Mid-Review Cycle Meetings for Complex Products

Nicholas Daniel, PharmD, BCPS

LT, U.S. Public Health Service

Regulatory Project Manager

Division of Project Management, ORO, OGD

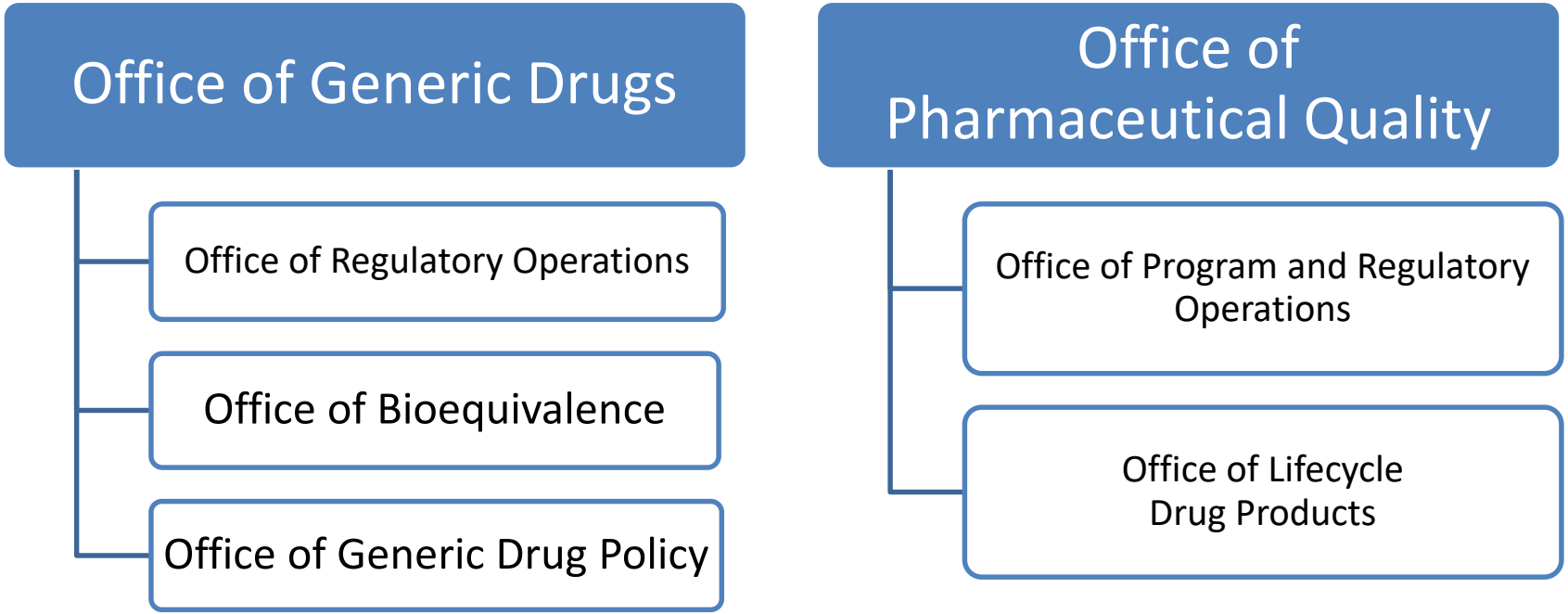
Learning Objectives

- 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?

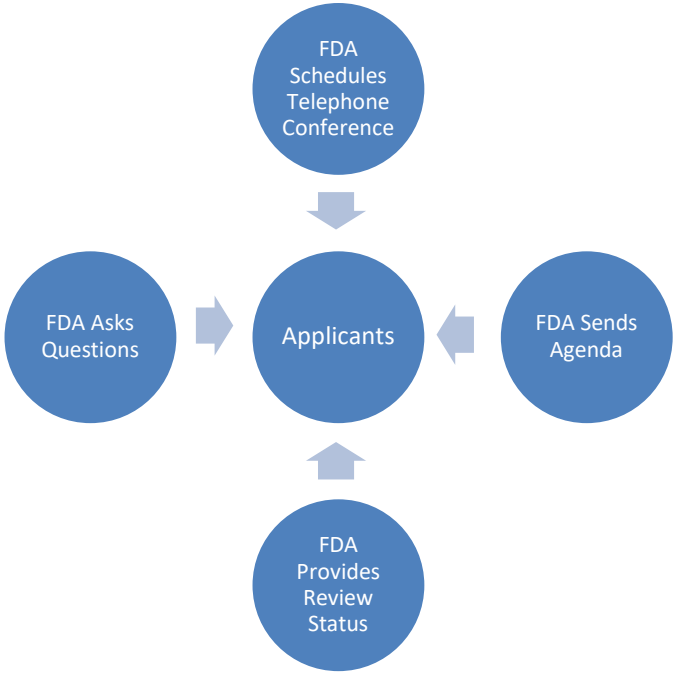
GDUFA II Establishes a Pre-ANDA Program for Complex Generic Drug Products

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

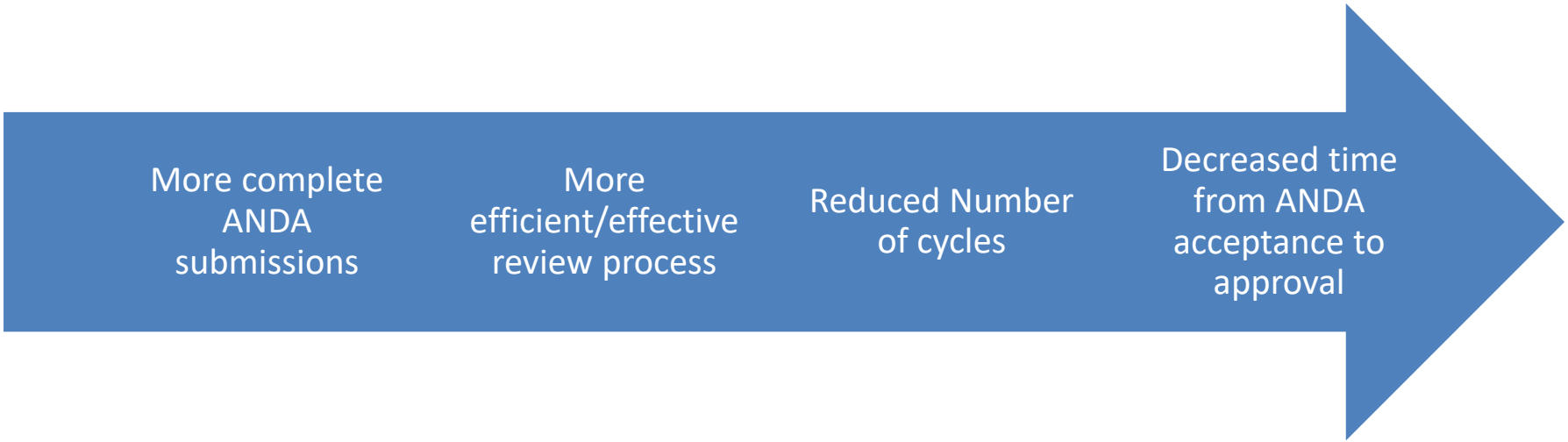
Goals:

Clarify regulatory expectations in early development	Assist applicants with developing more complete submissions	More efficient/effective review process	Reduce # of cycles

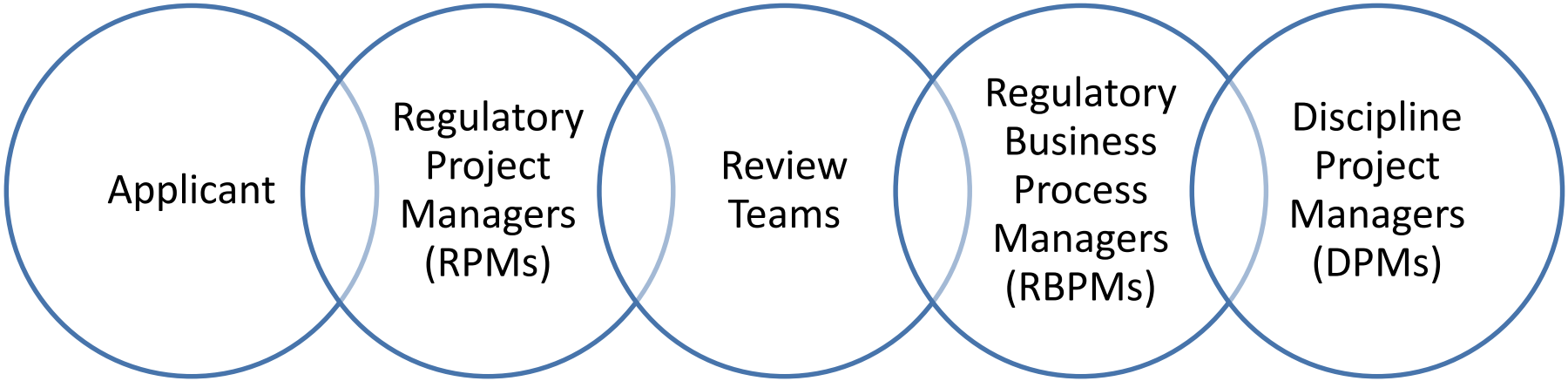
What Does it Mean?



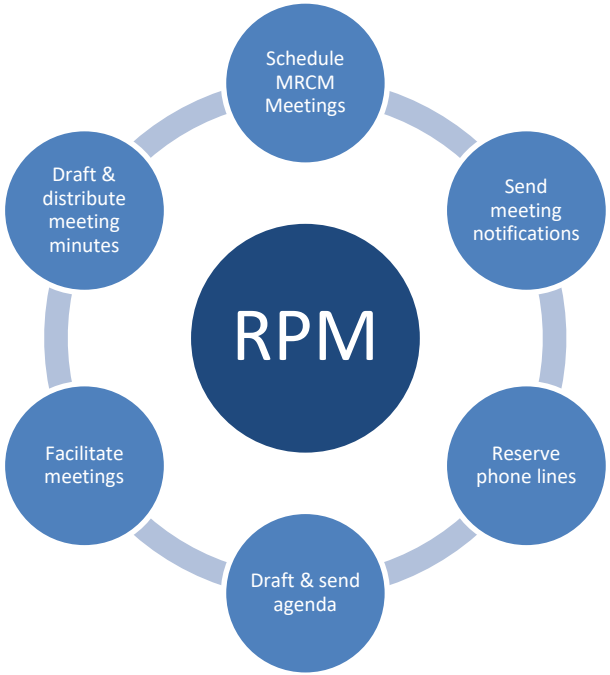
What is the Impact?



Who is Responsible?



What Will They Do?



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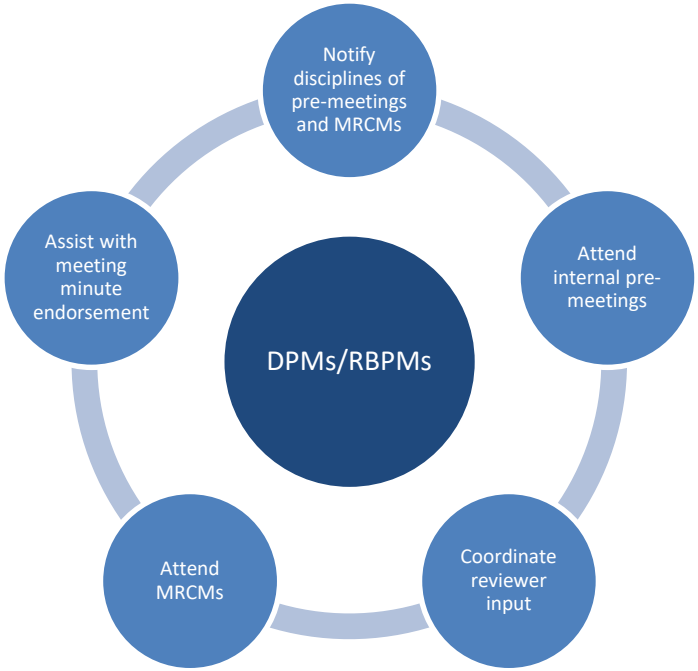
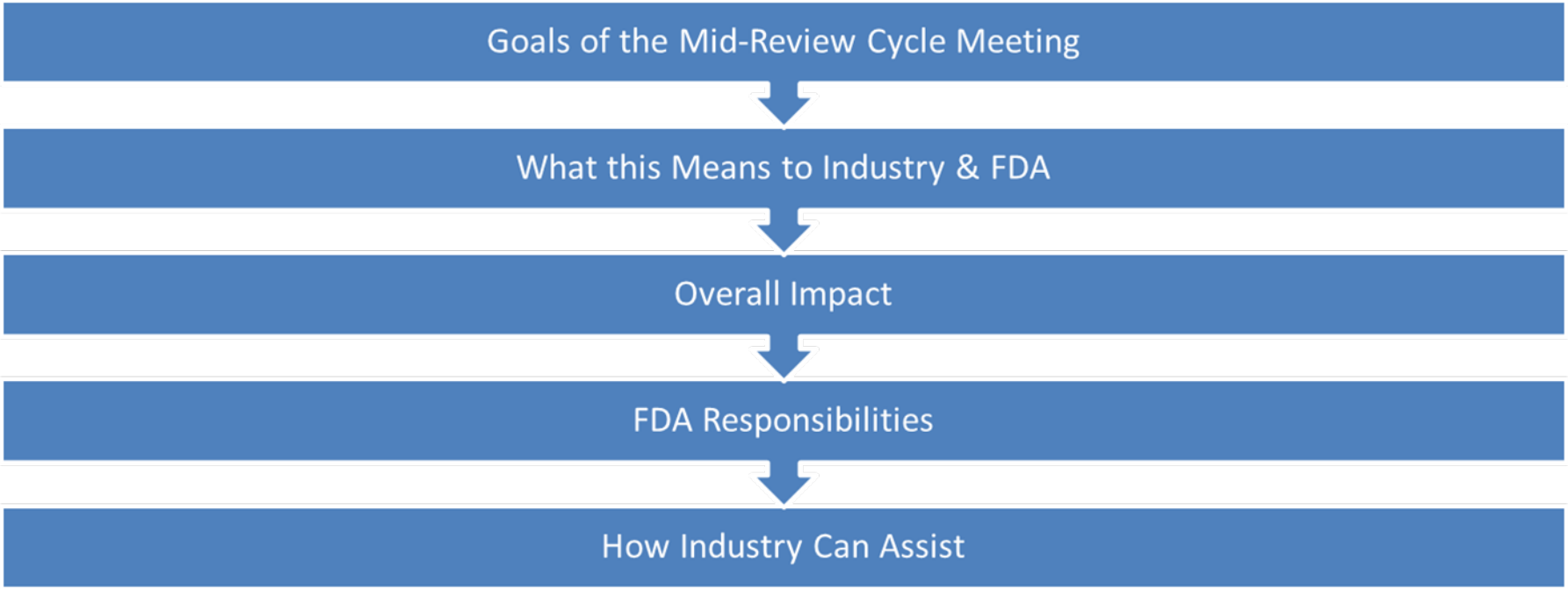


What Will They Do?

What Can Industry Do to Assist?

Summary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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


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