



# KNOWLEDGENET

Regulatory compilation and publishing Solution

## Purpose

These specifications are for creating documents in Portable Document Format (PDF) for submission to regulatory authority, that align with ICH M2 recommendations<sup>1</sup> and that are in a format that the receiving Center currently supports.



Business Solutions with Technology Edge

## VERSION

- PDF versions 1.4 through 1.7, PDF/A-1 and PDF/A-2 are acceptable for documents. Submitted PDF files should be readable by Adobe Acrobat X, should not require additional software or plug-ins to be read and navigated, and should be text searchable.
- PDF files must not contain JavaScript; dynamic content which can include audio, video or special effects and animations; attachments or 3D content.<sup>2</sup> Do not include PDF annotations in documents.<sup>3</sup> Ensure that all hypertext links in documents remain active after conversion to PDF/A.

## SECURITY

- Do not activate security settings or password protection. The integrity of the submitted files is maintained through Agency security and archival processes.

## FONTS

- Fully embed all non-standard fonts. PDF viewing software automatically substitutes a font to display text if the font used to create the text is unavailable on the reviewer's computer. In some cases, font substitution can occur even when the fonts are available.
- Font availability to the reviewer is ensured if all non-standard fonts are fully embedded.
- **List of standard fonts:**

Font Type	Font Name
Serif	Times New Roman, Times New Roman Italic , Times New Roman Bold, 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

- Use font sizes ranging from 9 to 12 point. Times New Roman 12-point font is recommended for narrative text. When choosing a point size for tables, a balance should be made between providing sufficient information on a single page that may facilitate data comparisons while still achieving point size that remains legible. Generally, point sizes 9-10 are recommended for tables; smaller point sizes should be avoided. Ten-point fonts are recommended for footnotes.
- When creating documents which include scanned images, ensure that any resizing of the image does not reduce the effective font size.
- Black is the recommended font color except that blue can be used for hypertext links. Light colors do not print well on grayscale printers.

## **PAGE ORIENTATION**

- Save the page orientation for proper viewing and printing within the document. Proper page orientation eliminates the need for reviewers to rotate pages.

## **PAGE SIZE AND MARGINS**

- Set up the print area for pages to fit on a sheet of paper that is 8.5 inches by 11 inches. A margin of at least 3/4 of an inch on the left side of page avoids obscuring information when pages are subsequently printed and bound.
- For pages in landscape orientation, a margin of 3/4 of an inch at the top allows more information to be displayed legibly on the page.
- Oversized documents (e.g., CAD drawings or other specialized documents) and promotional materials submitted in PDF format should be created according to their actual page size.

## **SOURCE OF ELECTRONIC DOCUMENTS**

- Avoid image-based PDF files whenever possible. PDF documents produced by scanning paper documents usually have poorer image resolution than PDF documents produced from electronic source documents such as word processing files.

- Scanned documents are generally more difficult to read and do not allow the reviewer to search or copy and paste text for editing in other documents. If scanned files must be submitted, they should be made text searchable where possible. If optical character recognition software is used, verify that imaged text is converted completely and accurately.

## METHODS FOR CREATING PDF DOCUMENTS AND IMAGES

- Scanned documents scanned at a resolution of 300 dots per inch (dpi) ensure that the pages of the document are legible both on the computer screen and when printed and, at the same time, minimizes the file size.

### Scanning Resolution

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

## IMAGE COMPRESSION TO REDUCE FILE SIZE

- Compress files using either Zip/Flate or CCITT Group 4. File compression is a method for reducing file size. Some methods of compression can result in loss of data and can introduce compression artifacts that affect the reviewability of the information. The following two methods provide lossless compression.

- Zip/Flate (one technique with two names) for lossless compression of color and grayscale images is specified in Internet RFC 1950 and RFC 1951.
- CCITT Group 4 Fax compression technique recommendations for lossless compression of black and white images is specified in T.6 (1988) - Facsimile coding schemes and coding control functions for Group 4 facsimile apparatus.

### **OPTIMIZE FOR FAST WEB VIEW**

- Create files from source documents using the “Optimize the PDF for fast web view” option to reduce file sizes and file opening times.

### **IMAGE COLOR MATCHING**

- Because color varies from monitor to monitor, it is difficult to ensure that the reviewer will see exactly the same color as in the actual image. However, for printing, there is more control over the color by using CMYK (Cyan, Magenta, Yellow, Black) color model as opposed to the RGB model. Pantone Matching using the color profile provided by CMYK ensure color consistency for printing. The International Color Consortium (ICC)6 color profile specification is used when PDF documents are printed.

### **USE OF THUMBNAILS**

- PDF documents do not need embedded thumbnails.

### **DOCUMENT NAVIGATION**

- A table of contents (TOC), hypertext links and bookmarks provide essential navigation through PDF documents. Include a hypertext linked TOC and bookmarks in documents 5 pages or longer.
- Hypertext links in text can be designated by rectangles using thin lines or by blue text. A consistent method of designating links in a document avoids confusion. Hypertext links that open a file or document should be set to open the file or document in a new window.

- When creating bookmarks and hyperlinks, set the magnification setting to “Inherit Zoom” so the destination page displays at the same magnification level used in the primary document.

## **INITIAL VIEW SETTINGS**

- Set the Navigation Tab to open to “Bookmarks Panel and Page.” This sets the initial document view when the file is opened. If there are no bookmarks, set the Navigation Tab to “Page Only.” Page Layout and Magnification should be set to “Default.”

## **PAGE NUMBERING**

- In general, it is easier to navigate through an electronic document if the page numbers for the document and the PDF file are the same, with the initial page of the document numbered as page one.

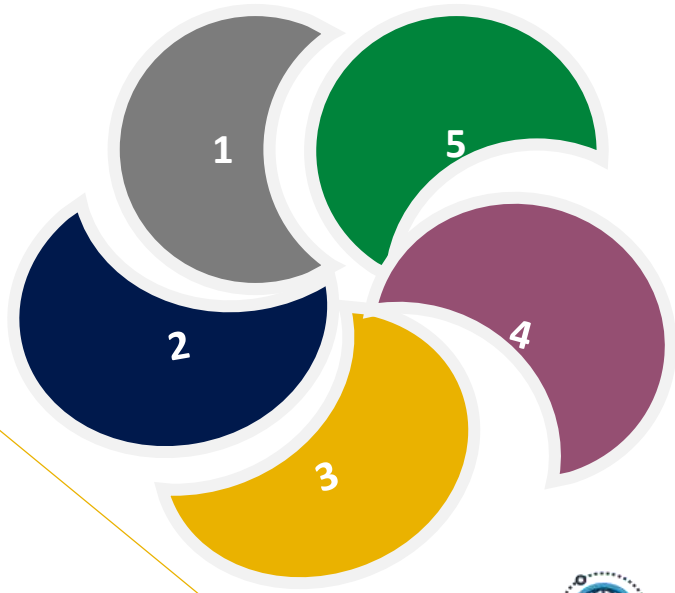
## **NAMING PDF FILES**

- Use lower case characters and avoid using special characters except hyphens and underscores in file names. Special characters to avoid include punctuation, spaces, or other non-alphanumeric symbols.

## **SPECIAL CONSIDERATIONS FOR PROMOTIONAL LABELING AND ADVERTISING MATERIAL**

- PDF restrictions for font size, color, and annotations stated in this document are not applicable to these materials.
- Provide images at the highest resolution and depth practical. For photographs, the image should be obtained with a resolution of at least 600 dpi.

# Contact us



## 1. Corporate Office:-----

6th floor, Arista,  
Anandnagar Road,  
Ahmedabad 380015  
Tel.: +91-79.66214899

## 2. Mumbai:-----

6, Krishna Kunj, Plot no.  
100,  
Dr. Ambedkar road  
(Sion main road),  
Sion (E), Mumbai 400022  
Tel.: +91-22.24303318

## 3. UK:-----

79 College Road,  
Harrow Greater  
London, HA1 1BD  
Tel.: +44-208.432.6393



## 4. Online Presence-----

Web: [www.sarjen.com](http://www.sarjen.com)  
E-mail: [sarjen@sarjen.com](mailto:sarjen@sarjen.com)



## 5. Social media:-----

