

# **Innovation at FDA**

## **Integrated Quality Assessment (IQA): Aligned Teams**

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[Pharmaceutical Quality Symposium] – October 26, 2021

## Pharmaceutical Quality

**A quality product of any kind consistently meets the expectations of the user.**



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**Drugs are no different.**



**Patients expect safe and effective medicine with every dose they take.**



Pharmaceutical quality is  
assuring *every* dose is safe and  
effective, free of contamination  
and defects.



It is what gives patients  
confidence in their *next* dose of  
medicine.

# Learning Objectives

- Understand IQA from business and project management perspective
  - Historical recap of our assessment before IQA
  - Assessment process after IQA
- Understand the benefits IQA aligned team effort
- Learn some Best Practices for Communications during the application assessment

# What is an Integrated Quality Assessment?



- Multiple assessors/team members with different expertise
  - Enhance overall quality
- Consolidation of review and inspection results
  - More informed decision
- Collaboration and communication amongst team members
  - One Quality Voice
  - Enhance Knowledge Management

# Integrated Quality Assessment (IQA): Process Management



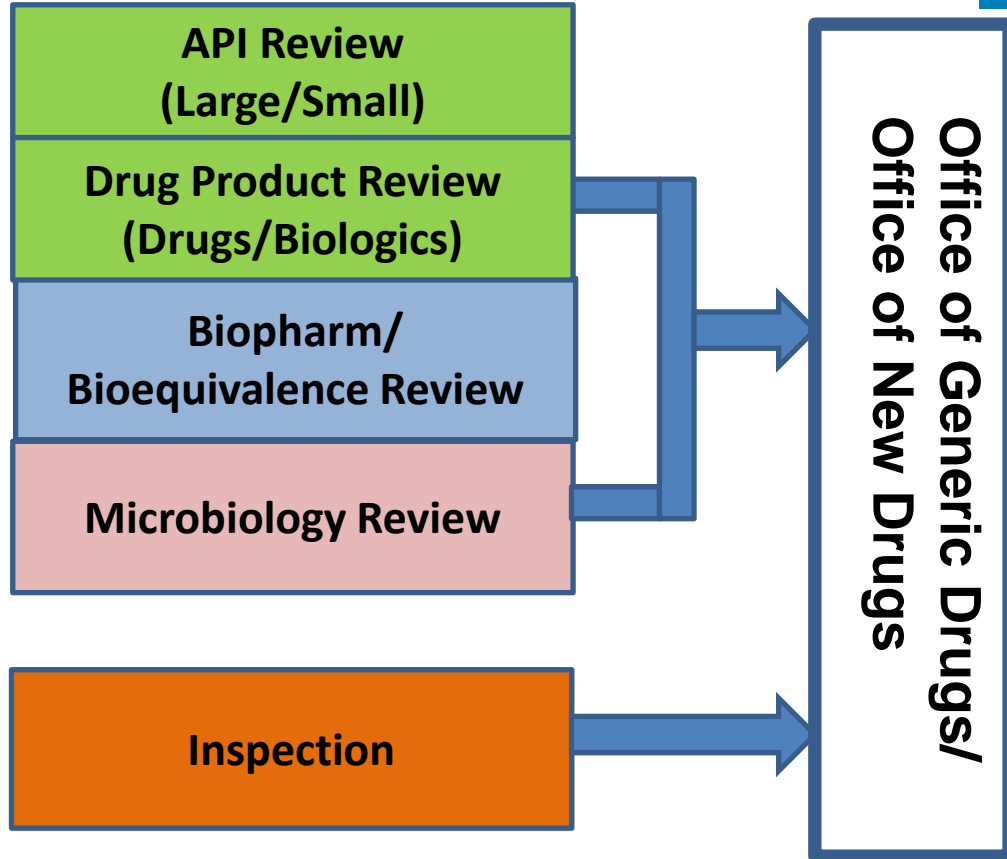
## Discipline Expert Assessor



# Quality Assessment for Before IQA

**CDER/Office of  
Pharmaceutical  
Science**

**CDER/Office of Compliance &  
Office of Regulatory  
Affairs**



# Quality Assessment Before IQA



- Assessor responsible for large portion of CMC module
- Review and inspection evaluated separately and in different offices
  - Challenging to synchronized activities
  - Inefficient communications
- New Drugs, Biologics and Generic Drugs programs were siloed
  - Inconsistency in assessments
  - Delay in policy development

# Origination of IQA

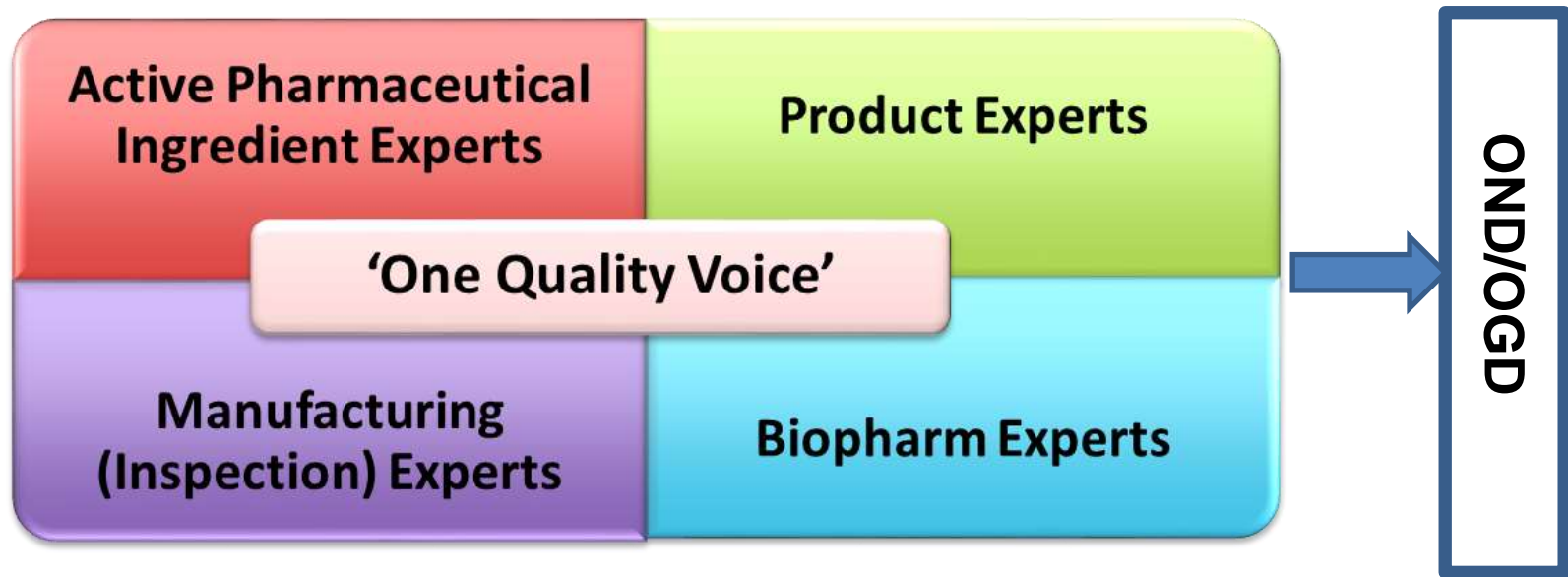
- CDER mission was confronted with complex challenges
  - Drug shortages
  - Novel technologies
  - Complicated product incidents (e.g. heparin, NDMA)
- Changes were warranted.
- IQA implemented along with initiation/creation of OPQ
- OPQ was formed to unify quality functions under one organization

# Origination of IQA

- The IQA idea was conceived with the following principles:
  - Expertise-based assessment
  - Team-based assessment
- Implementation involved extensive training/staff development
- IQA template created to facilitate the documentation of the assessment

# Quality Assessment After IQA

## Office of Pharmaceutical Quality



# IQA - Benefits

- Close collaboration and communication
  - More informed decision making
- Assures application of uniform quality standards
- Promotes consistent regulatory practices
- Promotes building an integrated knowledge base

# Quality Assessment After IQA



- IQA was implemented across OPQ for ANDAs, NDAs, and BLAs.
- IQA achieved some of its original goals
  - One quality voice
  - Increased consistency between user fee programs
  - Improved collaboration



# Quality Assessment After IQA

- Areas need to be improved
  - Risk-based assessment: KASA
  - Team work optimization: IQA Aligned Team

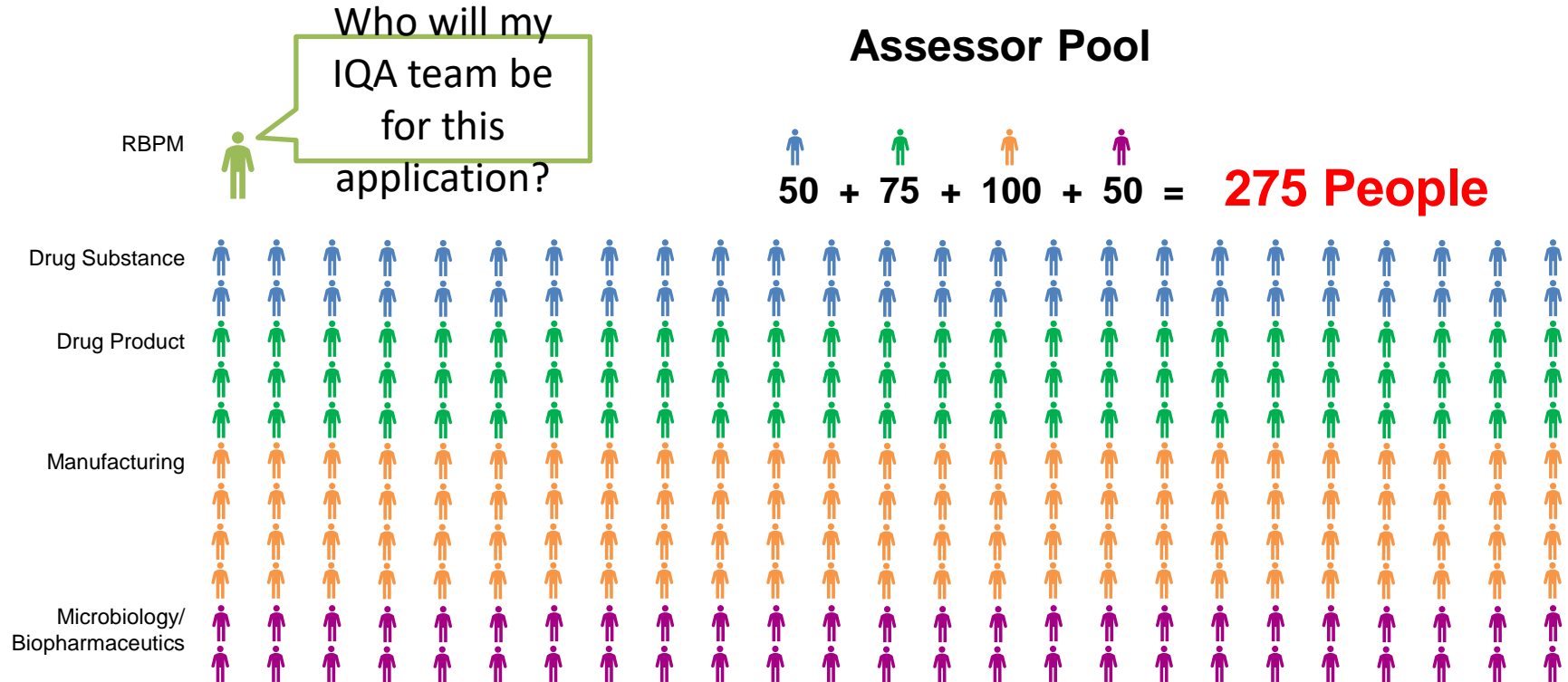
# What is the IQA Process?



# The Current IQA Team Formation Process: A Hypothetical Example

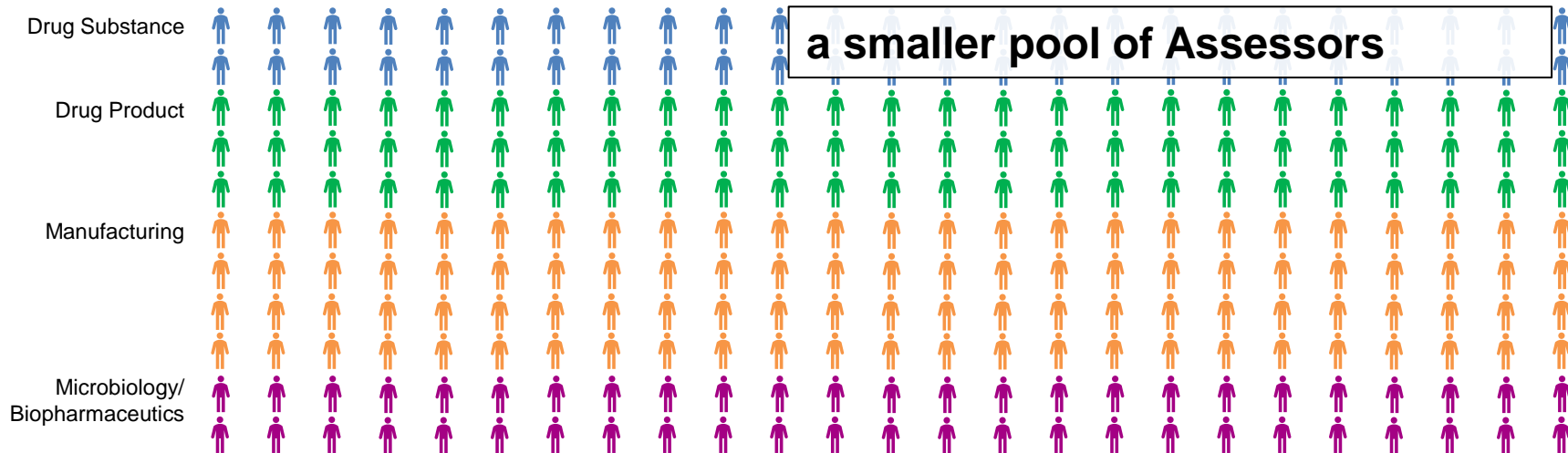
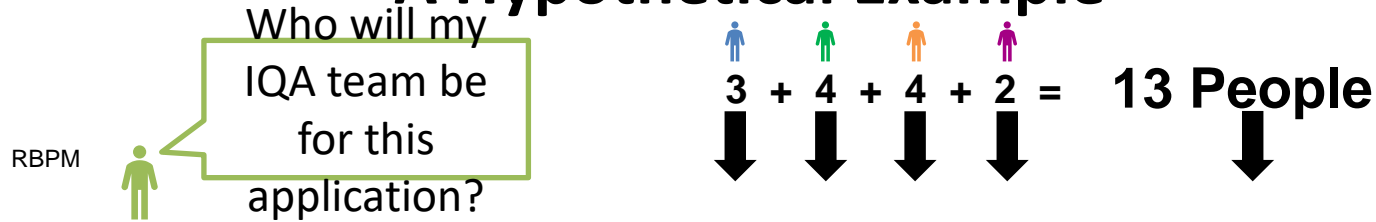


# The Current IQA Team Formation Process: A Hypothetical Example



# What is an “Aligned Team”?

## A Hypothetical Example



# An “Aligned Teams” Solution is Supported by External Research and Practices



## Team Composition Best Practices Research

An Harvard Business Review (HBR) study found that **high-performing teams tend to be smaller and *both* task-driven and relationship-oriented**. “New teams” have the lowest levels of performance. When 20%-40% of members were already well connected, the team exhibited strong collaboration and efficiency in achieving objectives.<sup>1</sup>

As individuals form more **new working relationships** with people, within-team **communication challenges increase**. Smaller team sizes decrease the number of working relationships, thereby improving overall communication and increasing process efficiency.<sup>2</sup>

The Project Management Academy states that, “Group sizes of **5 to 11 people are believed to make the best decisions**.”<sup>3</sup>

# Overall Benefits of IQA and Aligned Teams



- Team meeting to discuss scientific and timelines issues
- Synchronization of reviews and communications to applicant
  - More consolidation of IR deficiencies
- Eliminate redundancy in communications, including deficiencies
- Clearer communications, including deficiencies

# Best Practices for Communication



- RBPM is the POC
- Utilize Pre-submission communications
- Provide detailed cover letters
- Respond to IR letter by the due date. Contact the RBPM if needed

# Best Practices for Communication



- Elements of an IR/CR or deficiency includes
  - What was provided in the application
  - What is the issue or deficiency
  - What is needed
  - Why it is needed
- Respond to deficiencies with “what is needed” or provide a rationale
- Review IR/CR letter upon receipt. Contact RBPM
- Utilize the Post Action meeting request, when appropriate

# Summary

- IQA provides improvement based on expertise and teamwork
- Aligned teams improves collaboration and yields more informed decisions
- Proactive communication and transparency enhances the assessment process

*Thank you!*

