SBIA-DMF Drug substance workshop

March 3 & 4, 2021 (Virtual)

Optimization of Integrated Quality Assessment (IQA)
A Better Project Management Approach for API Quality Assessment
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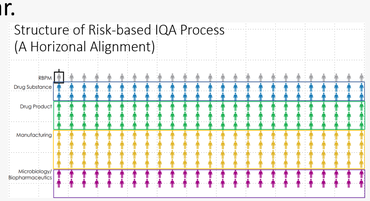
March 3 & 4, 2021 Virtual

PURPOSE: Increased submissions in GDUFA II put a strain on review resources. Therefore, optimization of current IQA practice is required to meet the mission of OPQ to assure that quality medicines are available to the American public.

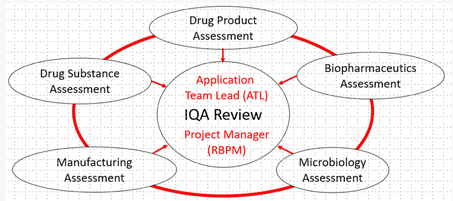
OBJECTIVES: The objective of the IQA team alignment is to reduce the variability in the assigned Assessors, and to increase collaboration and communication across the IQA team. Based on an internal study, each RBPM (Regulatory Business Process Manager) worked with about 17 different ATLs (Application Technical Leads) and about 109 different Primary Assessors over the course of a year.



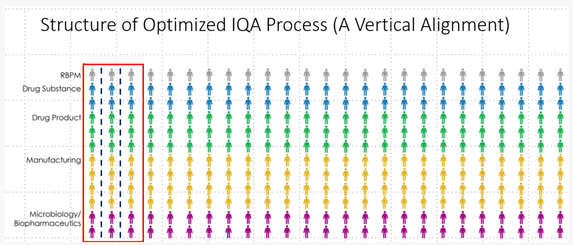
The communication barrier within an IQA team is significantly increased due to each team member being selected from a large pool.
. The small group structure reduces the communication barriers and increases process efficiency. Increasing internal communication and collaboration will improve the overall efficiency of IQA process

RESULTS

An internal working group established with representatives from all OPQ review disciplines to develop a vertical model for the improved IQA process and conducted a pilot study to validate the process. The risk-based IQA process includes the assessments of drug substance, drug product, manufacturing, microbiology, and biopharmaceutics. This approach maximizes each team member's expertise.



The optimization of IQA process re-designs the current team-based IQA practice. The new **aligned team** is a smaller pool of IQA teammates.



The small group structure reduces the communication barriers and increases process efficiency. Increasing internal communication and collaboration will improve the overall efficiency of IQA process. Aligned Teams promote consistent work practices. Increased interaction and familiarity within the team facilitates better communication.

For the Aligned IQA process:

- RBPM, ATL, and other assessors will meet regularly.
- Each team member will be informed on the process, understand the responsibilities and roles.
- Aligned team provides better continuity in discussion of technical issues and enable team decision to be made in timely manner.
- Both communication and collaboration is improved. .

Metrics for assessment of the Aligned Team IQA

- Ease of data sharing across team members.
- Collaboration between team members.
- Clear Communication.
- Clear Assessment Responsibilities.
- Meeting Goal Dates.

Best Practices for Industry to Facilitate Team Assessments

- Make sure the Letters of Authorization (LOAs) are up to date and submitted to the FDA in a timely manner.
- Respond to any communications (Deficiencies, Comments, or Information requests) by the requested date or sooner.
- Communicate between DMF holders and Applicants to avoid submission of DMF amendments which could impact the review timeline of applications.

CONCLUSIONS

The optimized Aligned of IQA process reduces the communication barriers, increases process efficiency, and enables RBPMs and ATLs to manage team more dynamically. The new aligned team is a smaller pool of IQA teammates. The workload of each IQA team fluctuates month by month due to the smaller team size. Several approaches have been implemented to achieve more workload balance without sacrificing the aligned team structure.

- The IQA Process is an integrated assessment process incorporating a broad expertise and is encapsulated in the OPQ motto, "One Quality Voice."
- The new Aligned Team IQA Process should lead to more timely reviews
- Official start of Aligned Teams for ANDAs was on 08/01/ 2020.
- The impact of the Aligned Teams process will be evaluated at the conclusion of each application.
- The DMF holder can assist the process by responding to FDA deficiencies, comments and information requests when requested or sooner.
- The DMF holder and Applicants can communicate with each other to make sure all information required for the assessment of the application is readily available to the FDA within the assessment cycle.

In This Poster

The Optimization of the IQA process leads to:

- The Description of the **Integrated Quality Assessment** (IQA);

- An Improved Approach to Team assignments in the IQA Process

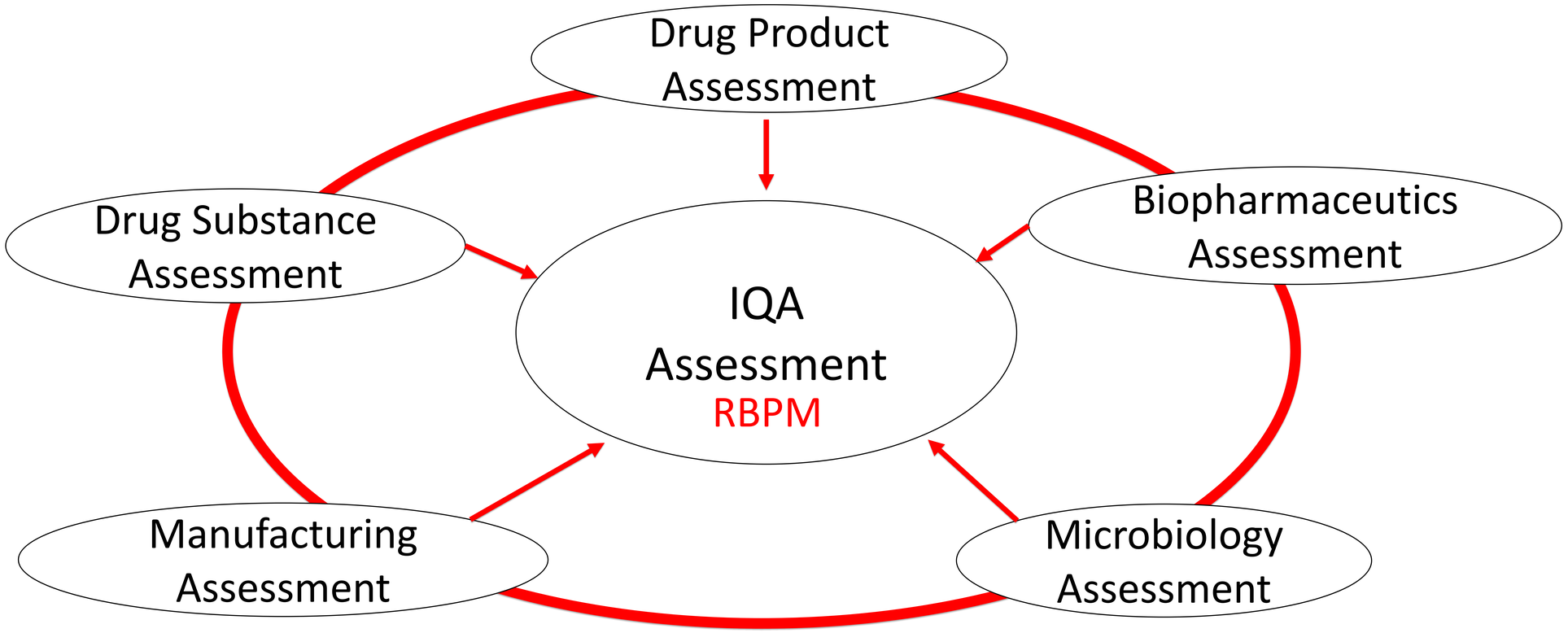
- How an Applicant and DMF Holder can help facilitate the IQA process

Integrated Quality Assessment(IQA)

IQA teams consist of:

- An **Application Technical Lead** (ATL), responsible for overseeing the scientific content;
- **A Regulatory Business Process Manager** (RBPM), responsible to coordinate the assessment process and meet goal dates;
- Discipline Assessors (Drug Substance, Drug Product, Manufacturing, Facilities);
- Additional technical advisors as needed based on Application content.

Integrated Quality Assessment



The IQA has improved:

- Quality, transparency and consistency of assessments;
- Reduced review documentation time;
- Facilitated team-based review and communication.

Integrated Quality Assessment(IQA)

Team-based Integrated Quality Assessment (IQA):

- Effectively aligns patient-focused and risk-based drug product quality recommendations.

- Encompasses biologics license applications (BLAs), new drug applications (NDAs), and abbreviated new drug applications (ANDAs)

- Includes Drug Substance, Drug Product, Manufacturing, and Facilities assessments

Structure of Risk-based IQA Process (A Horizonal Alignment)

- Based on an internal study, each RBPM worked with about **17** different ATLs and about **109** different Primary Assessors over the course of a year.

- The communication barrier within an IQA team is significantly increased due to each team member being selected from a large pool.

Structure of Aligned Team IQA Process (A Vertical Alignment)

- Provides a smaller pool of RBPMs, ATLs, and assessors for each IQA teams

- Aligned Teams promote consistent work practices.

- Increased interaction and familiarity within the team facilitates better communication.

Optimization of IQA Process

- The optimization of IQA process re-designs the current team-based IQA practice.

- The new **aligned team** is a smaller pool of IQA teammates.

- The small group structure:

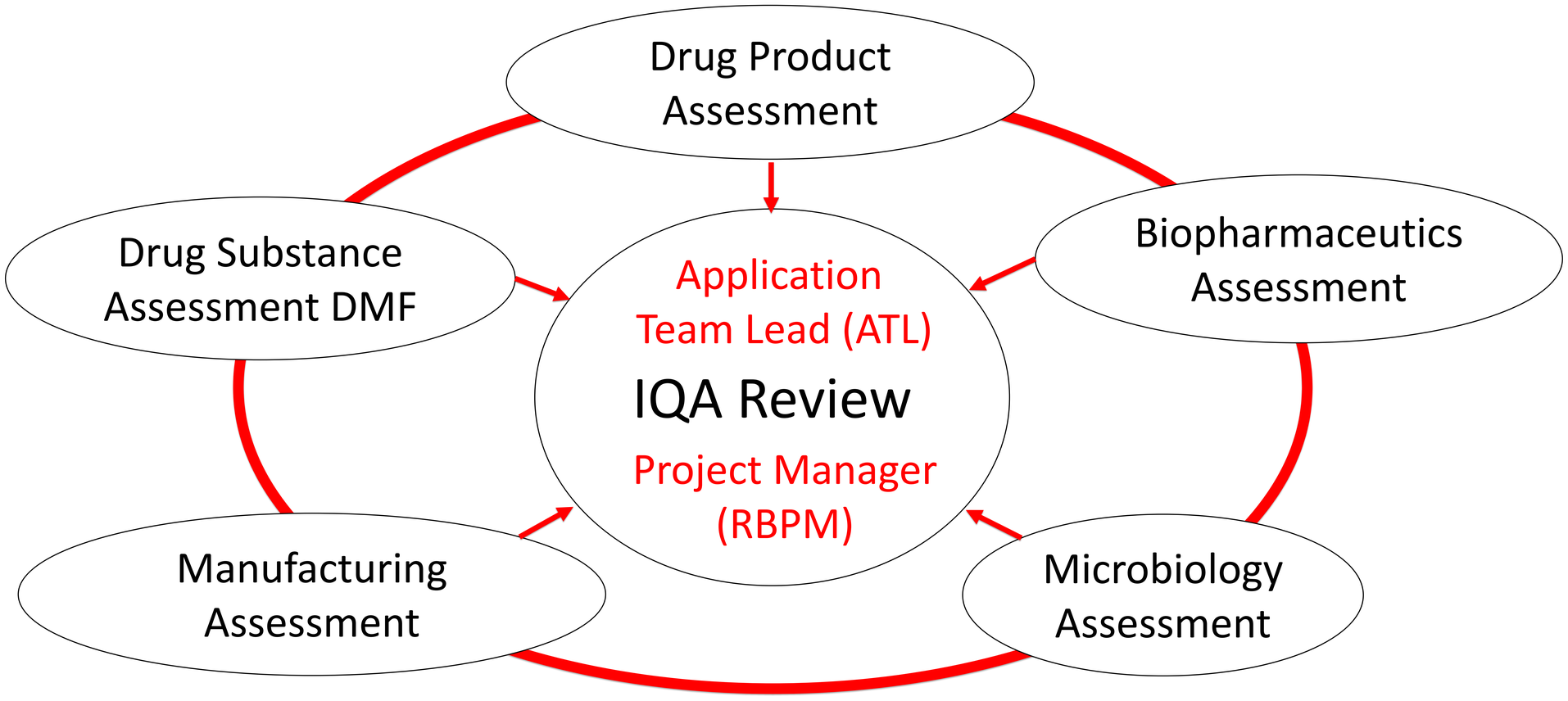
  - Reduces the communication barriers,
  - Increases process efficiency, and
  - Allows more efficient team managing.

Metrics for assessment of the Aligned Team IQA

- Ease of data sharing across team members
- Collaboration between team members
- Clear Communication
- Clear Assessment Responsibilities
- Meeting Goal Dates

The DMF and the IQA Process

- The DMF holder is usually not the Applicant submitting an ANDA or NDA.
- A DMF needs to be assessed as “Adequate” for the approval of a referencing Application.
- The IQA Process works only when all data is readily available.



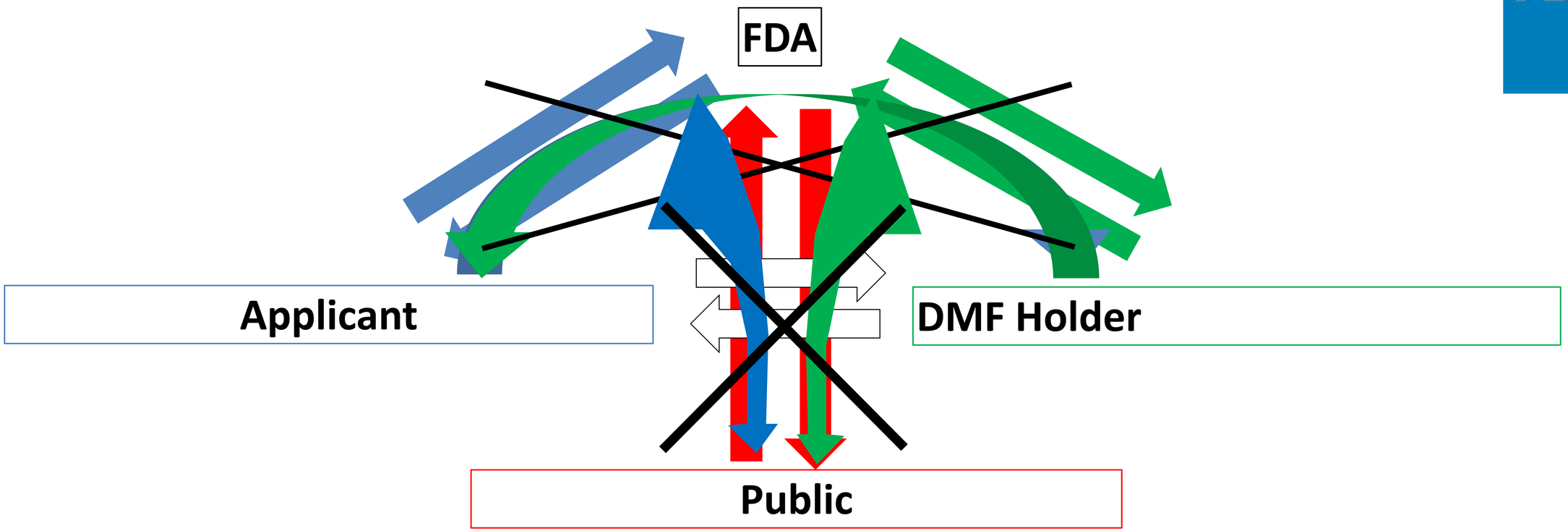
Best Practices to Facilitate Team Assessments

- Make sure the Letters of Authorization (LOAs) are up to date and submitted to the FDA in a timely manner.

- Respond to any communications (Deficiencies, Comments, or Information requests) by the requested date or sooner.

- Communicate between DMF holders and Applicants to avoid late submission of DMF amendments which could impact the review timeline of applications.

Communications between FDA, Applicants and DMF Holders



The FDA is required to protect proprietary information.

- A Letter of Authorization (LOA) is required before a DMF can be reviewed.
- Both the holder and the applicant must submit a copy of the letter to the FDA.

FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant.

Conclusion

- The IQA Process is an integrated assessment process incorporating a broad expertise and is encapsulated in the OPQ motto, “One Quality Voice.”

- The new Aligned Team IQA Process should lead to more timely reviews.

- The DMF holder can assist the process by responding to FDA deficiencies, comments and information requests when requested or sooner.

- The DMF holder and Applicants can communicate with each other to make sure all information required for the assessment of the application is readily available to the FDA within the assessment cycle.

Thank You!

- Send questions regarding this poster to: DMFWorkshop2021@fda.hhs.gov by 2/15/2021 for inclusion in the poster Q&A session on March 3rd
- Follow-on webinar for both posters/presentations on April 9, 2021. Questions can be sent to the above email by 3/19/2021 for the webinar.
- Please refer to the following posters for cross-referenced materials: *Timeline for the DMF review process by Wei Song and Steve Kinsley; Communications with DMF Holders and Applicants throughout the DMF Lifecycle by Fatima Sequeira.*
- Please refer to the following presentations on March 3rd and 4th for additional information: *Introduction to the DMF Review Process by Erin Skoda; Effective Communication strategies For Drug Master Files (DMF) by David Skanchy and Ben Danso.*