"This code is a complete hack, may or may not work, etc.." The Challenges of Validating R

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Whilst *R* usage has grown hugely in recent years the use of *R* in regulated industries, such as the pharmaceutical industry, is still limited. The *R* core team has provided documentation as guidance for the use of *R* in such industries [1], though *R* still comes with "absolutely no warranty" and there is no formal documentation related to the many additional packages available on CRAN. To comply with FDA guidelines [2] these add on packages must be validated along with core and recommended packages. Mango was first asked to validate a version of *R* in 2009. The growth of *R* and the number of companies wishing to validate *R* has led to a steady stream of *R* validations at Mango in recent months.

In this talk we will consider some of the challenges that we have faced in validating *R* packages and discuss some of the tools that we have developed to aid the process. We will discuss the challenge of creating large amounts of documentation for *R* packages and how **knitr** can be incorporated into an automated process to do this.

We will also talk about two new packages developed for code analysis, **testCoverage** and **functionMap**. The **testCoverage** package has been developed to determine how much of the code in a given R package is covered by associated unit tests, while the **functionMap** package has been developed in order to explore the functional relationship within a package and its dependencies.

References

[1] The R Foundation (2013). R: Regulatory Compliance and Validation Issues A Guidance Document for the Use of R in Regulated Clinical Trial Environments, http://www.r-project.org/doc/R-FDA.pdf.

[2] U.S. Food and Drug Administration (2013). 21 CFR Part 11: Electronic Records, Electronic Signatures, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1