RBPM Communication with Industry throughout the OPQ IQA Process

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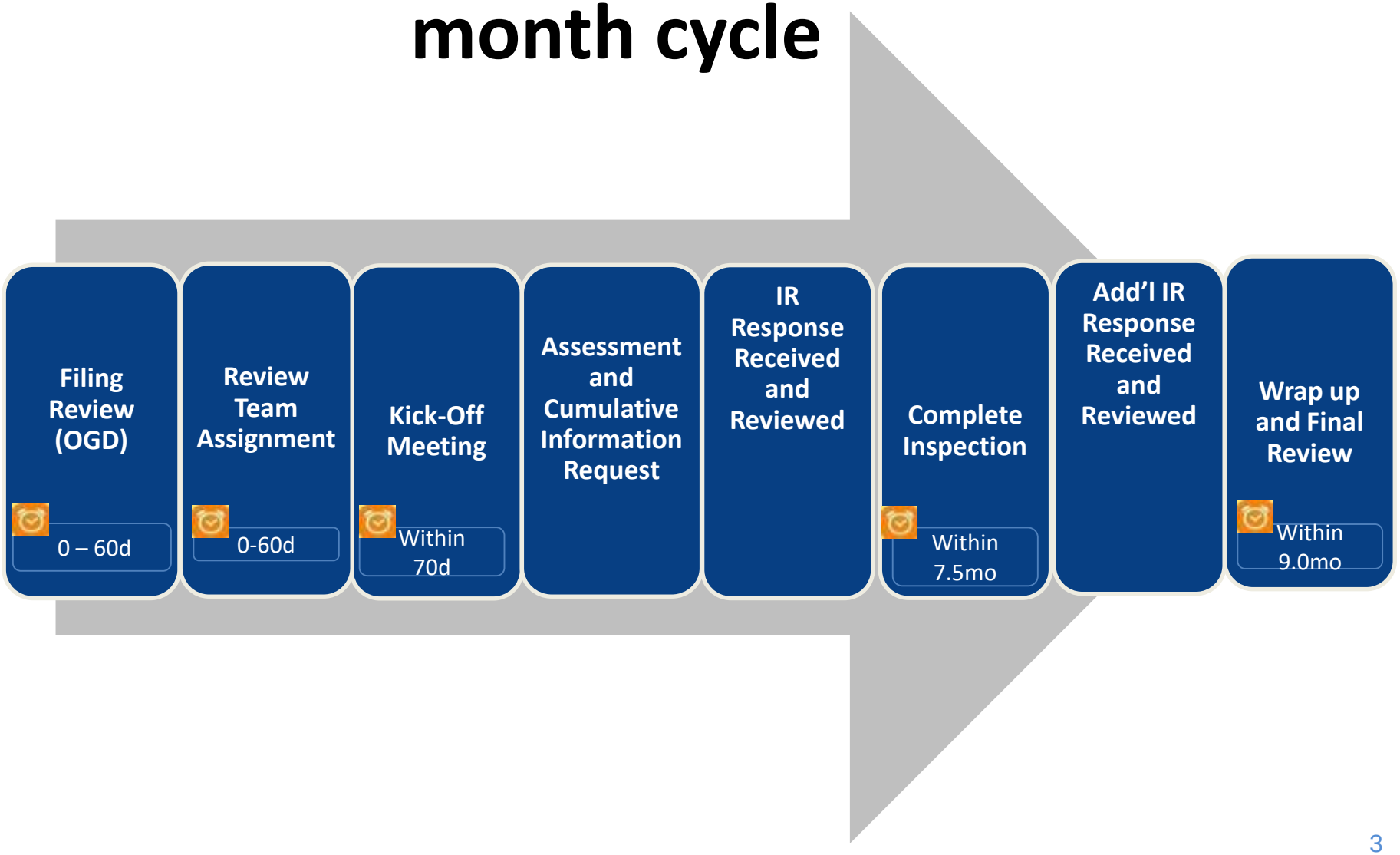
Agenda

- Review the ANDA review timeline and identify when communications may occur
- Describe typical OPQ Communications and highlight important points
- Provide suggestions
- Review frequently asked questions

Typical ANDA Original Process – 10 month cycle



Communication During the Review

- Primarily sent via Information Requests (IRs) aka RBPMs directly contact sponsor and send IRs
- Review team will relay all clarification questions and any other communication through the RBPM
- RBPM will always inform OGD RPM when IRs are sent

Important points to consider

- Contact the RBPM for all questions related to Quality-only correspondences received (IR).
- Continue to use the OGD/OND RPM as the point of contact for general inquiries.
- Be aware of your information request response deadline.
- Only respond to IR with requested information. Additional unsolicited information may impact review time and goal dates.
- Correctly code all submissions and amendments to ensure accurate triage and goal dates applied.

Important points continued …

- Clearly identify all facility changes for all submissions.
- Ensure all facilities and their responsibilities are clearly listed on the 356h.
- Reach out to your assigned RBPM for any quality specific areas of uncertainty when submitting information.

Suggestions for Common Themes

- Missing/unclear facility information and responsibilities

  - ensure that the 356H shows the most current and complete facilities for your application.
- Failure to link the development work to the proposed commercial process/product. This includes the scale up plan. Ensure you have the data to justify potential future scale ups.
- Missing in-process controls or inadequate justification for in-process criteria.

Suggestions Contd.

- Insufficient process/product knowledge.
- Address the issue of microbiological growth and controls during manufacturing of non-sterile oral dosage forms.

Frequently Asked Questions

- Can we submit a partial response to the Information Request?
  - Your ability to completely respond to the Information Request on time and completely should be discussed with the RBPM as soon as possible. This will allow the RBPM to advise you on the next best steps for you to take. Partial responses to Information Requests may lead to additional review cycles and/or may delay action on your application.

Frequently Asked Questions Cont.

- What do I do if I have a new facility or want to remove an existing facility?
  - ***All facility changes need to be reflected on the 356h as well as prominently showing on the cover letter***. If the facility change is a gratuitous amendment, please be aware that this will alter the GDUFA date or TAD.

Frequently Asked Questions Cont.

- What if we can not respond to the Information Request within the requested timeframe?
  - You should reach out to your RBPM within 7 days of receiving your IR to discuss your circumstances and to determine a best path forward.

Frequently Asked Questions Cont.

- Why can't we get more time to respond to our IR?
  - Extension requests should be made to the RBPM within 7 days of receiving your IR. At that time, there is the possibility that an extension can be negotiated. It is important to note that OPQ is working to meet internal TADs and GDUFA goal dates. There are many priorities which limit our flexibility at times when extensions are negotiated.

Frequently Asked Questions Cont.

- Where can I find the most recent 356h form?
  - The most recent 356h can be found at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/. If there are any questions or uncertainties about the form, please don't hesitate to ask your RBPM for clarification.

Thank you!

Please complete the session survey:

surveymonkey.com/r/GDF-D2S09