Todo list

MedRep – A Package to create eCTD-compliant PDFs

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1 Introduction and Scope

Regulatory data files about quality, safety and efficacy of medicinal products for human use that are intended to be transferred electronically to a regulatory agency must be provided in a specified format, the so-called "electronic Common Technical Document" (eCTD) - notably in the major industrial regions of the world.

The specification for the eCTD is based on XML technology (EXtensible Markup Language) and defines criteria based on which an eCTD is considered technically valid. The eCTD has been developed by the ICH M2 Expert Working Group as an internationally recognized format for electronic regulatory submissons (ICH eCTD Specification v3.2.2). The structure of an eCTD follows the modular pattern of the Common Technical Document (CTD) as was defined by the ICH M4 Expert Working Group beforehand. In addition, regionally differing eCTD specifications and validation criteria must be considered for Module 1, the non-common part of the CTD.

Data and text files included in an eCTD are mostly of Portable Document Format (PDF). Basic document layout (e.g. margins, font, header and footer, pagination) have already been defined in relevant CTD guidance documents (ICH M4/R3; The M4 General Questions & Answers Document). Additional properties and settings were specified for PDFs included in an eCTD in order to ensure navigation and accessibility of the files (ICH eCTD Specification v3.2.2).

2 Properties of PDFs Created with LaTeX by using Class PharmRep

While LaTeX in general is a tool to create documents with professional layout (please refer to related publications, e.g. the comprehensive works of Frank Mittelbach and Michel Goossens), the tools provided by the class PharmRep (for details see related package documentation) are intended to assist users with creating standardized regulatory documents in professional layout that meet the requirements laid down in the related eCTD specification.

(Table 1) provides an overview of the major format settings and properties of PDFs created with LaTeX/PharmRep. Apart from a few exemptions the PDFs created with PharmRep fulfil the requirements. The outstanding properties can easily be set by means of appropriate software.

Table 1: Layout, Settings and Properties of PDFs created by PharmRep

Layout, Settings, Properties	Requirement	PharmRep
Bookmark magnification setting	Inherit zoom magnification	No
Bookmarks	Bookmarks identical to ToC	X
Document structure	ToC, LoT, LoF; hyperlinked; blue	X
Hierarchy level	4 hierarchy levels	3 <only 3?>
Fast web view	Optimized for fast web view	No
Font color	Black	X
Font size footnote	TNR 10 pt recommened	X
Font size narrative text	TNR 12 pt recommended	X
Font size table	TNR 9-10 pt recommended	X
Font, embedded	Embedded fonts	X
Header or footer	Distinct identifier on every page	X
Hyperlink magnification setting	Inherit zoom magnification	No
Hypertext linking (color)	Blue text color or by thin lines	X (blue text)
Links, external	Links to external sources must be inactive	No
Open dialog box, inital view	"Bookmarks page and panel"	X
Open dialog box; magnification	"Magnification - Default"	No
Open dialog box; page layout	"Page Layout - Default"	X
Page orientation	Correct page orientation portrait or landscape	X
Page size and margins	Sufficient margins on the sides of each page	X
Pagination	Page numbering starting with "1" on first page	X
PDF version	Versions 1.4; 1.5; 1.6; 1.7	X (1.4)
Security setting	No security settings or password-protection	X

3 How to Use the PharmRep-Manual

The present manual is intended to provide guidance on how to easily create regulatory documents with LaTeX by using the class PharmRep. It is structured and formatted according to a typical regulatory document that is intended to form part of an eCTD. When creating a PDF by using PharmRep it is recommended to use it in connection with the respective PharmRep template.

If any specific formatting or style settings are required in the document in question (e.g. inserting a table in landscape format) the related LaTeX settings can be copy-pasted from the manual directly into this document. The settings provided in this manual are far from being all exclusive, but focus on typical format settings used in regulatory documents and were especially compiled for LaTeX-beginners. The manual will be amended and updated on a regular basis.

4 Practical Part - Commands for Typical Layout Features

In the following typical layout features of a submission-relevant PDF and their related commands in LaTeX will be discussed in detail. If any specific formatting or style settings are required in the document in question (e.g. the need to create a table) the related LaTeX settings can be copy-pasted from the manual directly into this document. The manual will be amended and updated on a regular basis.

4.1 Section Levels and Section Numbering

Numbering of sections, subsections and subsubsections is added automatically during the compilation.

The numbering is indicated by the command `\section` for title level 1, `\subsection` for level 2, `\subsubsection` for level 3, and `\paragraph` for level 4. Please note: Only the 'section', 'subsection',... titles will be automatically converted to bookmarks during the PDF creation.

For paragraphs, text is usually in the same layout as the title, but a paragraph is not numbered. The unnumbered 'paragraph' levels will not be converted to bookmarks during the PDF creation.

- Level 1 Title 1: sections: `\section{Title}`
- Subtitle 1.1 level 2 - Sub-Title 1.1: subsections: `\subsection{Title}`
- Section level 3 – Subsub-Title 1.1.1: subsubsections: `\subsubsection{Title}`
- Section level 4 – ParagraphTitle : paragraph: `\paragraph{Title}`
- Section level 5 – Sub-ParagraphTitle : subparagraph: `\subparagraph{Title}`

4.2 Common Formatting Functions

4.2.1 Paragraphs and Line Breaks

- new paragraph: insert 1 or more blank line(s) (more than 1 will be ignored during the compilation
- new line or line break: `\newline`

4.2.2 Hyphenation

- separate words: 1 or more blanks (more than 1 will be ignored during the compilation)
- no break between two words: ~
- enable hyphenation at specific locations of a word: `\-` (e. g. `reac\-tion`) Usually not necessary since hyphenation is already enabled by the loaded packages

4.2.3 Quotation Marks

- quotation mark ("double") ``` ``double'' ```
- quotation mark ('single') `` `single' ``

Hint to squotes

4.2.4 Font Style

- **bold** text: `\textbf{text}`
- *italic* text: `\textit{text}`
- small text: `{\small small text}`
- footnotesize text: `{\footnotesize footnotesize text}`
- tiny text: `{\tiny tiny text}` (usually too small)

4.2.5 Special Characters

In most cases a backslash (\) directly in front of a special character will work, e. g.

- % (percent): `\%`
- & (ampersand): `\&`

4.3 Page Orientation: Portrait and Landscape

Hello, here is some text without a meaning. This text should show what a printed text will look like at this place. If you read this text, you will get no information. Really? Is there no information? Is there a difference between this text and some nonsense like “Huardest gefburn”? Kjift – not at all! A blind text like this gives you information about the selected font, how the letters are written and an impression of the look. This text should contain all letters of the alphabet and it should be written in of the original language. There is no need for special content, but the length of words should match the language.

4.3.1 Landscape

`\landscapeformat`

Hello, here is some text without a meaning. This text should show what a printed text will look like at this place. If you read this text, you will get no information. Really? Is there no information? Is there a difference between this text and some nonsense like “Huardest gefburn”? Kjift – not at all! A blind text like this gives you information about the selected font, how the letters are written and an impression of the look. This text should contain all letters of the alphabet and it should be written in of the original language. There is no need for special content, but the length of words should match the language.

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4.3.2 Back to Portrait

```
\portraitformat
```

Hello, here is some text without a meaning. This text should show what a printed text will look like at this place. If you read this text, you will get no information. Really? Is there no information? Is there a difference between this text and some nonsense like “Huardest gefburn”? Kjift – not at all! A blind text like this gives you information about the selected font, how the letters are written and an impression of the look. This text should contain all letters of the alphabet and it should be written in of the original language. There is no need for special content, but the length of words should match the language.

4.4 Lists and Enumeration Items

Lists can be described with different enumeration items. Generally, bullet points, numbered and description are used.

Reference of lists (only useful for page number reference since lists do not have a number/internal counter): Define unique label using
`\label{list:listdescription}`
Label names do not work with special characters (except ‘:’) or blanks.

4.4.1 Bullet Point Lists

- item 1
- item 2

Code for bullet point list:

```
\begin{itemize}
\item item 1
\item item 2
\end{itemize}
```

4.4.2 Numbered List

1. item 1
2. item 2

Code for numbered list:

```
\begin{enumerate}
\item item 1
\item item 2
\end{enumerate}
```

4.4.3 Description List

description label 1 item 1

description label 2 item 2

Code for description list:

```
\begin{description}
\item[description label 1] item 1
\item[description label 2] item 2
\end{description}
```

4.4.4 List in a List

Lists can be combined arbitrarily and levels are automatically formatted, e. g. bullet point and numbered list:

- item 1
  1. subitem 1
  2. subitem 2
     - subsubitem 1
     - subsubitem 2
  3. subitem 3
- item 2

Code for the combined list:

```
\begin{itemize}
\item item 1
\begin{enumerate}
\item subitem 1
\item subitem 2
\begin{itemize}
\item subsubitem 1
```

```
\item subsubitem 2
\end{itemize}
\item subitem 3
\end{enumerate}
\item item 2
\end{itemize}
```

4.5 Tables

In LaTeX, 'table' is the name for a floating object (see p. 19), whereas 'tabular' provides the environment for tables. In a 'tabularx' environment, the table width can be set (e. g. to `\textwidth`) and page breaks are enabled [1]. Creating tables with LaTeX require some experience. In the following, basic instructions on how to create tables are described. Alternatively, tables can be created in MS Excel and converted into LaTeX tables by installing the Excel-add-in Excel2Latex. Tables can also be included as objects.

4.5.1 Caption of Tables

Every table included into a document requires a brief, informative title ('caption') that describes its contents in nonsentence format <Let.Ref. ACS Style Guide>. Tables are numbered sequentially with arabic numerals.

Please make sure that every table needs to be discussed within the text, whereas the tables should be discussed sequentially, so that Table 1 is discussed before Table 2, Table 2 before Table 3, and so on <ACS Style Guide>.

A table caption should be placed at the beginning of the table.

Please note that the word "Table" is only capitalized when it is followed by the table number – and in the beginning of the table caption that starts with "Table", followed by its numeral.

Each table with a caption is automatically listed in the list of tables.

4.5.2 General Layout Pptions for Tables

```
The instructions as given below create a basic table with two columns and t
are separated by the symbol \& (ampersand) and rows are ended by using the
\textbackslash\textbackslash (double backslash). The column format is defin
table, e.g. \verb|{rr}| for two right-aligned columns (more options see \au
```

[1] for PharmRep the package ltablex is used

```
\captionof{table}{first tabular}\label{tab:FirstTab}
\begin{tabular}{rr}
a & 1 \\
b & 2 \\
c & 3 \\
\end{tabular}
```

As an example, the instructions as given above create Table 2 with two columns and three rows.

Table 2: first tabular

a	1
b	2
c	3

The layout of a table can be modified with a huge number of commands and tools. The major characteristics of a table are the number and type of columns and lines. Table 3 shows some of the options using the following code:

```
\begin{minipage}{\linewidth}%
\captionof{table}[xyz]{Some Options for tables}\label{tab:TabGenLayout}
\begin{tabularx}{\linewidth}{rlcp{10mm}S}\toprule
\textbf{Col 1} & \textbf{ Col 2} & \textbf{Col 3} &
\textbf{Col 4} & \textbf{ Col 5} \\ \cmidrule{1-4}
right & left & centered & fixed width &
\text{justified at decimal separator} \\ \midrule
& & & & 12.97 \\
& & & & 0.4 \\
& & & & 10000.3 \\ \bottomrule
\end{tabularx}
\end{minipage}%
```

that results in the following PDF-printout:

Table 3: Some Options for tables

Col 1 `r`	**Col 2** `l`	**Col 3** `c`	**Col 4** `p`	**Col 5** `S`
right	left	centered	fixed width	justified at decimal separator
				12.97
				0.4
				10 000.3

4.5.3 General Commands for Table Layout

In the follwing, general commands for typical table layout is given.

4.5.3.1 Column without and with Linebreak

Column formats

without linebreak

`r` aligned right

`l` aligned left

`c` centered

`S` justified at decimal separator

with linebreak

`p<width>` parbox ('paragraph box') with predefined width

`X` only in `tabularx` environment: parbox with flexible width to meet the predefined tablewidth (e.g. `{\linewidth}`)

Header and footer (example see p. 15 ff.)

`\endhead[`⟨***optional argument***⟩**`]`** table content before this command will be used for the header on every page of a table

`\endfoot[`⟨***optional argument***⟩**`]`** table content between `\endhead` and `\endfoot` will be used for the footer on every page of a table. The footer is defined at the beginning of a table!

Lines Use horizontal lines rarely and avoid vertical lines always. Reasons and examples see e. g. http://ctan.org/pkg/booktabs

horizontal lines (avoid whenever possible)

`\toprule` first horizontal line at the top of the table

`\midrule` horizontal line within the table

`\midrule{a-b}` horizontal line starting at column `a` and ending at column `b`

`\midrule(lr){a-b}` horizontal line starting at column `a` and ending at column `b` shortened left (`l`) and right (`r`)

`\bottomrule` last horizontal line at the end of the table

vertical lines Vertical lines in tables should be avoided in general. (They are easy to use in LaTeX, but a huge challenge regarding the readability and usability of any document.)

4.5.4 Long Table – Portrait Format

Table 4: Example long table

Col 1	Col 2	Col 3	Col 4 with very long header using some more superfluous additional text
the	1	a	more and more text
quick	2	b	some more text
brown	3	c	some more text (in addition)
fox	4	d	more text
jumps	5	e	more text
over	6	f	more text
the	7	g	more text
lazy	8	h	more text
dog	9	i	more text
.	10	j	more text
the	11	k	more and more text
quick	12	l	some more text
brown	13	m	some more text (in addition)
fox	14	n	more text
jumps	15	o	more text
over	16	p	more text
the	17	q	more text
lazy	18	r	more text
dog	19	s	more text
.	20	t	more text
the	21	u	more and more text
quick	22	v	some more text
brown	23	w	some more text (in addition)
fox	24	x	more text
Foot 1	*Foot 2*	*Foot 3*	*Foot 4*

Col 1	**Col 2**	**Col 3**	**Col 4 with very long header using some more superfluous additional text**
jumps	25	y	more text
over	26	z	more text
the	27	a	more text
lazy	28	b	more text
dog	29	c	more text
.	30	d	more text
Foot 1	*Foot 2*	*Foot 3*	*Foot 4*

4.5.5 Long Table - Landscape Format

Table 6: Example long table on a landscape page

Col 1	Col 2	Col 3	Col 4 with very long header using some more superfluous additional text and extra words to stretch the tabular width to textwidth
the	21	u	more and more text
quick	2	b	some more text
brown	3	c	some more text (in addition)
fox	4	d	more text
jumps	5	e	more text
over	6	f	more text
the	7	g	more text
lazy	8	h	more text
dog	9	i	more text
.	10	j	more text
the	11	k	more and more text
quick	12	l	some more text
brown	13	m	some more text (in addition)
fox	14	n	more text
jumps	15	o	more text
over	16	p	more text
the	17	q	more text
lazy	18	r	more text

Col 1	**Col 2**	**Col 3**	**Col 4 with very long header using some more superfluous additional text and extra words to stretch the tabular width to textwidth**
jumps	25	y	more text
over	26	z	more text
the	27	a	more text
lazy	28	b	more text
dog	29	c	more text
.	30	d	more text
Foot 1	Foot 2	Foot 3	Foot 4

4.5.6 Table Footnotes

<include instructions here>

4.5.7 Positioning of Tables – Floating versus Manually

In LaTeX, tables and figures can basically be positioned in two different ways: They are included manually and appear exactly at this place (like in word processing software, e. g. Microsoft Word) or they can be included as a floating object.

4.5.7.1 Floating Table Floating objects are included where they are in the code if there is enough space for a eye-friendly layout. In case the place is too small floating objects are positioned automatically near the original insertion. 'Near' can be on the same page, the next page or farer away depending on the amount of text and/or other floating objects. Floating provides a more professional layout and should be used if possible to increase the readability.

A	B	C
1	has	6
2	a yellow	4
3	car	2

Table 8: Table as a floating object

Code for table 8 (page 19)

```
\begin{table}[hbpt]
\begin{tabular}{ccc}\toprule
A & B & C \\\midrule
1 & has & 6 \\
2 & a yellow & 4 \\
3 & car & 2 \\\bottomrule
\end{tabular}
\caption[short caption table]{Table as a floating object}%
\label{tab:tableFloatingObject}
\end{table}
```

printed in list of tables as "8 short caption table" . The optional short title `[short caption table]` in squared brackets is used for LOT. If no short title is given the whole caption is printed in the list of tables.
referred to by using:
`table \ref{tab:tableFloatingObject}` (result: table 8) or
`\autoref{tab:tableFloatingObject}` (result: Table 8)

page number:
`page \pageref{tab:tableFloatingObject}` (result: page 19) or
`\autopageref{tab:tableFloatingObject}` (result: page 19)

4.5.8 In-Text References to Tables

In general, the instruction `\label{key}` is used for names and references of tables, figures and everything else (e.g. sections, paragraphs).
If a table or figure is included directly at a specific place a caption is included by
`\captionof{figure}[short]{title}\label{fig:figurelabel}` or
`\captionof{figure}[short]{title}\label{tab:tablabel}`
For floating tables or figures in a floating environment `\begin{table}...\end{table}` (see 4.5.7) or `\begin{figure}...\end{figure}` (see 4.6.2):
`\caption[short]{title}\label{fig:figurelabel}` or
`\caption[short]{title}\label{tab:tablabel}`
`[short]`: optional 'short caption' being printed in the list of figures or list of tables, respectively, and 'title' used for the figure or table itself. The label is used for reference purposes, e. g.
`\ref{fig:figurelabel}` or `\ref{tab:tablabel}`
Label names do not work with special characters (except ':') or blanks.

4.5.9 MS Excel Add-in 'Excel2LaTeX'

Excel spreadsheets can be converted into a LaTeX tabular structure manually or using third party software, e. g. Excel2LaTeX (available on `http://www.ctan.org/pkg/excel2latex`).
Excel2LaTeX works for Windows, Mac OS X and Excel 2000 up to Excel 2010. For Excel 2007 and Excel 2010 the add-in has to be activated within the options menu in Excel. After a restart of Excel and the activation of 'Excel2LaTeX' as a secure macro the add-in excel2latex is available in the ribbon 'Add-In'. <diese Angaben müssen noch auf Korrektheit geprüft werden; ggfs. hier keine weiteren Angaben, sondern nur Referenz auf das package, wo in der readme alle weiteren Details beschrieben sind>.
Instead of converting Excel or Word tables (and other parts) into LaTeXthe part could be included using `\includegraphics` (see p.23). <hier: Hinweis auf Vorgehensweise, wenn PDF/A-1b gefordert ist>.

4.6 Figures

Figures are not directly inserted into the TEX file, but are created as separate files which are included during the compilation. For PDF generation, file formats png, jpg or pdf are allowed, all others will produce an error.The figure-files need to be stored in the same folder as the TEX file (alternatively, the complete file-path has to be provided).

4.6.1 Caption of Figures

Every figure included into a document requires a brief, informative title ('caption') that describes its contents in nonsentence format <Let.Ref. ACS Style Guide>. Figures are numbered sequentially with arabic numerals. Please make sure that every figure needs to be discussed within the text, whereas the figures should be discussed sequentially, so that Figure 1 is discussed before Figure 2, Figure 2 before Figure 3, and so on <ACS Style Guide>.
A figure caption should be placed below the figure.
Please note that the word "Figure" is only capitalized when it is followed by the figure number - and in the beginning of the figure caption that starts with Figure, followed by its numeral.
Each figure with a caption is automatically listed in the list of figures.

4.6.2 Positioning of Figures - Floating versus Manual

Figure 1: Figure as a floating object. CTAN lion drawing by Duane Bibby; thanks to `www.ctan.org`

4.6.2.1 Automatic Insertion of Figures ('Floating Figures')

Code for figure 1 (page 21)

```
\begin{figure}[hbpt]
\includegraphics[width=0.2\linewidth]{ctanlion}
\caption[short caption figure]{Figure as a floating object. CTAN lion drawi
\label{fig:figureFloatingObject}
\end{figure}
```

printed in list of tables as "1 short caption figure" . The optional short title in squared brackets `[short caption figure]` is used for LOF. If no short title is given the complete caption is printed in the list of figures.

referred to by using:
`figure \ref{fig:figureFloatingObject}` (result: figure 1) or
`\autoref{fig:figureFloatingObject}` (result: Figure 1)
page number:
`page \pageref{fig:figureFloatingObject}` (result: page 21) or
`\autopageref{fig:figureFloatingObject}` (result: page 21)

4.6.2.2 Manual Insertion of Figures

Figure 2: example of a manually inserted figure

Code for figure 2 (page 22)

```
\begin{minipage}[t]{\linewidth}%
\includegraphics[width=0.2\linewidth]{ctanlion}
\captionof{figure}{example of a manually inserted figure}%
{\label{fig:figureManuallyInserted}}
\end{minipage}%
```

Note: It is recommended to end the `\begin{minipage}` and `\end{minipage}` line with a percent sign (%) to avoid spurious blanks.

4.6.3 In-Text References to Figures

`\label{key}` is used for names and references of tables, figures and everything else (e. g. sections, paragraphs).
If a table or figure is included directly at a specific place a caption is included by
`\captionof{figure}[short]{title}\label{fig:figurelabel}` or
`\captionof{figure}[short]{title}\label{tab:tablabel}`
A table caption should be placed at the beginning of the table whereas a figure caption is usually beneath the figure.
For floating tables or figures in a floating environment `\begin{table}...\end{table}` (see 4.5.7) or `\begin{figure}...\end{figure}` (see 4.6.2):
`\caption[short]{title}\label{fig:figurelabel}` or
`\caption[short]{title}\label{tab:tablabel}`
`[short]`: optional 'short caption' being printed in the list of figures or list of tables, respectively, and 'title' used for the figure or table itself. The label is used for reference purposes, e. g.
`\ref{fig:figurelabel}` or `\ref{tab:tablabel}`
Label names do not work with special characters (except ':') or blanks.

4.6.4 Including Figures from external PDFs into the LaTeX File

Pictures, figures, tables and any other objects that are provided in PDF-files can be included into LaTeX by using the command `\includegraphics[⟨options⟩]{⟨filename⟩}`. Special characters and spaces should be avoided in the PDF file name!

Example

- The figure of the PDF-file `pdfexample.pdf` is planned to be included into the file `master.tex`
- `master.tex`: usual LaTeXfile with definition of styles, commands, etc.
- `pdfexample.pdf`: pdf file

```
%% master.tex file:

preamble, styles, etc.
[...]

\begin{document}
some text
\begin{minipage}{\linewidth}%
\captionof{figure}{example including pdf}
\includegraphics[page=1, trim=60mm 170mm 90mm 40mm, clip]{pdfexample.pdf}
\end{minipage}%
more text
\end{document}
```

4.7 Footnotes in Text

Footnotes are set by including `\footnote{text}` directly behind the word, where the footnote should be added. No space should be placed between word and instruction. The footnote will be automatically numbered and placed at the end of the page.

4.8 Splitting Large Documents

Large documents can be split into several `*.tex` files. Special characters should be avoided in the PDF file name!. For an example see below:

- three files: `master.tex`, `part1.tex` and `part2.tex`
- `master.tex`: usual LaTeX file with definition of styles, commands, etc.
- `part1.tex`, `part2.tex`: two files with content which is copy-pasted into `master.tex` using `\input`

Typical commands for splitting documents are the following: <Kommandozeilen sind nicht klar, sollten besser erläutert werden>.

```
%%% master.tex file:

[...]

\begin{document}
some text
\input{part1.tex}
more text
\input{part2.tex}
some more text
\end{document}
```

4.9 Clipping of PDF Page

Clipping of PDF pages is done via `trim=<left> <top> <right> <bottom>` (with arbitrary units, e. g. mm, pt) and (mandatory!) `clip`.
<nicht klar, was hier passiert>.
<NOTE: if a PDF/A-1b document is required, the external PDF needs to be PDF/A-1b compliant itself. This can be created from other files (e.g. MS WORD, MS VISIO,etc) by using the 'print as' function and choosing in the PDF-properties the setting to create a PDF/A-1b-compatible PDF>.

4.10 Bibliography with JabRef and Citations

4.10.1 Extenal Bibliography with JabRef

External sources (books, papers, websites, etc.) are stored in a separate file `literatur.bib`. bib-files can be created using JabRef (jabref.sourceforge.net/), online and versions for local installation available). Example `literatur.bib`:

```
...
@ELECTRONIC{Q1E,%
author = {{International Conference on Harmonization}},%
shorthand = {{International Conference on Harmonization (2004)}},%
month = {6},%
year = {2004},%
title = {Guidance for Industry: Q1E Evaluation of Stability Data.},%
url = {http://www.fda.gov/RegulatoryInformation/Guidances/ucm128092.htm},%
urldate = {2014-06-28},%
owner = {Jane Doe},%
}%
@BOOK{Krishnamoorthy,%
title = {Statistical Tolerance Regions},%
shorthand = {Statistical Tolerance Regions (2009)}%
publisher = {Wiley},%
```

Figure 1: a picture on pd

Table 1: a table on pdf

a small	tabular
for demonstration	purposes

Figure 3: example including pdf (colored box for demonstration purposes)

```
year = {2009},%
author = {Kalimuthu Krishnamoorthy and Thomas Mathew},%
isbn = {9780470380260},%
owner = {Jane Doe},%
timestamp = {2014-05-13},%
totalpages = {461}%
}
...
```

The bibliography entries are sorted during the compilation of the bibliography. This has to be done separately and in addition to the text compilation (e. g. in TeXstudio key `F8` or `F11`for bibliography and key `F6` for text compilation). Tool for generating BibTeX entries, e. g. http://lead.to/amazon/en/ (uses Amazon data base) and http://literatur-generator.de/ (uses google). It doesn't matter if the bib-file contains more bibliography entries than the tex-file; only cited sources are listed in the bibliography.
Test: Amazon.com Note: The configuration for TeXstudio has to be changed that biber is used for the bibliography (see figure 4).

4.10.2 Citations

All citations use the unique key for a bibliographical entry, e. g. `Q1E` or `Krishnamoorthy`.using `\cite{Q1E}`: International Conference on Harmonization (2004)

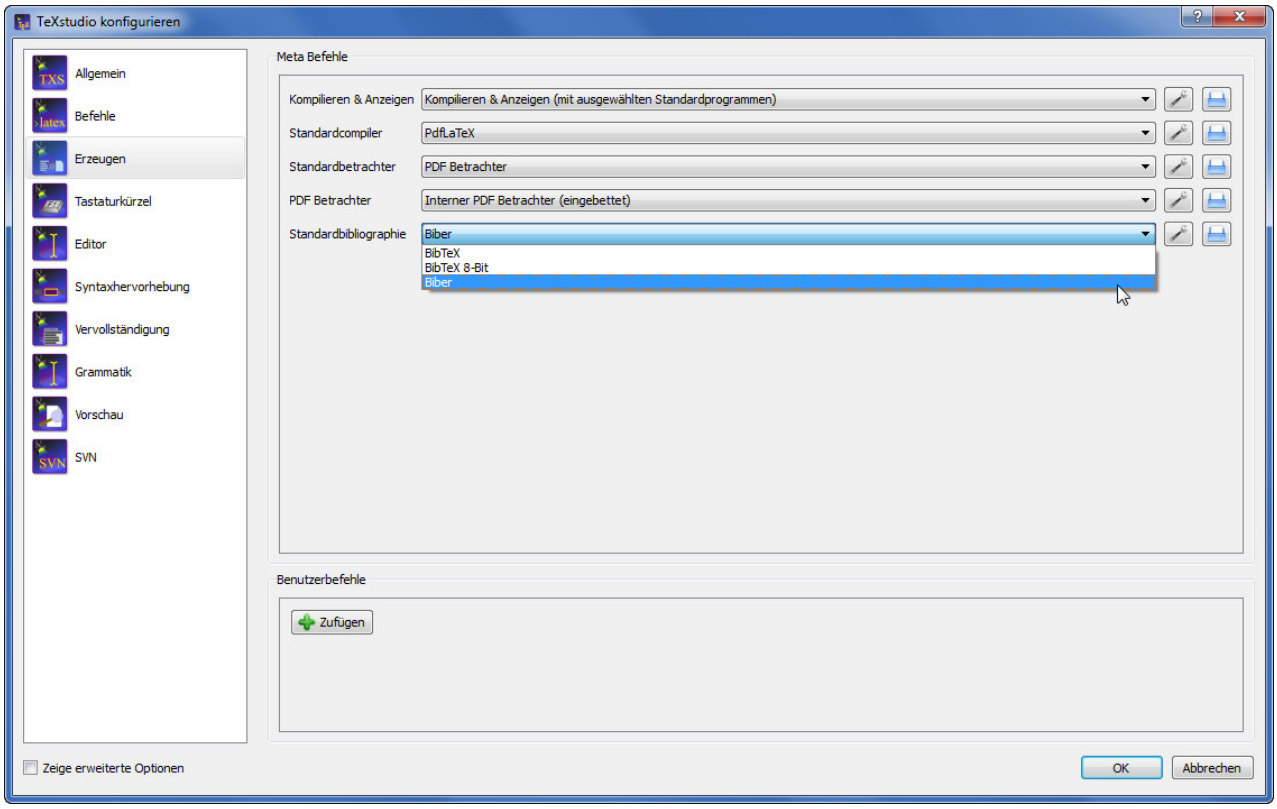


Figure 4: Configuration for biber in TeXstudio

using `\cite[123]{Q1E}`: International Conference on Harmonization (2004), p. 123
using `\cite[123--125]{Q1E}`: International Conference on Harmonization (2004), pp. 123–125
using `\autocite{Q1E}`: (International Conference on Harmonization (2004))
using `text\footcite{Q1E}`: text[2]
using `\fullcite{Q1E}`: **International Conference on Harmonization (2004):** *Guidance for Industry: Q1E Evaluation of Stability Data.* URL: `http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073380.pdf` (visited on 06/28/2014)
Print all bibliographic entries cited in the text (independent of the entries in the bibliography file) with a numbered section:`\printbibliography`

[2] International Conference on Harmonization (2004).

References

International Conference on Harmonization (2004): *Guidance for Industry: Q1E Evaluation of Stability Data.* URL: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073380.pdf (visited on 06/28/2014).

4.10.3 In-text Use of Universal Resource Locators (URLs)

A Universal Resource Locator URL (which is the path to a certain file on the World Wide Web) can be included directly into the text on two different ways:

- by including the instruction `\url{URL}` Inhalt...
- with different descriptive text or url: `\href{URL}{text}`

Examples:`\url{http://ctan.org}` http://ctan.org
`\href{http://ctan.org}{ctan.org}` ctan.org

4.11 Creating a 'List Abbreviations, Acronyms and Symbols'

Abbreviations, acronyms and symbols that are used within the text need to be pre-defined in the preamble <where exactly?>, e. g.

```
\newglossaryentry{abb:eCTD}
    {name={eCTD},
    description={electronic Common Technical Document}}
```

After an abbreviation has been defined in the preamble, it can be used in the following text, e.g. using `\gls{abb:eCTD}`: eCTD
using `\gls{abb:CTD}`: CTD
using `\gls{abb:ICH}`: ICH
Used abbreviations, their explanation and page number(s) where they are used within the text are automatically listed if a glossary is printed:

```
\printnoidxglossary[title={List of Abbreviations}]
```

ifferentiation etween eparate List of bbrevia- ons' and Glossary' oreseen?

4.12 Setting Intra-Text Cross-References

Define unique label using

```
\label{sec:secdescription}
```

Label names do not work with special characters (except ':') or blanks.
Labels can be used everywhere (sections, paragraphs, figures, tables,...)

4.13 Useful Commands to Facilitate Collaboration With Co-Authors

4.13.1 Annotations in a tex-file

Annotations in the TeX file may be used for explanatory purposes – or as a reminder that specific information is still missing and needs to be included into the document. Annotations only appear in the TEX file, the are not converted into the PDF.
Symbol for annotations in the TEX file is `%` (everything in a line after a % is ignored).

4.13.2 Commenting in TEX files

A practical tool during the creation of a document is the inclusion of comments into the TEX files. This may serve as reminders, remaining action items or comments required during document review.
Comments can be included with `\todo{text}` for comments in the margin and `[inline]{text}` for comments in the text. Do not use `\todo`-comments within other

comment n the mar- in

a green inline comment

```
\todo{a comment in the margin}
\todo[inline, color=green]{a green inline comment}
```

If at least one `\todo`-command is present in the text the 'list of todonotes' will be printed using `\listoftodos`.

4.13.3 How to Create PDF/A-1b Files

escription o convert rbitrary raphs and ocuments e.g. pow- rpoint lides) into df/a doc- ments us- ng printer unctional- y

ther use- ul things or pdf/a ompatibil- y using crobat rofes- ional

n BB: Diesen bschnitt itte auf Korrektheit rüfen

5 Organization of Different Types of Files created by LATEX

LATEX uses a number of file types. For details, reference is made to relevant LATEX publications, e. g. Frank Mittelbach, Michel Goossens, Der LaTeX Begleiter. Some basic information about the different types of files, however, is required, in order to correctly organize these files when creating documents that are planned to be organized in an eCTD file and folder structure.
<hier: Auszug aus Tab. 1.1 von Mittelbach/Goossens einfügen>.
With reference to different "texwelt" discussions in this field,the question on how to handle the auxiliary files that are created when creating TEX and the corresponding PDF files, shall be addressed in this subsection. In summary, and in order to enable a correct and smooth PDF creation, it can be concluded that the auxiliary files are recommended to be listed together with the TEX files in one and the same folder and or sub-folder.
For further information, please find the respective discussions listed below:
http://texwelt.de/wissen/fragen/2530/was-sind-hilfsdateien-und-wo-finde-ich-diese

http://texwelt.de/wissen/fragen/5501/wie-kann-ich-mit-latex-dateien-hilfsdateien-ordnern-ordnung-halten http://tex.stackexchange.com/a/11125 http://tex.stackexchange.com/a/24787
In this respect, it is recommended to created sub-folders for each CTD-related submission-file as given in Figure 5.

n BJ: ubfolder nit CTD Example- Datei rzeugen nd als creenshot- igure ein- inden

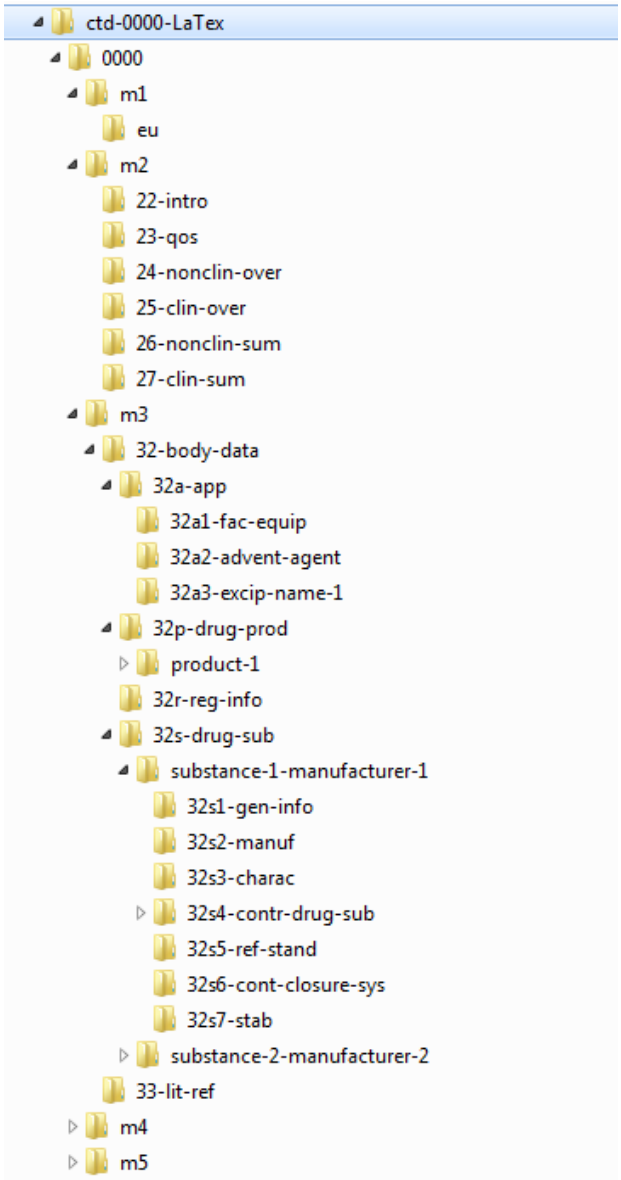
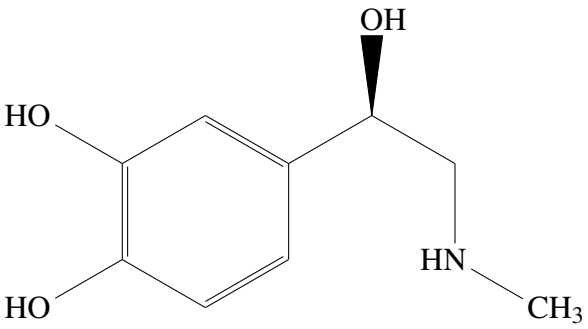


Figure 5: Organizing of LaTeX Files in an eCTD File and Folder Structure

6 Extra Packages Which are recommended, but which are not included into PharmRep

6.1 Structural Formula of Chemicals with Package chemfig

To draw molecules and reaction schemes different packages can be used, e. g. with package chemfig something like that:



6.2 Graphs and Plots with Package TikZ

One of the most powerful packages to create graphs and plots is TikZ which can be used for nearly every kind of graphical representation, e. g. flowcharts, mathematical graphs, 3D visualization, etc. See http://www.texample.net/tikz/examples/ for a gallery of examples.

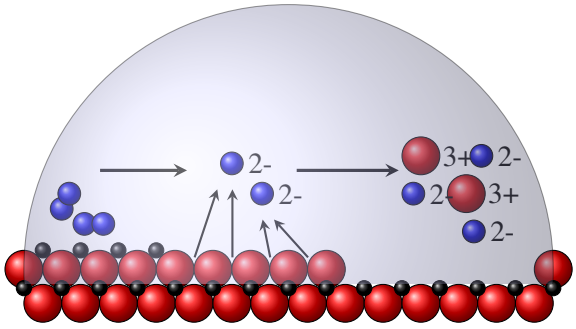


Figure 6: TikZ example graph rusting iron, http://www.texample.net/tikz/examples/rusting-iron/

List of Abbreviations

CTD Common Technical Document

eCTD electronic Common Technical Document

ICH International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

URL Universal Resource Locator

A Short List of Common Commands

Table generated by Excel2LaTeX from sheet 'Tabelle1'

Appendix Numerierung A'/ A.1. tc. und n ToC bernehmen

Command	Result
\section{⟨*title*⟩}	starts a new section
\subsection{⟨*title*⟩}	starts a new subsection
\subsubsection{⟨*title*⟩}	starts a new subsubsection
\paragraph{⟨*title*⟩}	starts a new paragraph
\label{⟨*key*⟩}	defines label (must be unique throughout document)
\ref{⟨*key*⟩}	references label
\autoref{⟨*key*⟩}	references label and type of reference
\pageref{⟨*key*⟩}	references pagenumber of label
\autopageref{⟨*key*⟩}	references pagenumber of label and type of reference
\textbf{⟨*text*⟩}	bold text
\textit{⟨*text*⟩}	italic text
\small{⟨*text*⟩}	small text
\footnotesize{⟨*text*⟩}	footnotesize text
\%	percent (%)
\&	ampersand (&)
\url{⟨*URL*⟩}	url
\href{⟨*URL*⟩}{⟨*text*⟩}	text instead of url
\landscape	page orientation landscape
\portrait	page orientation portrait
\captionof{table}{⟨*title*⟩}	caption of table
\captionof{figure}{⟨*title*⟩}	caption of figure
\begin{tabular}	simple table
\begin{tabularx}	table with automatic width and optional pagebreaks
\begin{figure}	figure environment (floating)
\includegraphics{⟨*filename*⟩}	include 'figure' (format png, jpg or pdf)
\begin{itemize}	bullet point list
\begin{enumerate}	numbered list
\item text	item in list
\begin{description}	description list
\item[label] text	item with label (description list only)
\input{⟨*filename.tex*⟩}	copy-paste contents of tex-file
\todo{⟨*text*⟩}	comment or todo
\cite{⟨*bibkey*⟩}	citation of source stored with 'bibkey' (in 'filename'.bib)
\newglossaryentry{⟨*glskey*⟩}{⟨...⟩}{⟨...⟩}	define new glossary entry (at the beginning of the TEX file)
\gls{⟨*glskey*⟩}	use abbreviation stored with 'glskey'