

# **Integrated Quality Assessment Process for Abbreviated New Drug Applications**

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Generic Drug Forum

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# Agenda

- Background
- Roles and Responsibilities
- Process Overview
- Process Changes
- Summary

# Background

- Prior to IQA Process:
  - Assessors from different Quality disciplines were siloed
  - Little communication between assessors
  - Inefficiencies in the assessment
  - No defined timeline

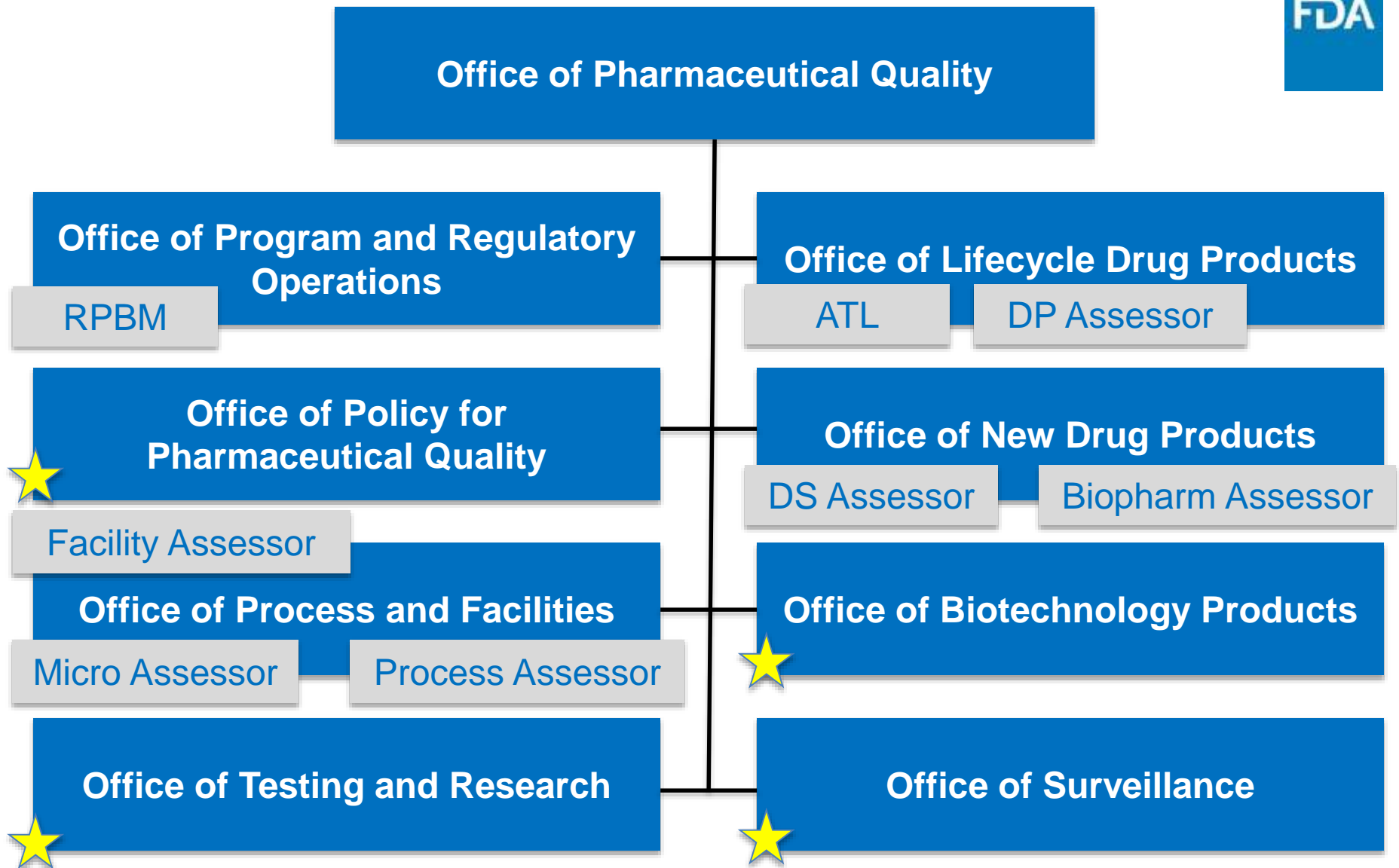
# Background

- OPQ was established under CDER
- Created a single unit for quality recommendations
- IQA process adopted to bring together different Quality disciplines into one assessment team
- Creates patient-focused and risk-based quality recommendations

# Roles and Responsibilities

# Roles

- **Application Technical Lead (ATL) Co-Lead**
- **Regulatory Business Process Manager (RBPM) Co-Lead**
- Drug Product Assessor
- Drug Master File Assessor
- Process Assessor
- Facility Assessor
- Biopharmaceutics Assessor (when needed)
- Microbiology Assessor (when needed)
- Office of Regulatory Affairs (ORA) Investigators
- Others (Office of Testing & Research, CDRH, Policy, Surveillance, etc.)



Sub offices are pulled into ANDA application assessment as needed

# Regulatory Business Process Manager (RBPM) Responsibilities



- Co-Lead IQA team with ATL
- Track progress of assessment
- Help navigate assessment team through obstacles during review process
- Point of Contact for:
  - Assessment team when external communication is needed
  - Other offices within the FDA in regards to quality portion of ANDA
- Organize and facilitates assessment meetings
- Maintain administrative record of assessment
- Keep stakeholders informed about status of assessment



# ATL Responsibilities

- Co-Lead IQA team with RBPM
- Responsible for overseeing scientific content of assessment
- Work with RBPM and IQA team to address issues
- Help in resolution of any differences arising between disciplines
- Ensure no gaps or overlaps in IRs and DRLs
- Provide an Executive Summary of application assessment outcome

# Primary Assessor Responsibilities

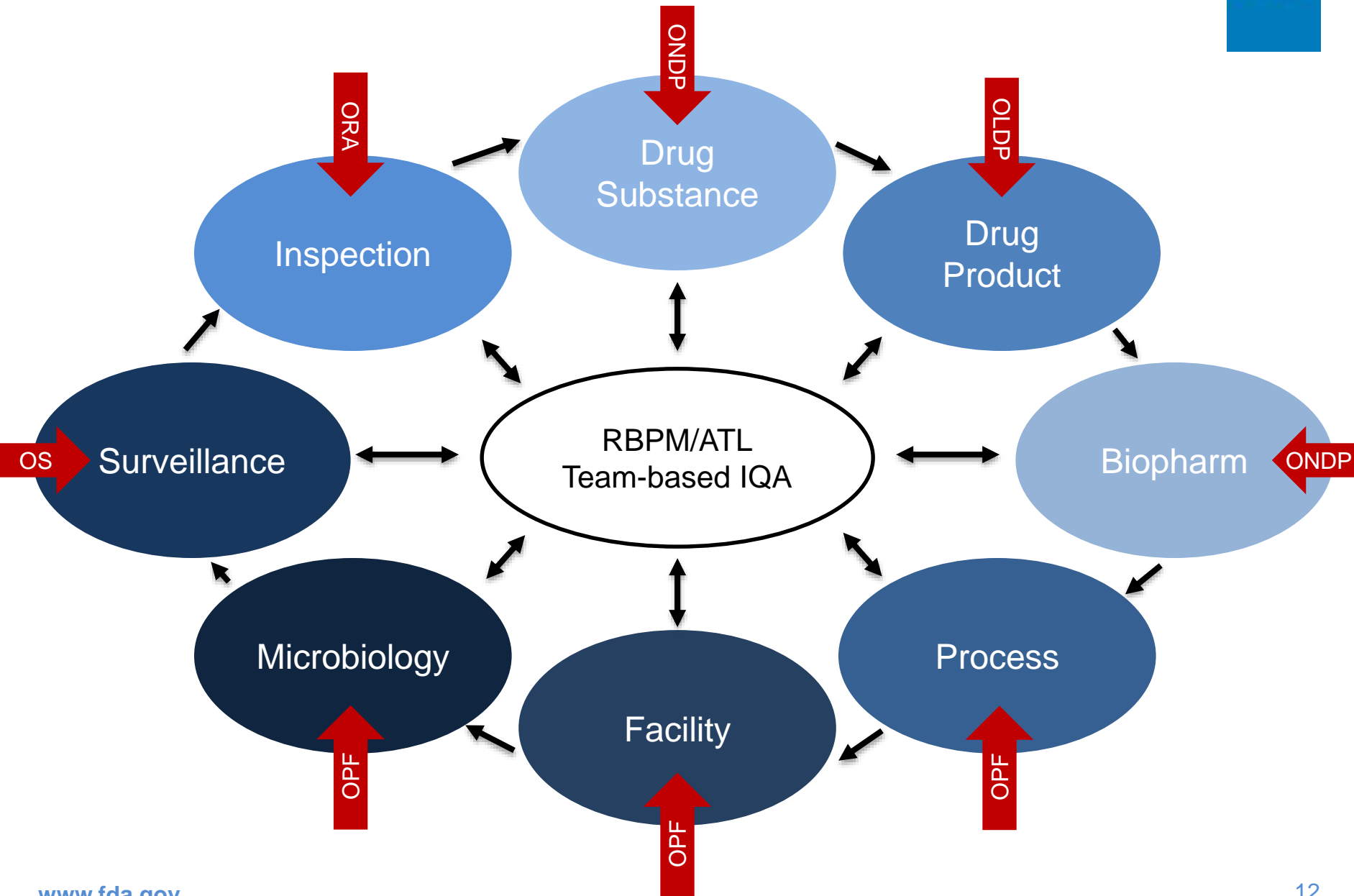


- Perform scientific assessment and recommend action
- Raise issues and identify potential solutions to management and IQA team (as appropriate) throughout assessment
- Identify and raise precedent setting issues to management and IQA team
- Participate on inspections, as needed

# Secondary Assessor Responsibilities

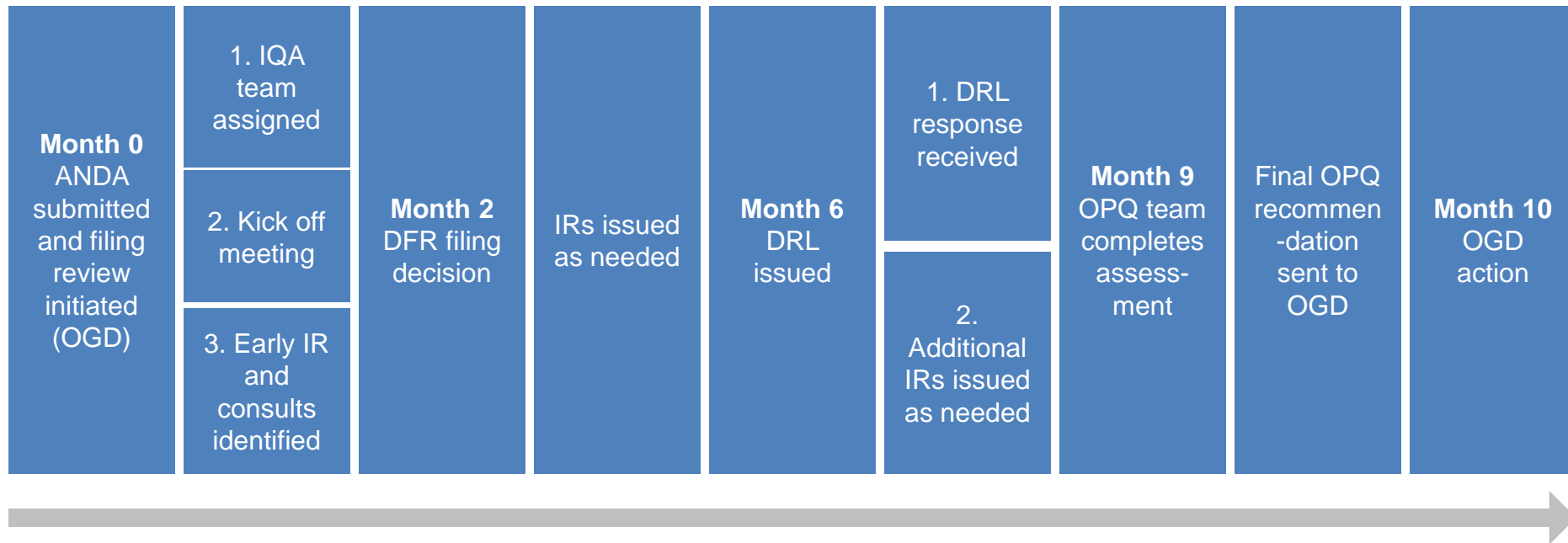


- Provide clear direction to primary reviewers; meeting regularly to provide feedback and discuss issues
- Provide discipline concurrence on the IQA document
- Identify and raises precedent setting issues to management
- Resolve conflicts related to discipline area



# Process Overview

# Standard IQA Process



# Process Changes

# IQA Process Changes

- Process has evolved since implementation
- Changes since IQA process initiated:
  - Assessment teams identified before filing decision
  - Kick off meetings initiated before the filing decision
  - Consults identified earlier
  - Introduction of DRL letter to the IQA process



# Summary

- Maximizes each team member's expertise
- Enhances staff communication and collaboration
- Allows for agreement among assessment team with a defined timeline
- Improves uniformity in the deficiencies issued to the applicant



# One Quality Voice



**Thank you!**