

pharmrep – A L^AT_EX package for Medical Reports an MS: Package Titel muss noch harmonisiert werden s.a. Manual-Part^{*}

Barbara Bredner[†] Barbara Jentges[‡] Martin Sievers[§]

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Abstract

The class `pharmrep` provides a set of tools for authors of submission-relevant documents in a consistent way. The package has an extended set of configuration options to make it possible to

`pharmrep` helps users to write standardised scientific pdf documents in professional layout that have to be sent (electronically) to authorities. The class setups a layout (page layout, fonts etc.) and different properties of the resulting output file (bookmarks, hyperlinks, tagging, fast web view etc.) to match given requirements. In addition a template can be used as a starting point for new documents.

1 Installation

TODO:text for installation needs to be included here
include general description about the package here.

1.1 Specific Packages included into PharmRep

The PharmRep package includes a number of other packages that facilitate editing scientific texts and guarantee a level of harmonization throughout the complete submission-relevant documentation.

1.1.1 siunitx – A Comprehensive (SI) Units Package

package `siunitx`

“Physical quantities have both numbers and units, and each physical quantity should be expressed as the product of a number and a unit. Typesetting physical quantities requires care to ensure that the combined mathematical meaning of the number-unit combination is clear. In particular, the SI units system (International System of Units) lays down a consistent set of units with rules on how these are to be used. However, different countries and publishers have differing conventions on the exact appearance of numbers (and units). The ‘siunitx’ package provides a set of tools for authors to typeset quantities in a consistent way. The package has an extended set of configuration options which make it possible to follow varying typographic conventions with the same input syntax. The package includes automated processing of numbers and units, and the ability to control tabular alignment of numbers.”

In addition, numbers are automatically formatted.

Example: TODO:description of siunitx and examples

^{*}This file describes version v2.0, last revised 2016/04/26.

[†]Email: bredner@bb-sbl.de

[‡]Email: barbara.jentges@phact.ch

[§]Email: martin.sievers@schoenerpublizieren.de

1.1.2 hyperxmp – Creating PDF 1b Format

Hier kurze Beschreibung zum Package einfügen.

2 Dealing with Typical Problems by using PharmRep

One typical problem that may occur when using Latex respectively the PharmRep package may occur, when the PDF that was successfully compiled remains opened when further editing the tex-file. With the PDF opened, the compilation process cannot be performed and the following error message appears: PharmRepStyle.tex: Fehler; Zeile 30: I can't write on file 'PharmRepManual23.pdf'. Once the PDF is closed, compilation can be performed without any problems.

3 User Feedback and Reporting Bugs

Feedback on PharmRep is always welcome and will help us in improving the package and correct any problems. Is there an 'official' channel for reporting problems?

4 Thanks

We would like to express our particular thanks to Martin Sievers, who supported the development of the PharmRep with valuable input and tested the beta version, including identifying any incorrect output, bad documentation and spelling mistakes in the documentation. His specific focus was the support in solutions on how to create PDF/A-1b compatible files with the PharmRep package. BJ an MS: Da Du, Martin, jetzt als Autor dabei ist, koennte dieses Kapitel geloescht werden, oder?

5 zu behebende Probleme

- Einbindung von externen Grafiken bzw. Tabellen macht Probleme, siehe Test-Page.pdf (in der Praxis: Einbindung von Plots, HPLC-Chromatogrammen, etc.)
- Excel2Latex bei umfangreichen Tabellen mit Text ber mehrere Zeilen ergibt Probleme

6 Implementation

```
1 \class
2 \RequirePackage{kvoptions}
3 \SetupKeyvalOptions {
4   family = pharmrep,%
5   prefix = pharmrep@,%
6   setkeys = \kvsetkeys,%
7 }
8
9 \DeclareStringOption[utf8]{inputenc}
10 \DeclareStringOption[sRGB_IEC61966-2-1_black_scaled.icc]{colorprofile}
11 \DeclareBoolOption[true]{pdfa}
12 \DeclareBoolOption[false]{letter}
13 \DeclareVoidOption{US}{\pharmrep@lettertrue}
14 \ProcessKeyvalOptions*\relax
15 \PassOptionsToPackage{\pharmrep@inputenc}{inputenc}
16 \RequirePackage{etoolbox}
17
18 \input glyptounicode.tex
19 \input glyptounicode-cmr.tex
```

For pdf 1.4 output and xml metadata

```

20 \pdfgentounicode=1
21 \pdfobjcompresslevel=0
22 \pdfinclusioncopyfonts=1

Load KOMA documentclass scrartcl with required options
23 \ifpharmrep@letter
24   \PassOptionsToPackage{paper=letter,pagesize}{typearea}
25 \fi%
26 \LoadClass[parskip=half,fontsize=12bp,%
27   bibliography=totoc,listof=totoc,%
28   numbers=noendperiod]{scrartcl}

pdf 1b format
29 \RequirePackage{hyperxmp}

Input encoding
30 \RequirePackage{inputenc}

Font encoding
31 \RequirePackage[T1]{fontenc}
32   \hyphenchar\font=\string"7F

Language definition, typesetting and hyphenation
33 \RequirePackage[english]{babel}
34   \addto{\captionenglish}{\renewcommand*{\contentsname}{Table of Contents}}
35   \addto{\extrasenglish}{\def\figureautorefname{figure}}
36   \addto{\extrasenglish}{\def\tableautorefname{table}}
37

Font evtl. TeXGyre einbinden, z.B. ber eine Option
38 \RequirePackage{mathptmx} % times font
39 \RequirePackage{couriers} % monospace fonts
40 \RequirePackage[scaled=0.91]{helvet} % for sans serif fonts (\textsf{...} or \sffamily)
41 \RequirePackage{pifont} % symbols
42 \RequirePackage[full]{textcomp} % symbols
43 \RequirePackage{upquote}
44 \RequirePackage{microtype}% microtypographic extensions
45 \RequirePackage{xspace} % automatic spacing with own commands

Graphic extensions
46 \RequirePackage{graphicx}
47 \RequirePackage{grffile}

Color profile
48 \RequirePackage[rgb]{xcolor}
49 \ifpharmrep@pdfa
50   \IfFileExists{\pharmrep@colorprofile}
51     {\immediate\pdfobj stream attr{/N 3} file{\pharmrep@colorprofile}
52       \pdfcatalog{%
53         /OutputIntents [ <<
54           /Type /OutputIntent
55           /S/GTS_PDFA1
56           /DestOutputProfile \the\pdflastobj\space 0 R
57           /OutputConditionIdentifier (\pharmrep@colorprofile)
58           /Info(\pharmrep@colorprofile)
59         >> ]
60       }{\ClassError{pharmrep}{Color profile \pharmrep@colorprofile not found!}{Please check y
61 \else
62   \ClassInfo{pharmrep}{PDF/A support is disabled!}
63 \fi%

SI number formatting
64 \RequirePackage{siunitx}

Page layout, header and footer
65 \RequirePackage{geometry}
66   \geometry{textheight=600pt,head=50pt,left=60pt,right=60pt,includeheadfoot}
67   \setlength{\footheight}{38pt}
68 \RequirePackage[section]{placeins}
69 \RequirePackage{lastpage}

```

```

70 \RequirePackage{totcount}
71   \regtotcounter{figure}
72   \regtotcounter{table}
73 \IfFileExists{scrlayer-scrpage.sty}
74   {\RequirePackage[headsepline,footsepline]{scrlayer-scrpage}}%
75   {\RequirePackage[headsepline,footsepline]{scrpage2}}%
76   \setkomafont{pageheadfoot}{\small}
77   \setkomafont{pagenumber}{\small}
78   \clearscrheadfoot
79   \ihead{\begin{minipage}[b][16mm]{0.48\textwidth}Applicant: \@Applicant\\Drug Product:
80   \@DrugProduct\hspace{0pt}\end{minipage}}
81   \ohead{\begin{minipage}[b][16mm]{0.48\textwidth}\raggedleft\@PharmRepTitle\hspace{0pt}\end{minipage}}
82   \ifoot{\begin{minipage}[t][10mm]{0.3\textwidth}\vspace{0pt}\@eCTDno\end{minipage}}
83   \cfoot{\begin{minipage}[t][10mm]{0.3\textwidth}\vspace{0pt}\centering\jobname{}\end{minipage}}
84   \ofoot{\begin{minipage}[t][10mm]{0.3\textwidth}\vspace{0pt}\flushright\pagemark/\upshape\@PharmRepTitle}
85   \pagestyle{scrheadings}

Portrait- and Landscape-Format
86 \newcommand{\landscapeformat}{%
87   \clearpage%
88   \pdfpagewidth=\paperheight%
89   \pdfpageheight=\paperwidth%
90   \newgeometry{textwidth=600pt,left=50pt,top=60pt,bottom=60pt,includeheadfoot}}
91 \newcommand{\portraitformat}{%
92   \clearpage%
93   \pdfpagewidth=\paperwidth%
94   \pdfpageheight=\paperheight%
95   \restoregeometry}

Tables and figures
96 \renewcommand{\fps@table}{htbp}
97 \renewcommand{\fps@figure}{htbp}
98 \RequirePackage[justification=RaggedRight,singlelinecheck=false,labelfont=bf,hypcap=false]{caption}
99 \RequirePackage{rotating}
100 \RequirePackage{booktabs}
101 \RequirePackage{multirow}
102 \RequirePackage{ltabx}

Lists
103 \RequirePackage{enumitem}
104   \setlist[1]{parsep=4pt}

Notes and comments
105 \RequirePackage[backgroundcolor=orange!40,%
106   linecolor=black!20!orange,%
107   textsize=footnotesize,%
108   colorinlistoftodos]{todonotes}
109   \reversemarginpar
110   \setlength{\marginparwidth}{20mm}
111
112 \RequirePackage[autostyle]{csquotes}

Bibliography
113 \RequirePackage[backend=biber,%
114   style=authoryear,%
115   ]{biblatex}
116 \RequirePackage{xpatch}% author bold
117   \xpretobibmacro{author}{\mkbibbold\bgroup}{-}{-}
118   \xapptobibmacro{author}{\egroup}{-}{-}
119   \xpretobibmacro{bbx:editor}{\mkbibbold\bgroup}{-}{-}
120   \xapptobibmacro{bbx:editor}{\egroup}{-}{-}
121   \renewcommand*{\labelnamepunct}{\mkbibbold{\addcolon\space}}
122 \AtEndPreamble{%
123   \ifdefempty{\@BibFileName}{%
124     \ClassError{pharmrep}{You have to provide a bib file!}{Please use the macro
125     \string\BibFileName{<MYFILE.bib> in the preamble}}%
126     {\addbibresource{\@BibFileName}}%

```



```

187 \clearpage
188 \ifnum\totvalue{table}>0
189     \listoftables
190     \clearpage
191 \fi%
192 \ifnum\totvalue{figure}>0
193     \listoffigures
194     \clearpage
195 \fi%
196 \cleardoubleemptypage
197 }%
198 </class>

```