



Handbook of Investigation and Effective CAPA Systems, Second Edition

José Rodríguez-Pérez

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Understanding and improving the CAPA system as a whole is the focal point of this book, the only of its kind dealing exclusively with this critical system within highly regulated industries. Features include:

- Information about the importance of the CAPA system within the quality system for the medical products regulated industry.
- Fully updated with current versions of regulations (U.S. FDA, EU, ISO 13485, and so on), and a new section covers the regulatory expectation of customer complaint investigations.
- Investigation and CAPA elements of the 2015 revision of the ISO 9001 standard.
- New coverage on the investigation plan and the new U.S. FDA quality metric guidance, as well as a section discussing the tight relationship between CAPAs and FMEA.
- A new chapter fully devoted to human errors and human factors, and their impact in the investigation and CAPA system.
- Discussion of a dozen of the most common pitfalls commonly encountered in the investigation and CAPA world of regulated companies.
- An example of an investigation and CAPA expert certification program being used for many companies.
- Forms and examples of the different elements (investigation report, root causes checklist, human error investigation, CAPA plan, and so on) covered in the book. Fully usable forms are also included in the companion CD in Microsoft Word format.

While the first edition of this book was aimed solely at the FDA-regulated industry, the title of this second edition reflects the importance of the investigation/root cause analysis stage as the necessary preceding step of any effective corrective and preventive action system. Investigation and CAPA are concepts used in many sectors besides the FDA-regulated industry, such as: automotive, electronics, aerospace, telecommunications, process industry, and many more. This book will become an essential reference for those in these other industries.

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