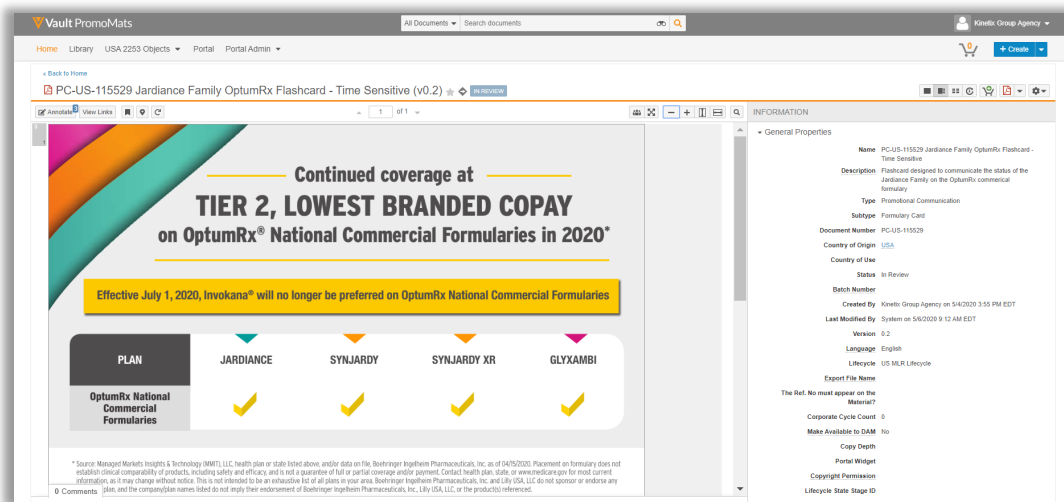




MLR Overview

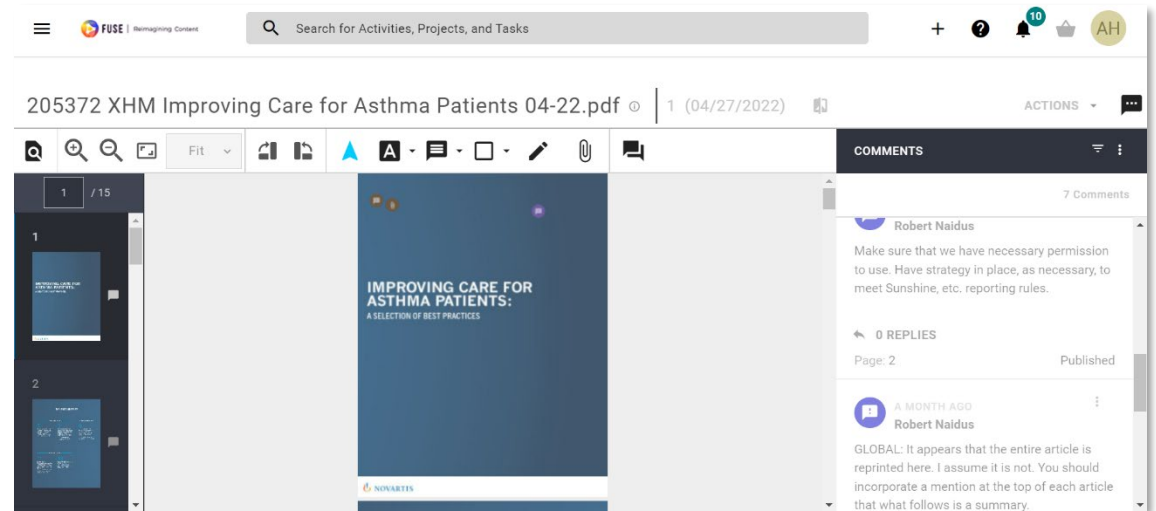
What is MLR?

- Formal **medical, legal, and regulatory** review to ensure consistency and guidelines are met in all resources
- Used across *all* pharmaceutical companies (system/process varies by company & brand, but overall objective is the same)



Vault System

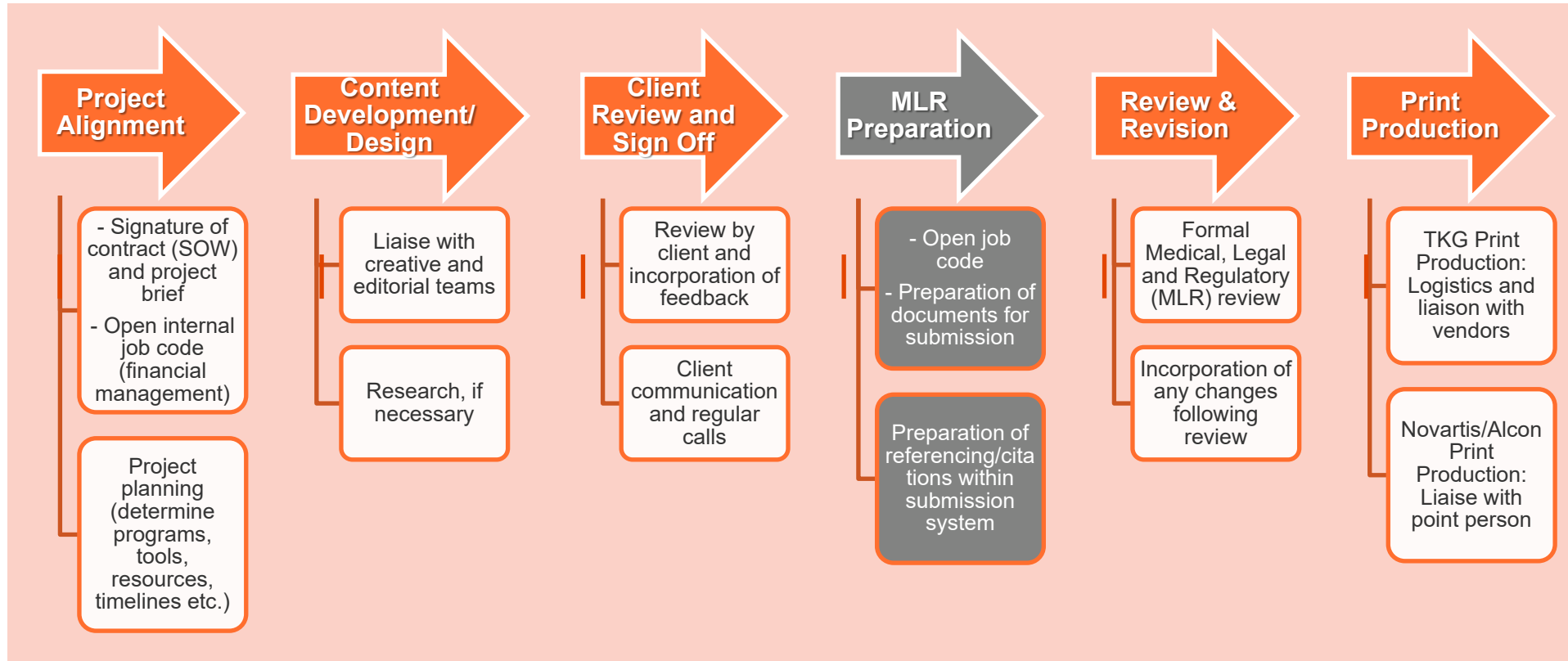
- BI
- Alcon
- UCB
- Genentech
- Intercept
- Ipsen



FUSE System

- Novartis
- Sandoz

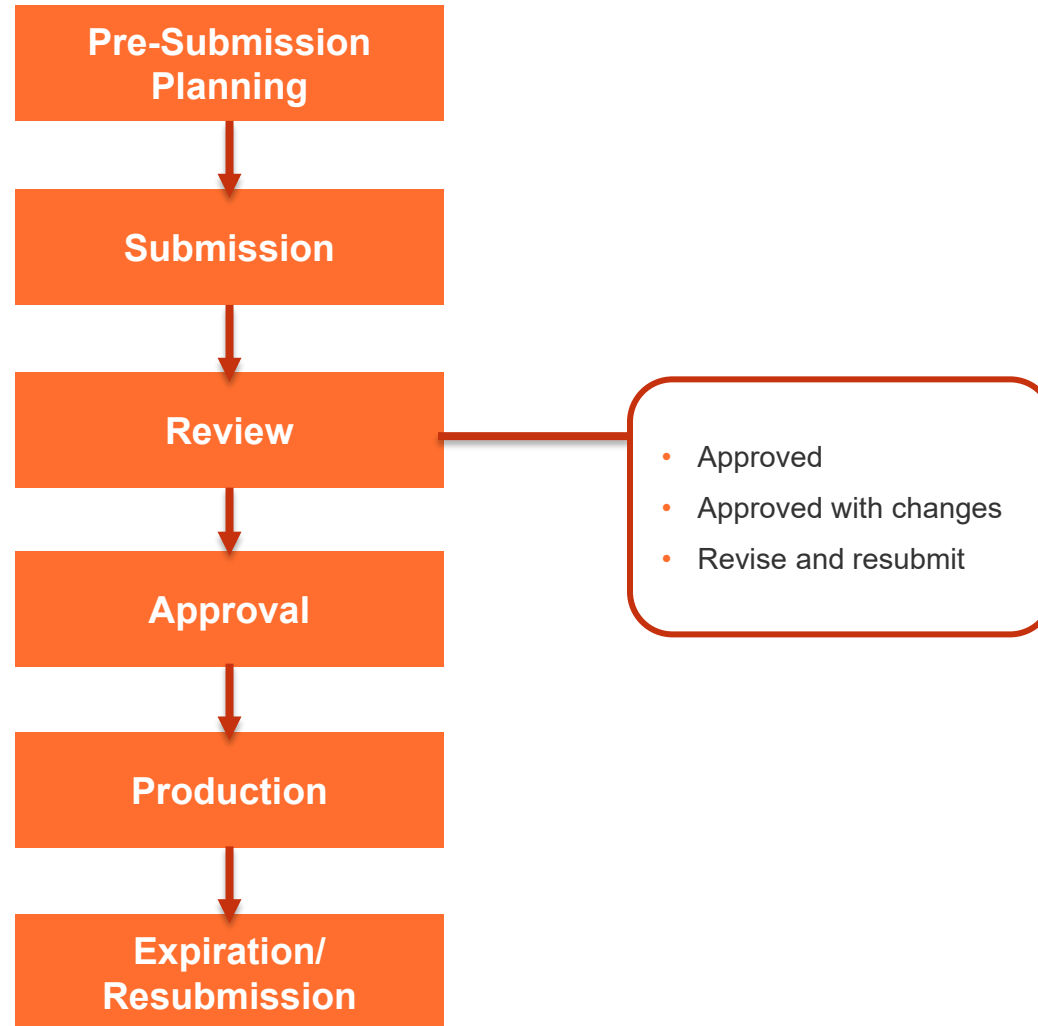
Project Lifecycle



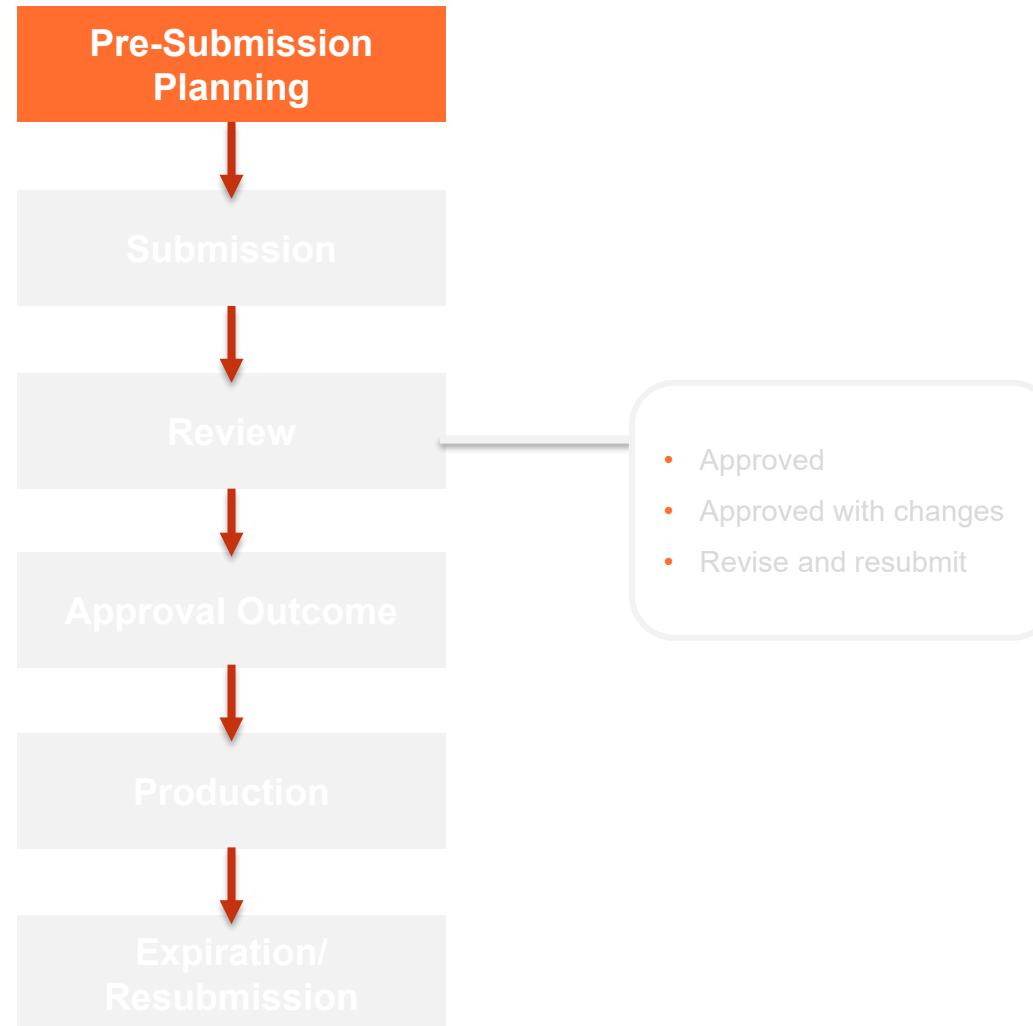


Process Overview

MLR Review Process Overview



MLR Review Process Overview: Pre-Submission

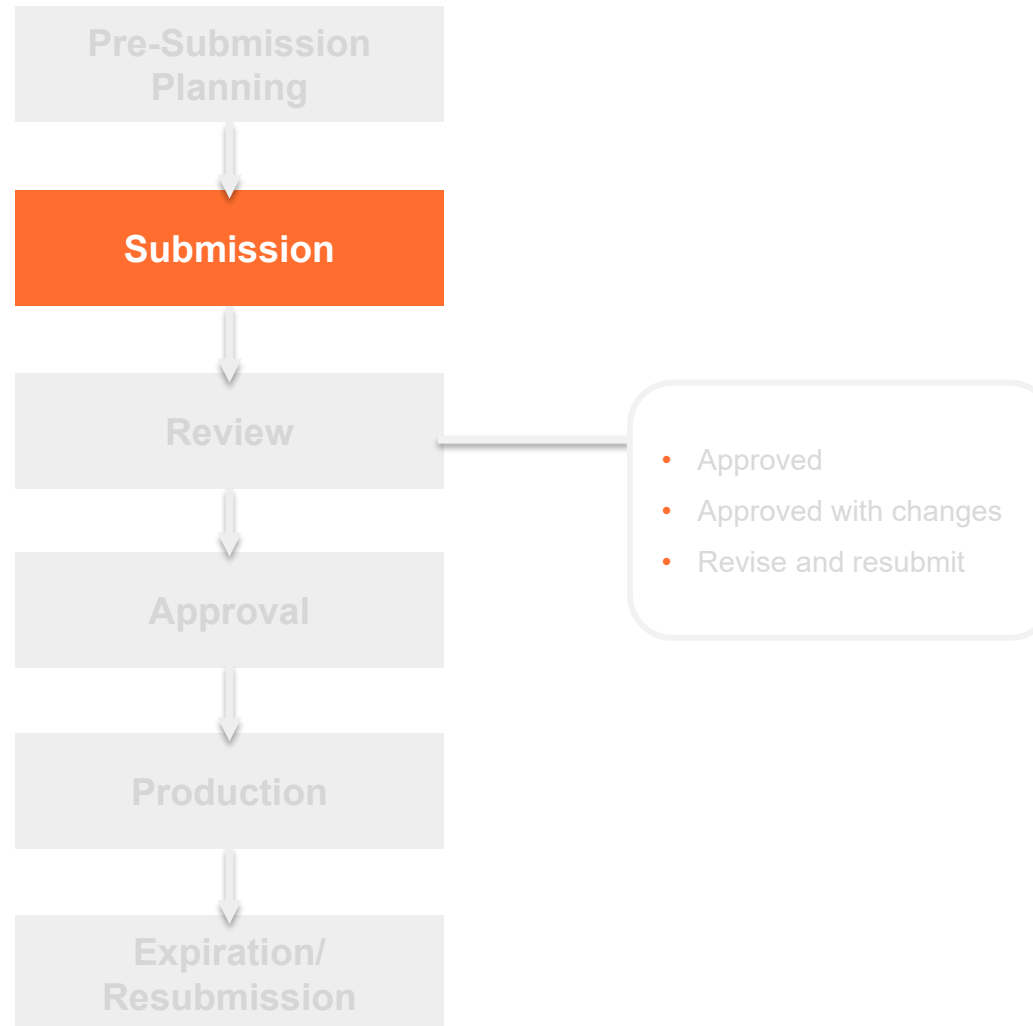


Pre-Submission Planning Workflow

	Task
Resource Development	<ul style="list-style-type: none">• Medical Writer:<ul style="list-style-type: none">– Creates the content or marks up changes to a previously approved piece– Provides the TKG Project Owner with necessary references
	<ul style="list-style-type: none">• Art Director/Designer move content into layout
	<ul style="list-style-type: none">• Proofer/Editor reviews the piece and ensures there are no grammatical errors, misuse of words, and that all content has been put into layout or all changes were made
	<ul style="list-style-type: none">• Client approves the piece for MLR submission
MLR Project Creation	<ul style="list-style-type: none">• TKG Project Owner opens job code in system (FUSE or Vault)
	<ul style="list-style-type: none">• TKG team begins prepping for submission

Note: This is a high-level overview. Specific processes and guidelines vary by MLR platform and brand.

MLR Review Process Overview: Submission



MLR Submission: Claims & References

Linking to Claims/References

- Check for existing claims/references that can be used
- Always use Primary Medical and/or Industry sources as references
- Only include references that are needed to back up your claim
 - If one reference completely supports your claim, that is all that is needed
- When linking references for submission, the box placement is critical and helps the Reviewers quickly evaluate the piece. If the Reviewers cannot see each individual box, it will be very difficult for them to access the reference tag. To avoid confusing the Reviewers:
 - Place a small box at the end of the sentence or around the footnote number
 - Never place a link box on top of or around the text
 - Never place a box in a location where it will be difficult for reviewers to determine its purpose
 - Never overlap multiple boxes

MLR Submission Workflow

	Task
MLR SUBMISSION	<ul style="list-style-type: none">• TKG team and client decide if piece needs a concept review, or can move right into review• Once the client approves the piece for submission, the TKG Project Owner prepares a submission package for the TKG submission team to include:<ul style="list-style-type: none">– Clean PDF for upload– Annotated PDF for reference annotating and marking up changes– ISI Claim Info (if applicable)– Supporting Documents (if applicable)– Source Files (if applicable)
	<ul style="list-style-type: none">• MLR Project Owner:<ul style="list-style-type: none">– Ensures piece meets submission standards and passes job to MLR reviewers to review
	<ul style="list-style-type: none">• TKG team tracks piece through submission

Note: This is a high-level overview. Specific processes and guidelines vary by MLR platform and brand.

MLR Review Process Overview: Review & Approval

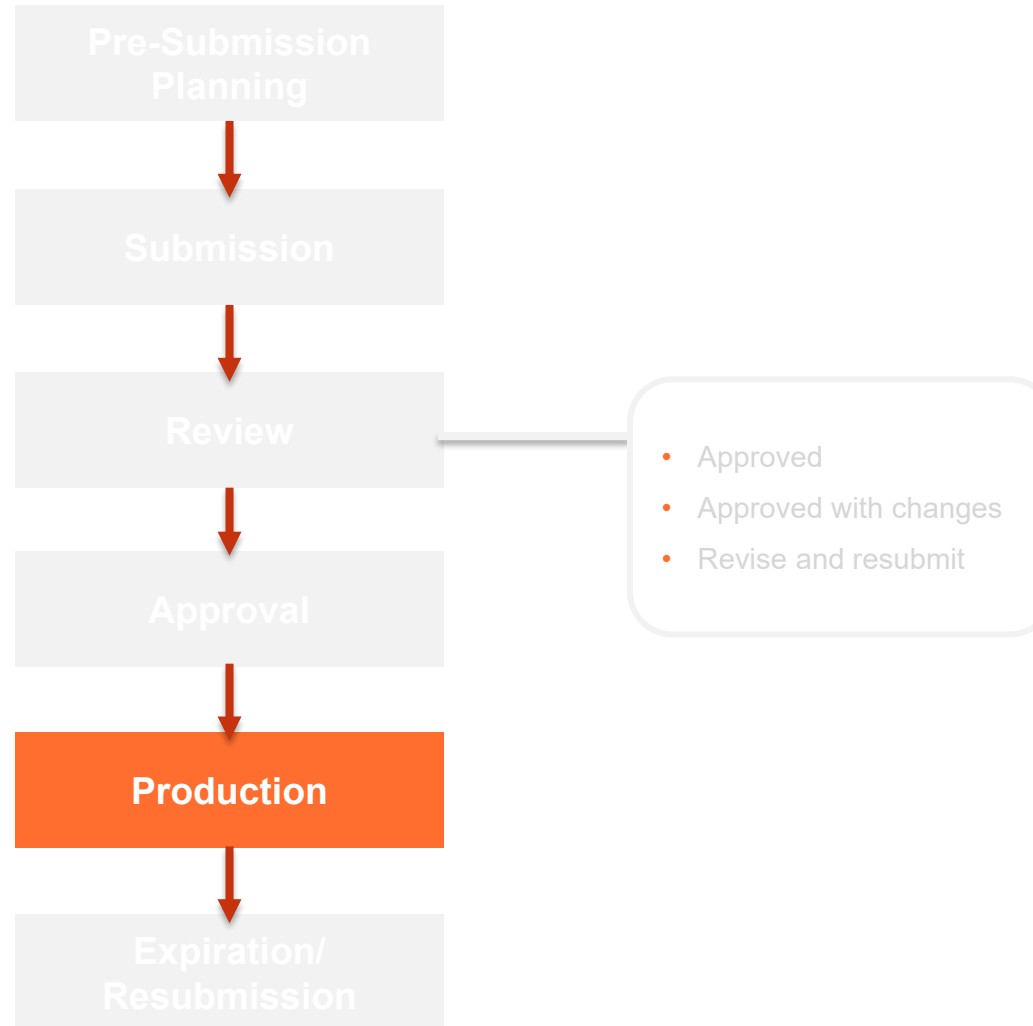


MLR Review and Approval Workflow

	Task
MLR Review	<ul style="list-style-type: none">• MLR team reviews the piece. Depending on size of resource, review will take 1-2 weeks• The MLR review team votes on the piece and can choose from 3 outcomes: Approved as is, approved with changes, revise and resubmit• If needed, the piece will go to a live review
Post-MLR Review	<ul style="list-style-type: none">• TKG sends comments from the MLR review to the Art Director/Designer to update the piece• Proofer/Editor reviews the piece and ensures there are no grammatical errors, misuse of words, and that all changes were made• TKG re-uploads the piece to FUSE/Vault for approval and continues monitor the review• TKG Project Owner notifies the client once the piece is approved• If print/digital production is needed, it's then done at this stage

Note: This is a high-level overview. Specific processes and guidelines vary by MLR platform and brand.

MLR Review Process Overview: Production

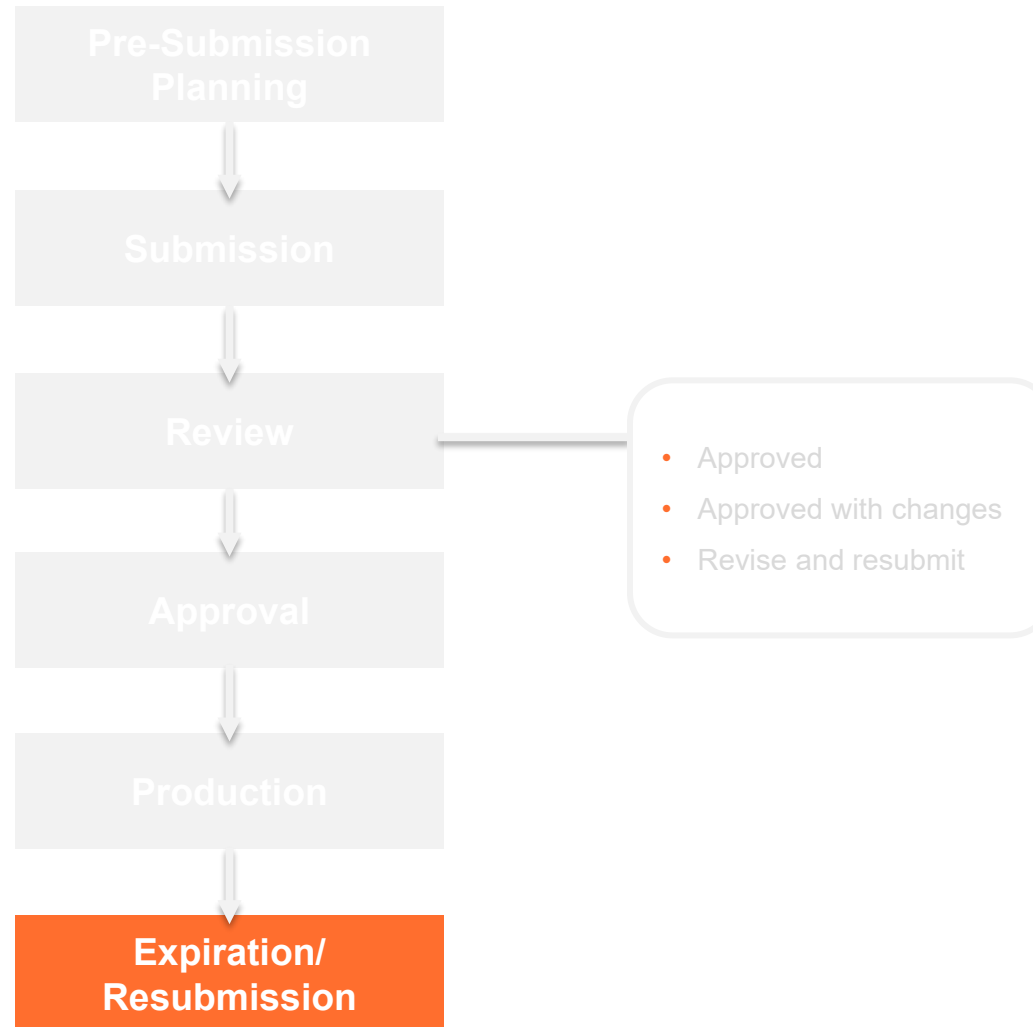


Production Workflow

	Task
MLR Approval	<ul style="list-style-type: none">• Once MLR has approved the piece, TKG moves into print/digital production if needed
Production	<ul style="list-style-type: none">• Print production process<ul style="list-style-type: none">• Gather final art/source files and spec sheet from Art Designer• Note: Process for this varies by company/brand• May be done by the client team, or may be requested to complete by TKG team• Digital production<ul style="list-style-type: none">• Ensure the functionality works and all mechanisms are clean with the digital team• E.g.- Interactive PDF, iPad, Website, App, eMails etc.

Note: This is a high-level overview. Specific processes and guidelines vary by MLR platform and brand.

MLR Review Process Overview: Expiration/Resubmission



Expiration Workflow

	Task
Re-Review Monitor	<ul style="list-style-type: none">• Once the piece is approved for use, it will receive an expiration date• TKG Project Owner must monitor the date<ul style="list-style-type: none">• Once the expiration date approaches, TKG confirms with the client lead if the piece should be re-approved, updated, or expired

Note: This is a high-level overview. Specific processes and guidelines vary by MLR platform and brand.