



# GRx+Biosims™

**Generic + Biosimilar Medicines Conference**

Drug Substance and Drug Product Manufacturers -  
Partnering to Improve the Process

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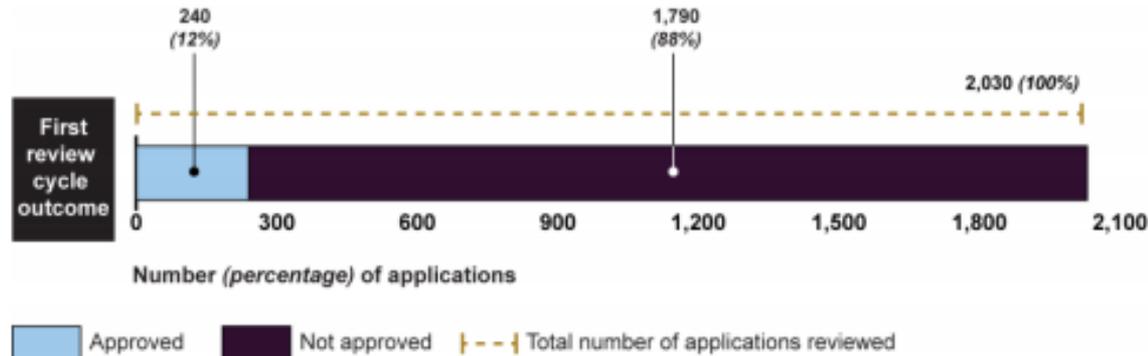


# Drug Substance and Drug Product Manufacturers - Partnering to Improve the Process: The ANDA Sponsor's Perspective

November 4-6, North Bethesda MD

# Administration/Industry Mutual Goal – Increasing One Cycle Review Success

Figure 1: Number and Percentage of Generic Drug Applications Approved in the First Review Cycle, Fiscal Years 2015–2017



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-19-565

- 12% of ANDAs achieved one-cycle review
- How do DMFs factor in?



## DMF Role in One Cycle Review Success

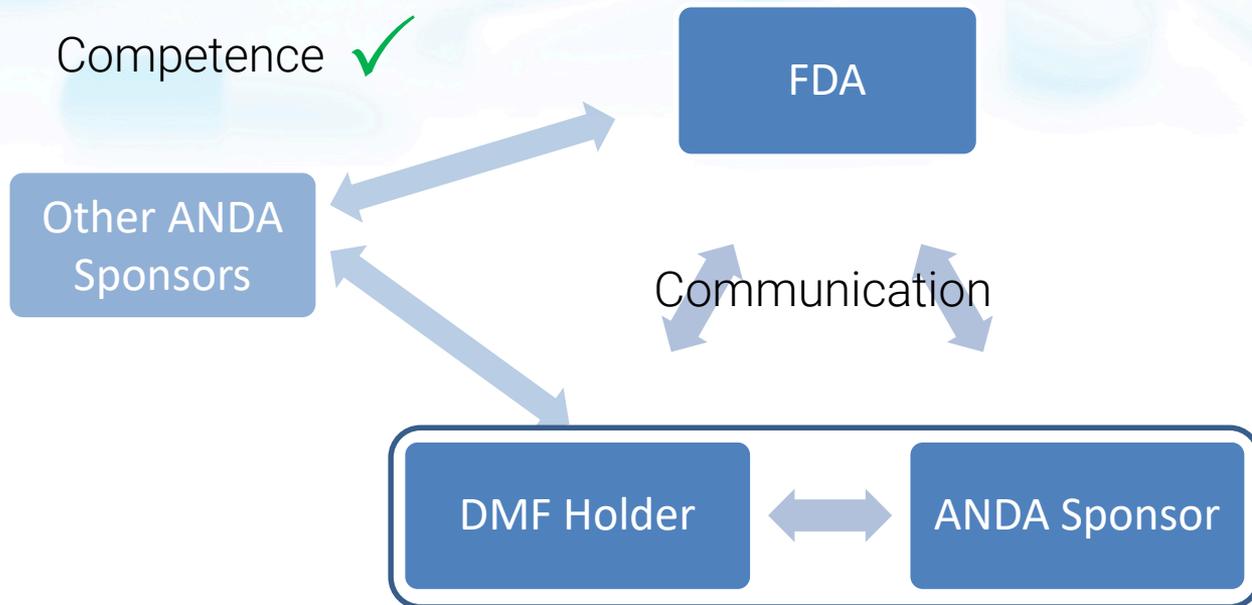
- “98% of DMFs being reviewed for the first time are found inadequate and issued a DMF CR letter.”

R.S. Randad, 2017 AAM CMC Workshop May, 2017

- About half of ANDA submissions reference DMFs being reviewed for the first time
- How to improve –  
Submit better quality DMFs, respond to DLs within GDUFAII targets times

# Keys to increased one cycle review success

Competence ✓



Common Cause (recognition of) ?

## Improving the Quality of DMFs –

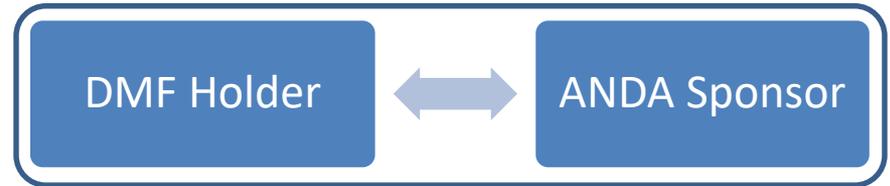
### *Technical/Scientific Content*

- Qualification of an unqualified impurity
- Failure to provide adequate analytical methods or method validation
- Starting material selection
- Deficiencies in a secondary DMF
- Characterization (especially complex APIs)

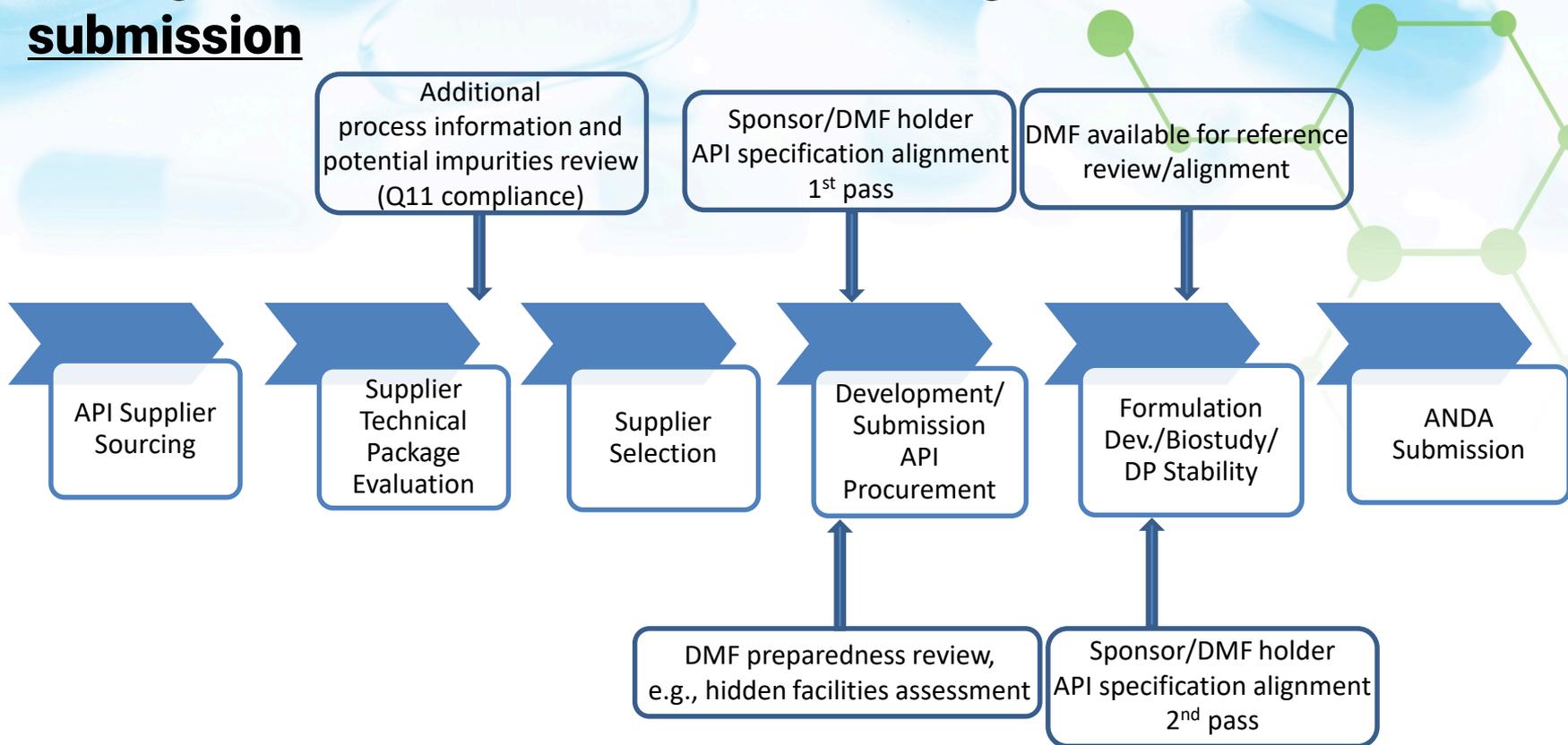
L.E. Woodward, Gen. Drugs Forum, April, 2019

### *Coordination/Alignment*

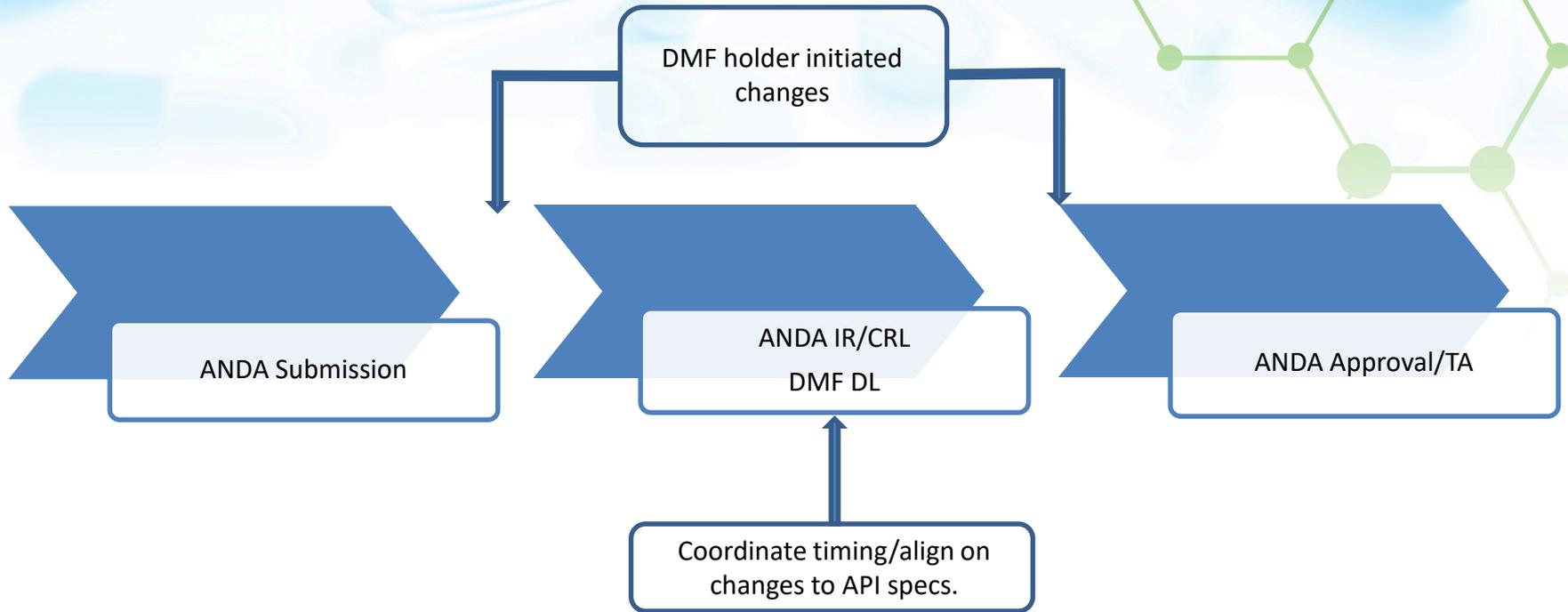
- Hidden facilities “unhidden”
- DMF available for reference
- Post-submission DMF holder changes/deficiency responses



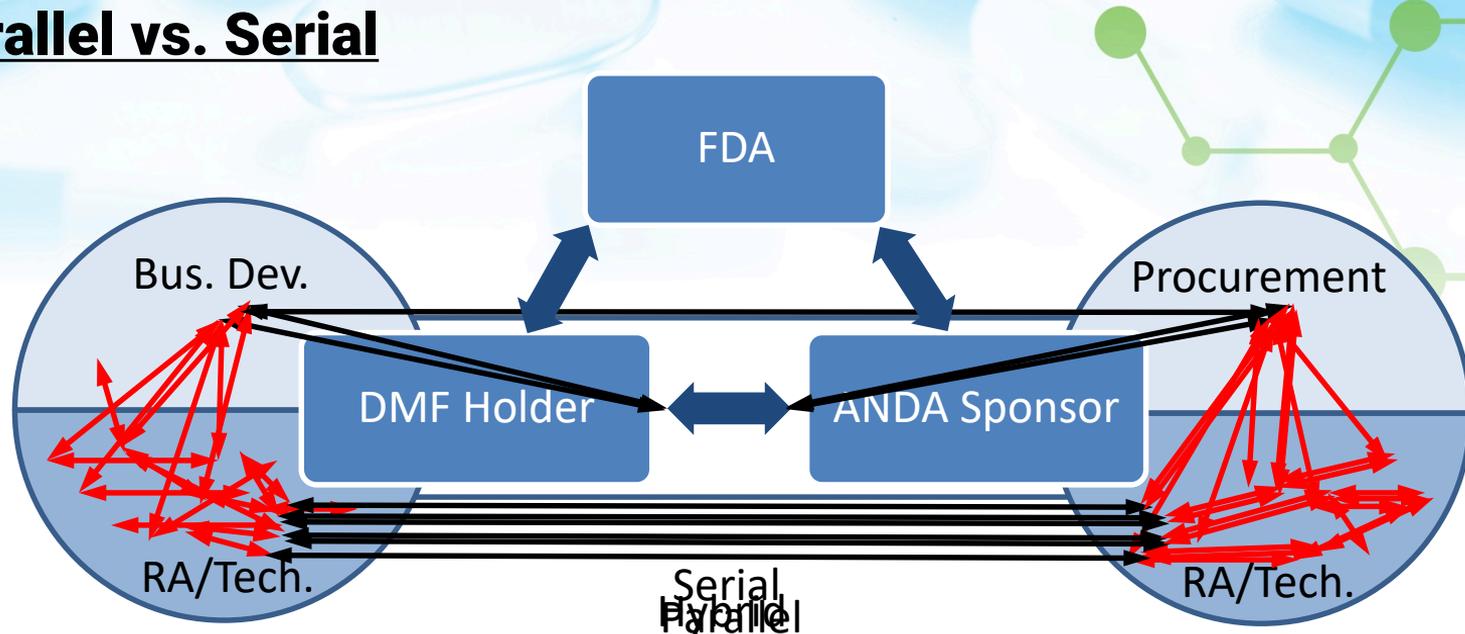
# Timing of communication – API sourcing to ANDA submission



# Timing of communication – post-ANDA submission to approval



# DMF holder-ANDA sponsor communication challenges: Parallel vs. Serial



## Concluding Remarks

- ANDA sponsors and DMF holders are partners seeking to bring affordable medicines to patients through thorough and technically sound applications to the agency
- Communication between us engendered with collaborative intent will hasten approvals helping-
  - ✓ the performance commitments of the FDA,
  - ✓ the mutual success of our businesses and
  - ✓ to meet the needs of patients.



Thank you.