUFA II Establishes a Pre-ANDA Program for Complex Generic Drug Products

Applicants granted a Product Development Meeting OR a Pre-submission Meeting have the option of a Mid-Review Cycle Meeting (MRCM) in the form of a 30-minute teleconference



### Goals:

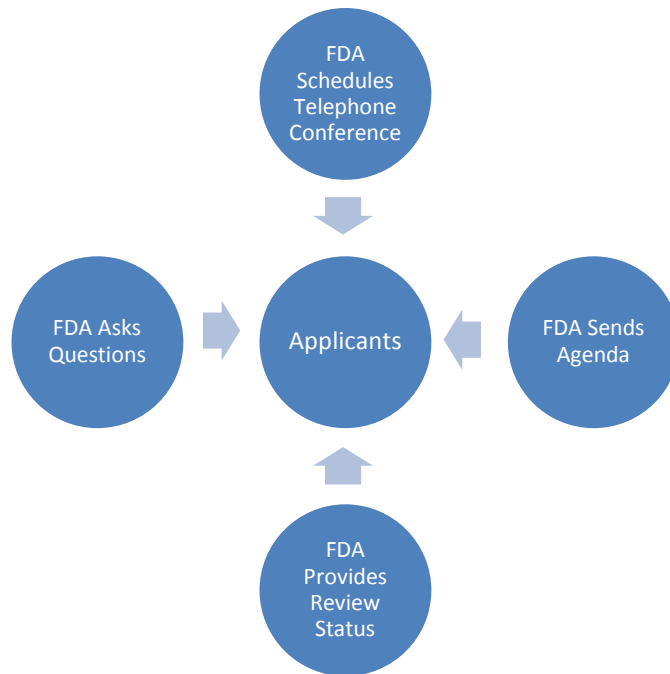
Clarify regulatory expectations in early development

Assist applicants with developing more complete submissions

More efficient/effective review process

Reduce # of cycles

# What Does it Mean?



# What is the Impact?



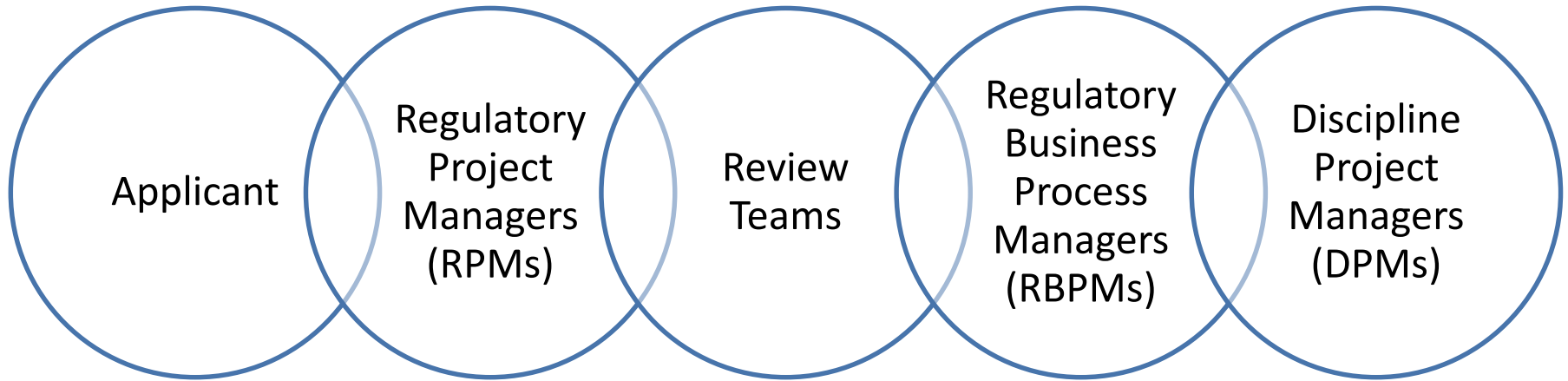
More complete  
ANDA  
submissions

More  
efficient/effective  
review process

Reduced Number  
of cycles

Decreased time  
from ANDA  
acceptance to  
approval

# Who is Responsible?

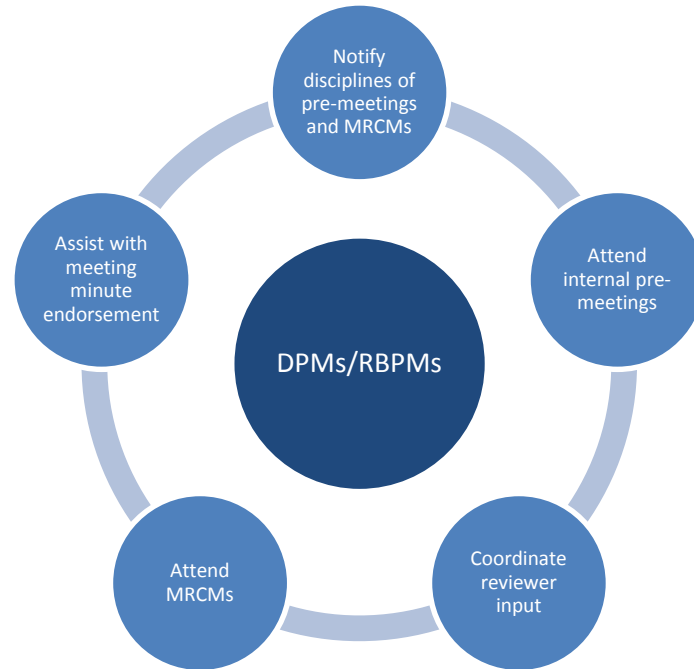




# What Will They Do?



# What Will They Do?



# What Will They Do?



# What Can Industry Do to Assist?



# Summary

Goals of the Mid-Review Cycle Meeting



What this Means to Industry & FDA



Overall Impact



FDA Responsibilities



How Industry Can Assist

For questions, please contact the  
Regulatory Project Manager  
assigned to the respective ANDA

