

# **OPQ Integrated Quality Assessment (IQA) Process for Abbreviated New Drug Applications (ANDAs)**

**Don Henry**

Associate Director for Business Operations (acting)  
Office of Program and Regulatory Operations

April 5, 2017

# OBJECTIVES

- Provide background information regarding the IQA process
- Identify roles and responsibilities of the IQA team
- Provide overview of the IQA process
- Provide overview of the IQA Review Document

# OPQ ORGANIZATION

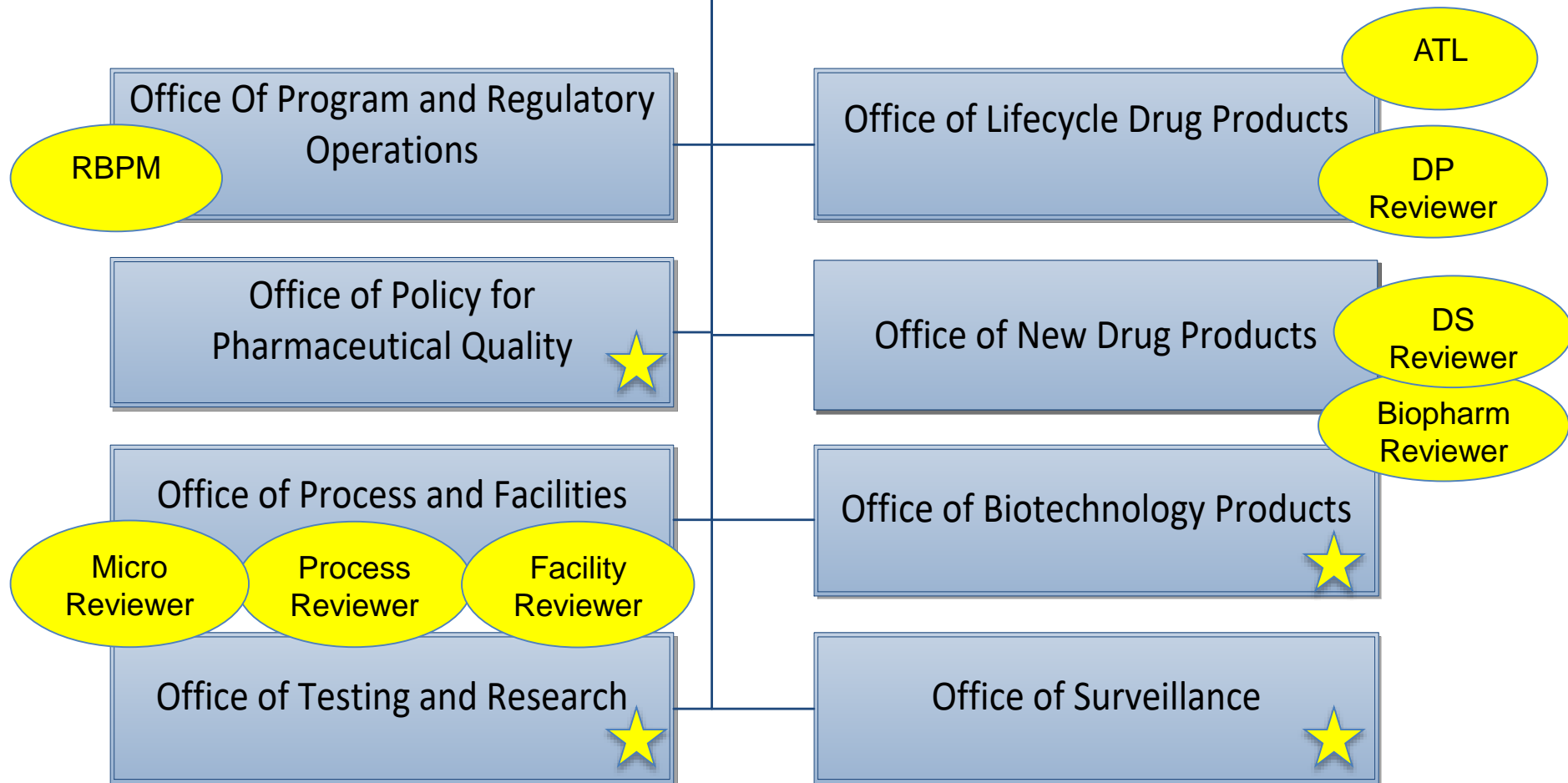
- Launched in Jan 2015
- Created a single quality discipline
  - Consolidate Review and Inspection
- Leverage specific expertise
  - Knowledge in chemical synthesis vs process engineering
- Create Quality review team that communicates “one quality voice”



# Core Team Members - Roles

- Regulatory/Business Process Manager (RBPM) – co lead
- Application Technical Lead (ATL) – co lead
- Drug substance (DMF) Reviewer
- Drug Product Reviewer
- Process Reviewer
- Facility Reviewer
- Biopharmaceutics Reviewer – mainly oral dosage forms
- Microbiologist – sterile products
- ORA investigator(s)
- Others (Laboratory, Policy, Environmental, CDRH, etc.)

# Office of Pharmaceutical Quality



 Sub offices are pulled into ANDA application assessment as needed

# RBPM ROLES

- Provides day-to-day leadership to the review team and oversight of the regulatory process and goals
- With the ATL, manages day-to-day review team activities
- Convenes, organizes, and facilitates review-related meetings
- Tracks review progress, addresses potential review process barriers, and resolves obstacles while keeping the ATL and the review team informed
- Serves as the point of contact for communication with the applicant
- Maintains an accurate administrative record of the review
- Communicates recommendation to the appropriate stakeholder(s)

# ATL ROLES

- Provides day-to-day leadership to the review team and oversight of the scientific review
- Works with the RBPM, and secondary reviewer(s), where applicable, to address issues.
- Facilitates resolution of differences that may arise within and across disciplines and to ensure efficient and timely reviews
- Makes an informed decision regarding the approvability of an application

# PRIMARY REVIEWER ROLES

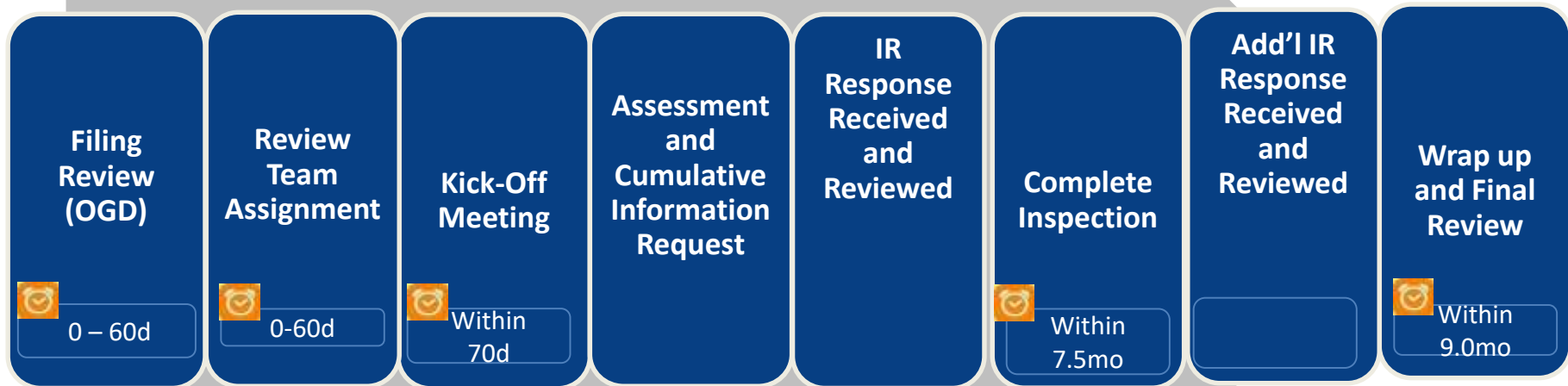
- Performs scientific review and recommends action
- Raises issues and identifies potential solutions to management and the IQA team (as appropriate) throughout the review
- Identifies and raises precedent setting issues to management and to the IQA team
- Participate on inspections, as needed



# SECONDARY REVIEWER ROLES

- Provides clear direction to the primary reviewers; meeting regularly to provide feedback and discuss issues
- Provides discipline concurrence on the IQA document, as appropriate
- Identifies and raises precedent setting issues to management
- Resolves conflicts related to discipline area

# Typical ANDA Original Process – 10 month cycle

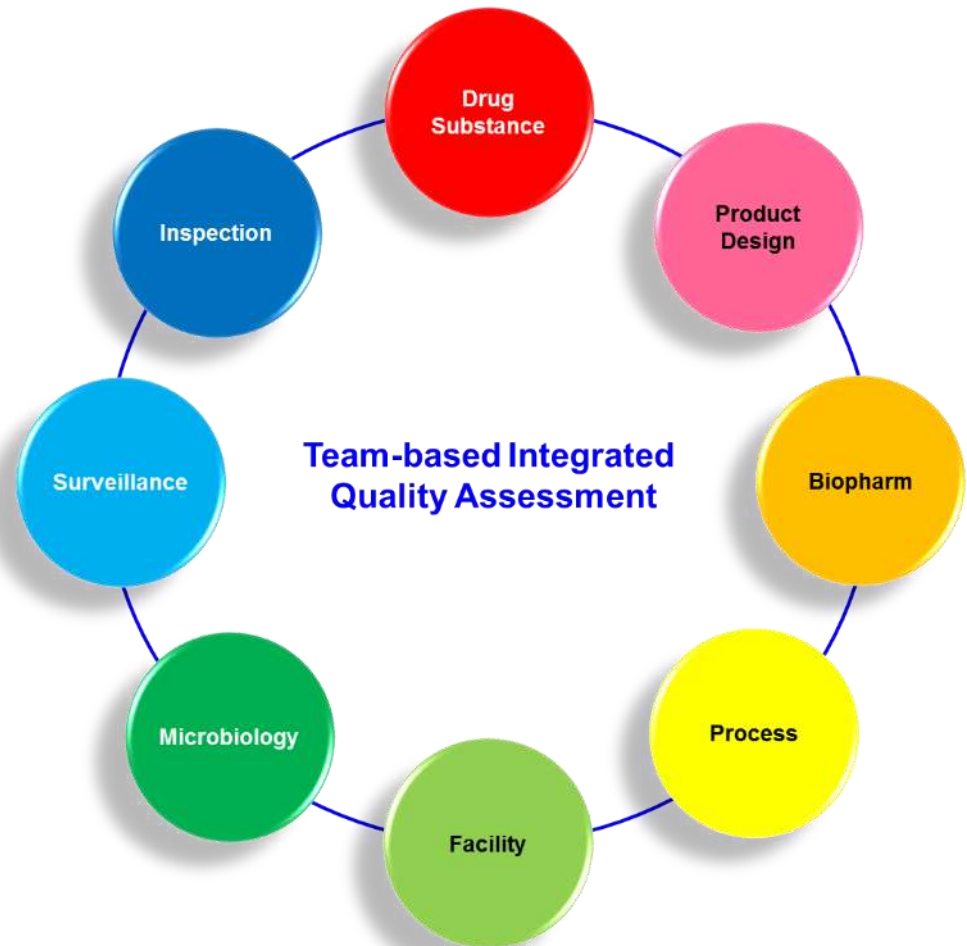


# TEAM COLLABORATION

- Kick off meetings
  - Align on team roles and responsibilities
  - Agree on internal timelines
- Additional meetings to discuss scientific topics as needed
- Facility reviewer act as POC for collaboration with investigators conducting inspections

# Integrated Quality Assessment (IQA)

A team of experts performing a quality assessment (review) of an application based on risk management principles

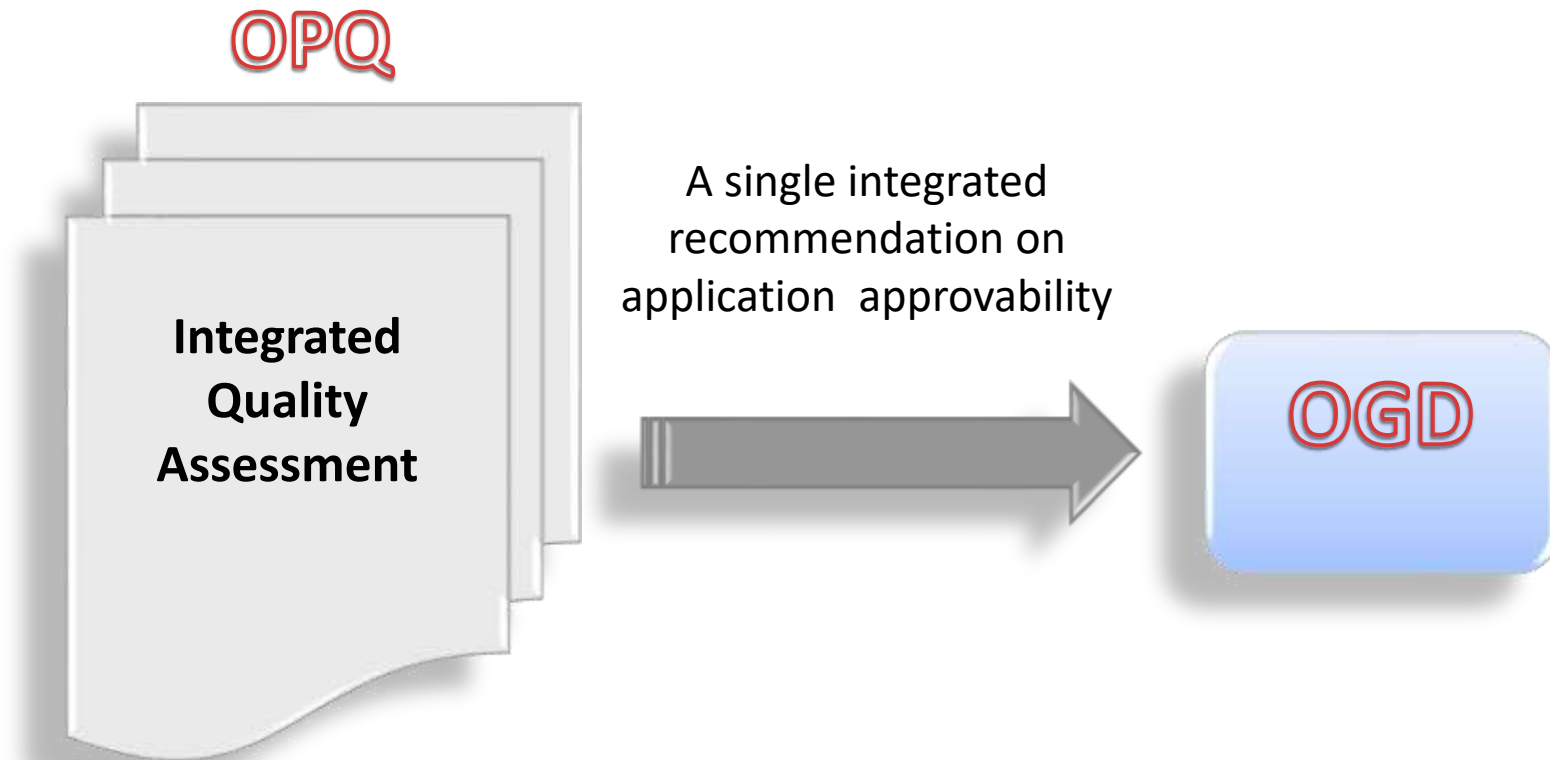


# IQA DOCUMENT



- Executive summary
  - Overall Quality recommendation
  - Summary of key findings
  - List of deficiencies, if appropriate
- Detailed quality assessment
  - Includes assessment from all quality sub-disciplines
  - Individual sub-discipline recommendations
- Provided to OGD to document Final Quality Recommendation

# The Integrated Quality Assessment (IQA) and OPQ support other super-offices



# SUMMARY

- IQA establishes quality sub-disciplines to create a team
- Team collaborates throughout the review cycle
- ATL and RBPM lead the team to complete a high quality assessment within the goal date
- A single quality assessment and recommendation is rendered

**Thank you for your attention!**

Please complete the session survey:  
**[surveymonkey.com/r/GDF-D2S08](https://surveymonkey.com/r/GDF-D2S08)**