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# Валидация таблиц EXCEL

по GAMP 5®

# Аутсорсинг

GmpRussia предлагает валидировать Ваши таблицы Excel

Все шаги процесса валидации внесены в два документа:

## 1 - План валидации

- Стратегия валидации
- Спецификации и требования к ячейкам таблицы
- Анализ рисков
- Ответственность
- Критерии приемлемости

## 2 - Протокол / Отчет

- Проведение тестов
  - Правила проектирования
  - Безопасность
  - Форматы данных
  - Эксплуатация таблицы
- Заключение выполнения тестов
- Заключение валидации

# Аутсорсинг

Мы пишем все документы / тесты

Мы выполняем все тесты

Вам надо будет утвердить:

- План валидации
- Протокол / Тесы
- Отчет

# Нормы

Методика GmpRussia, создана с GAMP 5®, соблюдает:



GAMP 5  
A Risk-Based Approach to Compliant GxP Computerized Systems

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Appendix S3

## End User Applications Including Spreadsheets

### 1 Introduction

This appendix gives guidance on the use of end user applications such as spreadsheets or small databases in a GxP environment.

Application tools are available for creating a wide range of end user applications, including customized statistical analyses, the creation of local databases, data mining, and multivariate analysis. These may be used for GxP regulated activities, and they present particular compliance challenges.

End user applications tend to be among the most under-documented systems used in GxP environments, for the following reasons:

- users regard them as part of the desktop
- the ease with which applications can be built without much training
- the data processing power that they can have

The flexibility and power of the spreadsheet allows users to create tools that range from performing simple calculations to sophisticated analysis of a major clinical study. Special emphasis is placed on spreadsheets in this appendix because PC users may have the opportunity and ability to create a spreadsheet application, and may use them to process regulated data.

The level and rigor of specification and verification applied to end user applications should be based on risk, complexity, and novelty. This appendix provides guidance to help users determine the appropriate approach. While the examples given in this appendix are mainly spreadsheets, the same principles can be applied to other end user applications.

**GmpRussia является членом ISPE и валидирует таблицы для следующих компаний:**



**С другими клиентами GmpRussia можно ознакомиться тут:**  
**<https://www.gmprussia.com/mm-projects>**



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## Вопросы?

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