

# Exception Handling and CAPA (RC-CAPA)



# Rescop

## RC-CAPA

### Objective

Manage and support:

- handling of exceptions, incl. deviations, complaints, audit findings, etc.
- registration and monitoring of corrective and preventive actions in accordance with GxP regulations.

### Main functionality

- Configurable workflows per exception type (deviation, complaint, audit finding, etc.), incl. steps like:
  - Initiation, incl. specification of affected product / process / object
  - Risk Assessment
  - Root Cause Investigation
  - Proposed Mitigation Actions (corrective and preventive)
  - Results of Mitigation Actions
  - Closure
- Content and document management
- Configurable roles and rights
- User interface depending on roles and rights
- Notifications and alerts (incl. escalation) by e-mail
- Integration with RC-Change possible for linking of actions to Change Requests
- Management Reporting

### Advantages

- GxP compliant exception handling and CAPA
- Centrally and readily retrievable exceptions and CAPAs
- Consistent exception handling and CAPA processes through standardization of approach, documentation and content
- Efficient review and approval through automated workflow
- Paperless compliance
- Traceability of all open and closed activities
- 21 CFR part 11 and Eudralex Annex 11 ready

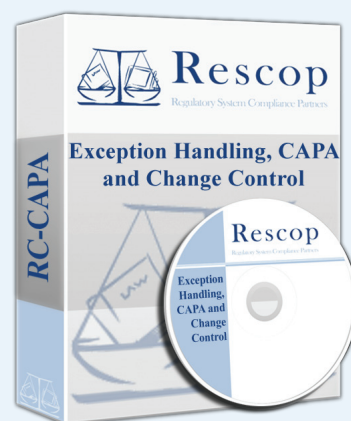
Victorialaan 15  
P.O.Box 3009  
5203 DA 's-Hertogenbosch  
The Netherlands

Phone +31(0)73 750 66 25

Fax +31(0)73 750 66 27

E-mail [info@rescop.com](mailto:info@rescop.com)

Website [www.rescop.com](http://www.rescop.com)



Rescop also offers other innovative software products:

- Document Management System (RC-DMS)
- Training Management System (RC-Training)
- Change Management System (RC-Change)
- System Management and Electronic Logbook (RC-Logbook)
- Validation, Qualification and Commissioning (RC-SDLC)
- Automation Compliance Management Suite (RC-ACMS)

