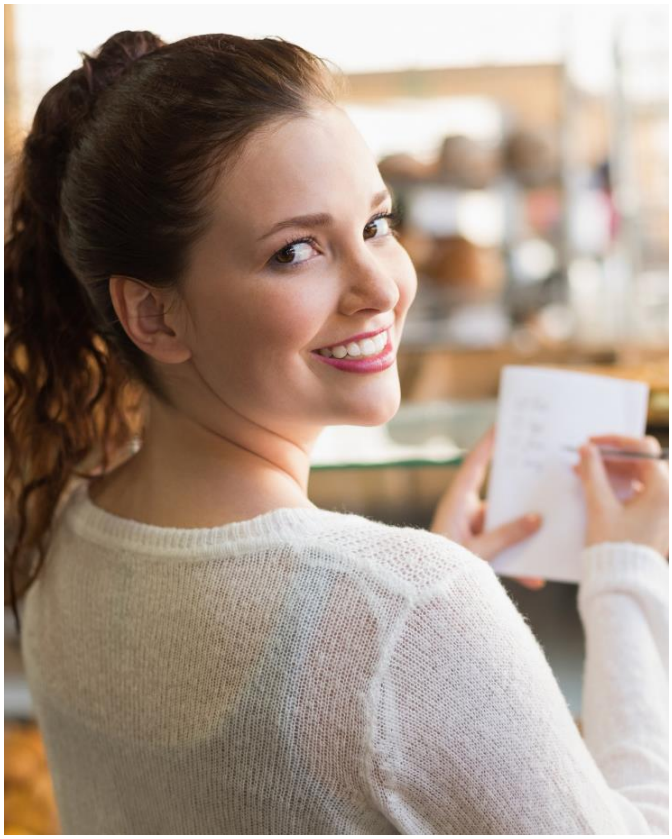

FDA PDF CHECKLIST

Validate the technical compliance of your PDF documents against FDA requirements

ABSTRACT

Compiling regulatory submissions is never easy. Fighting against deadlines to make sure you get the submission out the door on time; your time to market held hostage by the regulatory landscape.

Despite cutting-edge technology, there are still many challenges to overcome.

Many of the original source documents need manual rework before they are ready to share with any Health Authority. And when multiple agencies are involved, the complexity and time needed increases exponentially.

We created this checklist to help organizations understand the checks needed to ensure full content compliance in their FDA submissions.

This document can help you optimize your existing FDA PDF content preparation processes by ensuring you have the information needed to identify any content related issues as early as possible.

Thank you for downloading it.

REQUIRED TO COMPLY WITH HA GUIDELINES

- ☐ Content needs to be in PDF format regardless of original source.
- ☐ File naming conventions are followed.
- ☐ PDF must include all content from the original source.
- ☐ PDFs must not require any plug-ins for Adobe Acrobat to be displayed and navigated through correctly.

- ☐ **PDF File Specification**
  - ☐ Correct PDF Version (1.4 - 1.7, or PDF/A-1, PDF/A-2)
  - ☐ No JavaScript or dynamic content should be included.
  - ☐ No security settings, passwords or other restrictions should be set.
  - ☐ Files should be optimized for Fast Web View.
  - ☐ Filenames should be all lowercase.
  - ☐ Filenames should not include special characters except hyphens and underscores.

- ☐ **Correct Font Usage**
  - ☐ All non-standard fonts (see list below for standard fonts) should be fully embedded.
  - ☐ Font sizes from 9 - 12 only should be used.
  - ☐ Times New Roman, 12-point font is recommended for narrative text.
  - ☐ Font sizes 9-10 recommended for content in tables.
  - ☐ Font size 10 recommended for footnotes.
  - ☐ Font sizes should be considered even in scanned images, especially when resizing is required.
  - ☐ Black text should be used (with exceptions in specific types of content such as labelling)
  - ☐ Hyperlink text should be blue.

Table: FDA Standard Fonts

Font Type	Font Name
Serif	Times New Roman
	Times New Roman Bold
	Times New Roman Italic
	Times New Roman Bold Italic
Sans Serif	Arial
	Arial Italic
	Arial Bold
	Arial Bold Italic
Non Proportional	Courier New
	Courier New Italic
	Courier New Bold
	Courier New Bold Italic
Other	Symbol
	Zapf Dingbats

☐ **Page Formatting**

- ☐ Initial Page View correct
- ☐ Ensure all pages orient correctly when viewed, whether in landscape or portrait
- ☐ Letter (8.5 x 11 inch) page size.
- ☐ Headers & footers should not appear within the margins.
- ☐ Actual page size can be used for oversized drawings such as CAD files.

☐ **Scanned Content is Handled Correctly**

- ☐ Avoid image based only files wherever possible. If necessary, make these text searchable where possible.
- ☐ If OCR has been used, check for accuracy.
- ☐ Scanned documents have been scanned to the correct resolution (see table on the next page).

Document Type	Resolution
Handwritten notes	300 dpi (black ink)
Plotter output graphics	300 dpi
Photographs - black & white	600 dpi (8 bit gray scale)
Photographs - colour	600 dpi (24 bit RGB)
Gels and karyotypes	600 dpi (8 bit gray scale depth)
High pressure liquid chromatography	300 dpi

- ☐ **Images Compressed and Colour Matched Correctly.**
  - ☐ Colour and greyscale images compressed with ZIP/Flate
  - ☐ Black & White images compressed with CCITT Group 4 Fax.
  - ☐ CYMK colour model used rather than RGB (for printing).

- ☐ **Correct Navigational Aid Usage**
  - ☐ Table of Contents should be included for any document 5 pages or larger.
  - ☐ Hyperlinks should be created to link to annotations, related sections, references, appendices, tables or figures that are not on the same page as the narrative text.
  - ☐ Hyperlink text should be blue or have a rectangle surrounding it.
  - ☐ Hyperlinks to other files or documents should open the target file in a new window.
  - ☐ Relative paths should be used to link to other documents.
  - ☐ Bookmarks should be available for each entry in the Tables of Contents.
  - ☐ Correct number of bookmark levels should be included.
  - ☐ Hyperlinks and bookmarks zoom level set to inherit-zoom.
  - ☐ Page numbers of the PDF file should be the same as the original source document and begin at page 1.
  - ☐ PDF annotations should not be included (with exceptions for promotional labelling and advertising material)

- ☐ **Initial View Settings**
  - ☐ If bookmarks are included, the initial view should show “Bookmarks Panel and Page”.
  - ☐ If no bookmarks are included, the initial view should show “Page Only”.
  - ☐ PDF Page Layout and Magnification should both be set to “Default”.
  - ☐ When opening the PDF, the correct number of levels of bookmarks only are displayed.

- ☐ **Special Considerations for Labelling and Advertising Material**
  - ☐ Restrictions for other PDF documents ignored for font sizes, colours and annotations.
  - ☐ Include images at highest resolution and depth possible.
  - ☐ Photographs should be at least 600 dpi.
  - ☐ Scanned pages should be scanned at least 600 dpi.
  - ☐ Promotional material should use actual page size.
  - ☐ 3D images must show all sides and components.
  - ☐ Links can be included that simulate navigation between web pages.
  - ☐ Dynamic content such as audio, video, special effects, animations, attachments or 3d content are allowed IF embedded in the PDF file and playable from Acrobat without requiring plug-ins or other special software.

ABOUT DOCSHIFTER

DocShifter is a leading server-based document conversion and enrichment software, specializing in Life Sciences.

Compared to other solutions, DocShifter reduces licensing costs, manual correction required to finalize documents and the burden on IT to maintain desktop software and train users.

This is why many small and large Life Sciences organizations use DocShifter to automatically:

- Check and fix Word documents for compliance.
- Generate compliant, submission-ready PDF renditions from source content.
- Fix and validate PDFs against a range of Health authority requirements.
- Convert and enrich a range of different file formats from multiple content repositories.
- Monitor e-mail inboxes and automatically convert messages and attachments to PDF to be stored in tracking systems.

OPTIMIZE REGULATORY SUBMISSIONS TO IMPROVE SPEED TO MARKET

- Are you getting ready for your next submission?
- Are you spending too much manual time finalizing content for submission readiness?
- Are you looking to speed up time-to-market?
- Are you looking to reduce risk of non-compliance drastically?
- Are you looking to reduce the reliance on Adobe technology and other PDF manipulation tools?
- Are you having to reconfigure your PDF settings for each region before each submission?
- Are you looking to centralize the creation of technically compliant PDF renditions from source documents in 1 platform?

CONTACT ME FOR AN INTRO & DEMO SESSION

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20+ years in helping to provide regulatory software and service solutions to Life Sciences organisations globally. Industry and commercial experience in delivering Content Rendering, Regulatory Information Management, Submission and Report-level Publishing, and Electronic Document Management solutions.