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| **S. No** | **Check Parameters** | **QC Type** | **Activity Type / Automation Possibility Type** | **Tool** | **Estimate to build tool** | **Other Costs if applicable** |
| 1 | Ensure Word doc format type is always “Microsoft Word Document”, if it is not the case before editing the document just save the document as “Microsoft Word Document (.docx). | Word formatting related | Automation |  |  |  |
| 2 | Spell check for correctness and also for UK/US spellings as applicable- (Use only Merriam Webster and not any other reference documents) | Content Related | Automation |  |  |  |
| 3 | Consistency check for trade name/active substance name, singular and plural words | Content Related | Automation |  |  |  |
| 4 | Check for Quality of the images (i.e. if they are blurry or unclear)  Keenly check for the Illustration number (ILL number) and text used in the graphs and ensure that images are matching with reference label (if provided) or check in RIM Illustration Library.  Also check for legibility of Illustration number and add in “ALT text” field looking at the ILL number in English reference document. Word settings change to “Do not compress images in file” and “High Fidelity” to ensure clarity in images is maintained while replacing the image.  Make sure the ILL number on the image and in the “ALT text” are same in the English reference document. | Content Related | Manual |  |  |  |
| 5 | Automatic hyphenation should be switched off when authoring labeling text (for new RPI creations). | Word formatting related | Automation |  |  |  |
| 6 | Heading/Subheading consistency | Word formatting related | Automation |  |  |  |
| 7 | Abbreviations/Acronyms present in Figures, Graphs and Tables must be checked if they are expanded in foot note  Check if there is already an expansion present in the Figures, Graphs and Tables, in that case it should not be commented.  Whenever the Graphs and Figures are modified ensure that footnotes are amended accordingly  Tables/Figure numbering must be in a sequence | Content Related | Automation |  |  |  |
| 8 | Page layout should be portrait | Word formatting related | Automation |  |  |  |
| 9 | Page Margins-  EU Central Region-Page setup must be done as per QRD requirements  Russia country -Documents must have page specifications as mentioned below  Line interval – 1.5, head margin – 2 cm, bottom margin – 2 cm, left margin – 3 cm, right margin – 1.5 cm | Word formatting related | Automation |  |  |  |
| 10 | Use of “Keep with Next” appropriately  Apply widow orphan control for the entire document (Only for new RPI creations) | Word formatting related | Automation |  |  |  |
| 11 | Consistency of text within the documents [e.g. Bold, italics, underline, parenthesis, upper and lower case]  Terms *in vitro, in vivo, in utero, in situ, de novo* and other Latin terms must be italicized | Word formatting related | Automation |  |  |  |
| 12 | Font size and style must be checked for consistency throughout the document | Word formatting related | Automation |  |  |  |
| 13 | Consistent use of scientific units [e.g. “mcg” or “µg”; ml or mL] | Content Related | Automation |  |  |  |
| 14 | Non-breaking space:  Number and the corresponding unit or measure check for non-breaking space it is mandatory between “a number and a unit” [e.g. 10 mg; 10 mg/kg, 10 ml etc.]. but not required between “Numbers and words” [e.g. 10 days, 10 weeks, 10˚Tablets/Days/Patients/ Months etc.]  Non-breaking hyphens for ranges [20-30%, 2-4 etc.] | Word formatting related | Automation |  |  |  |
| 15 | Double space: Check for consistency and delete the extra spaces. | Word formatting related | Automation |  |  |  |
| 16 | Line spacing (for EU-Central - “Single” and Russia-1.5 Lines). For other regions, it MUST be consistent within the document | Word formatting related | Automation |  |  |  |
| 17 | Indent check (1.0 cm Special: Hanging for EU-Central). For other regions, it MUST be consistent within the document. | Word formatting related | Automation |  |  |  |
| 18 | Check for correctness of cross reference in the text and also the representation of the cross references must match at all instances. | Content Related | Automation |  |  |  |
| 19 | Gray shaded text consistency within EN document or, as per reference (If available) | Content Related | Manual |  |  |  |
| 20 | Appropriate use of punctuations (e.g., commas, end period, colons, semi colons, inverted comma, etc.) | Content Related | Automation |  |  |  |
| 21 | Appropriate representation of Superscript and Subscript | Content Related | Automation |  |  |  |
| 22 | Missing/addition of text in EN document with respect to reference (if reference provided) | Content Related | Manual |  |  |  |
| 23 | Scientific symbols should be inserted from the Insert Symbol Menu only, also make sure symbols are in same font as the running text. | Content & Word Formatting Related | Automation |  |  |  |
| 24 | Color highlight of text must not be removed [Applicable for EU Non-Central and CDS ONLY].  Color highlight of the text to be checked and only commented for other Regions | Content Related | Manual |  |  |  |
|  |  |  |  |  |  |  |
| 25 | Check for Alignment in the document  For EU Central – Left alignment and for other regions, it MUST be consistent within the document | Word formatting related | Automation |  |  |  |
| 26 | Header and footer:  Page numbers in Footer to be Arial 8pt centered [Applicable for EU-Central ONLY].  For other regions, the footer style should be consistent within the document  Page numbers must be inserted only from “Insert page number” menu | Content & Word Formatting Related | Automation |  |  |  |
| 27 | Table text formatting, and alignment. Footnotes font size and alignment.  Repeat header to be given for all the tables. | Word formatting related | Automation |  |  |  |
| 28 | Document to be checked in “No Markup” view once the QC check is complete (to identify any issues with color of text, keep with next, underlined texts, alignments etc.). | Word formatting related | Manual |  |  |  |
| 29 | Once QC check is complete, a “Word Comparison” to be done of original document received by Freyr against the reviewed document to identify – typo errors, casing errors etc. that might have been introduced in Untracked mode. This is to be done for both level of reviews by Freyr (1st and 2nd). | Content & Word Formatting Related | Manual |  |  |  |
| 30 | Refer Source Text Authoring Guide  Check the Regulatory guidance (if available) and Country Specific Templates (QRD stylistics and QRD Templates for EU)  Refer to Work instructions (EQC)  Read and analyze/understand the EQC request completely before starting the task.  Verify previous tasks (Document IDs) in Tracker/ECS for the Amgen RLL/LRR responses in RIM to the queries raised. | Content & Word Formatting Related | Manual |  |  |  |
| 31 | Document properties must be checked in INFO tab [Applicable for EU-Central only] | Word Properties related | Automation |  |  |  |
| 32 | Check for Title A and Title B style parameters [Applicable for EU-Central only]  Page setup must be done as per QRD requirements | Word formatting related | Automation |  |  |  |
| 33 | Check for thousand separators in EU QRD stylistic guide and for consistency within the document  Colons must NOT be present after Lot/Exp(in any form) and PC/SN/NN for all languages[Applicable for EU-Central ONLY].  Commas present in Amgen address for Carton ONLY[Applicable for EU-Central ONLY]. | Content Related | Automation |  |  |  |
| 34 | No formatting changes e.g. Hard spaces, Hard hyphens, Bold, Unbold etc. must be done in the tables [Applicable for EU-Central only] | Word formatting related | Automation |  |  |  |
| 35 | Hyperlinks:  Ensure hyperlinks of cross references, (including table of contents (TOC), “see Boxed Warning”, “see Medication guide”, “See IFU”) are active and correct.  Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document.  Also, the cross references must be italicized in USPI e.g. [ see Warnings and Precautions (5.2)].  Check if the representation of all the headings/ cross references are consistent at all instances | Content & Word Formatting Related | Automation |  |  |  |
| 36 | Left vertical sideline bars:  Check for left horizontal lines/vertical sideline bars (Recent Major Changes) only for the below sections in USPI  BOXED WARNINGS, INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS | Content Related | Automation |  |  |  |
| 37 | Table of Content (TOC):  Check if main headings in TOC are in uppercase bolded, and subheadings in sentence case and not bolded. | Word formatting related | Automation |  |  |  |
| 38 | Check if all  First level headings in USPI are in uppercase and bolded  Second level headings are in case form and bolded  Third level sub-headings are in case form underlined | Word formatting related | Automation |  |  |  |
| 39 | CDS  All end notes must be checked for hyperlinking if they are active and correct in CDS along with the cross-reference’s representation  Check if End notes are consecutive, if any number is deleted the next number must be checked if the number is the next consecutive one.  Check on version number and date format in the Appendix (Applicable to the entire appendix)  Colored text should not be changed or commented.  Cross references must be checked for correctness but not consistency in the level of headings represented. . | Content & Word Formatting Related | Automation |  |  |  |
| 40 | Also the representation of USA or US must be checked for consistency in the documents and mandatorily must have end periods after each letter ex: U.S.A. | Content Related | Automation |  |  |  |