Development of Rshiny applications for the biopharmaceutical industry

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Context

The drug development and production processes generally requires a tremendous amount of statistical supports, both in the clinical and the non-clinical areas. In some cases, this support is very specific and require the full attention of a statistician. In other cases, the support is required for very repetitive analyses, for which the statistical methodology to be applied is well-defined. In the latter case, the development of applications to automate the analysis may prove itself the best solution to optimize time and resource allocation.
R/shiny offers a convenient tool for the development of tailored applications. In this session, example of such applications, developed for clinical and non-clinical purposes will be presented with their objectives.
In the process of developing an application, the question of validation will come up, the sooner the better

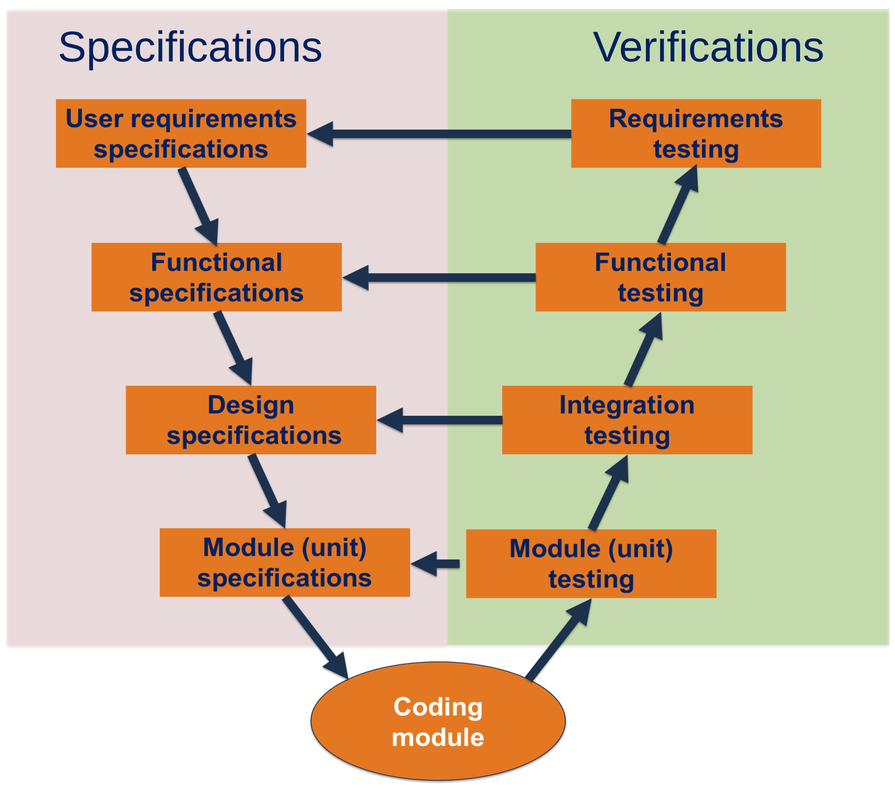
What is software Validation ?

FDA considers software validation to be "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."

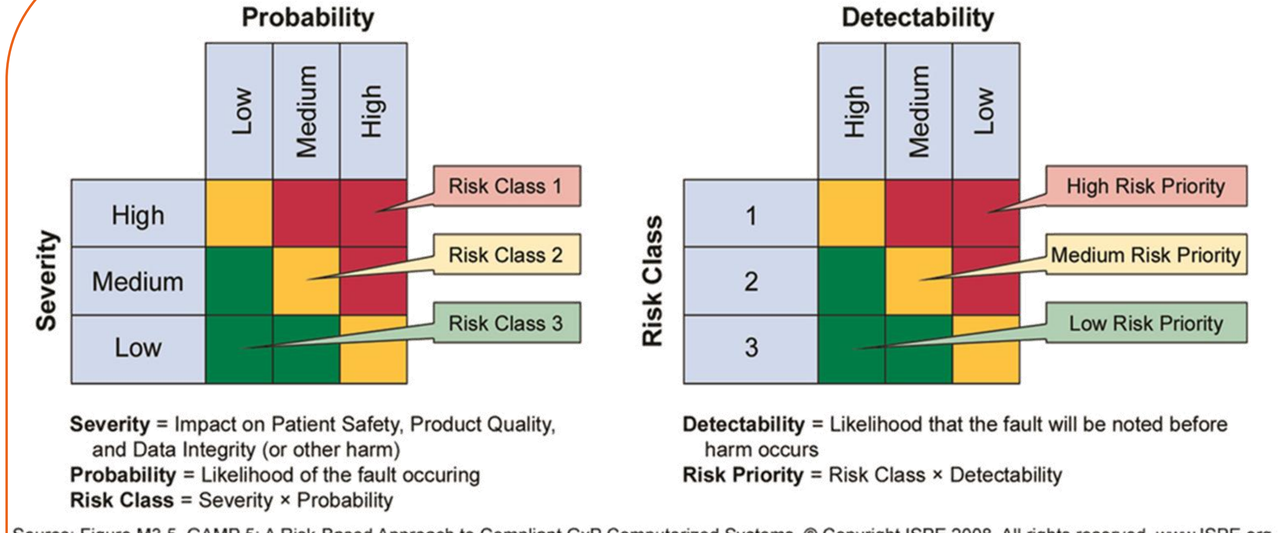
When is validation needed ?

- **Validation of software is required in regulated (GxP) environments.**
- **Validation is required for projects concerned by 21 CFR part 11**
- **If patient safety is concerned, validation might be needed**

Agile model:
- **Break the software down into manageable parts that can be delivered earlier to the customer.**
- **Ability to respond to the changing requirements of the project**



V-model:
- **Each phase of development proceeds in**
- **order without any overlapping.**
- **Very rigid and not flexible**



Source: Figure M3.5, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

The extent of the testing phase is defined by the risk analysis

FYI

- **Deaths of cancer patients were due to overdoses of radiation resulting from a race condition between concurrent tasks in the Therac-25 software**
- **Death resulted from inadequate testing of the London Ambulance Service software**
- **Errors in medical software have caused deaths. Details in B.W. Boehm, "Software and its Impact: A Quantitative Assessment," *Datamation,* 19(5), 48-59(1973).**
- **http://www.csl.sri.com/users/neumann/illustrativerisks.html#15**

Conclusion

The question of validation is ubiquitous in the (bio)pharmaceutical industry. It is required for the analytical methods, the manufacturing process and the automated actions. Therefore, for softwares