



# **BIOVIA QUMAS COMPLAINT PROCESS ENTERPRISE PACKAGE**

Datasheet



BIOVIA Services offers a number of **Packaged Solutions** providing pre-defined and pre-tested configurations of Document content management or Process management for specific, common industry problems. This Package addresses the business process management requirements of a Complaint process. The pre-defined configuration supports the electronic capture, management and reporting of Complaint occurrences, root cause analysis and follow-up CAPAs, as necessary.

### PACKAGE FEATURES

The Complaint Process Package combines the BIOVIA QUMAS EQMS application with a pre-defined configuration designed according to current best and common industry practices to manage Complaints in highly regulated industries.

This package contains advanced, out-of-the-box business process management functionality including the following features:

- **Data Dictionary**
- **Configurable Forms Builder**
- **Business Rules Engine**
- **Workflow**
- **Reporting**
- **Audit Trails**
- **Messaging**
- **Role-based Security / Permissions**
- **21 CFR Part 11 Electronic Signatures**
- **Integrated with QUMAS EDMS**

This package comes complete with the following pre-defined configurations and professional services:

- **EQMS configuration, designed specifically for Complaint Management, including:**
  - Workflow of tasks from Initiation through Supervisor Approval, Complaint Investigation, Complaint Response and Closeout
  - Appropriate user selection from pre-defined roles per task
  - Pages of pre-defined mandatory and optional fields to Ocapture the information, analysis and decisions
  - Dynamic forms with inline help that guide users to provide the information needed
- **Documentation**
  - Design Document detailing the pre-defined configuration
  - Client-specific Picklist values document (to be filled in by client and returned to BIOVIA for inclusion in configuration prior to installation)
  - Validation Pack: IQ, PQ, Functional Specification, Design Specification, and Trace Matrix (OQ not required because this Package contains a pre-defined configuration)
  - End-user training course (PDF Guide)

- System Access Plan (to be filled in by client and returned to BIOVIA for inclusion)
- **Professional Services including full Package installation, delivery of End-user training and Train-the-Trainer training**

### Complaint Overview

A complaint process is initiated following receipt of a complaint. It captures the key details of the complainant and the problem either with product or documentation to be routed for analysis. A decision can be made and recorded on the need to return samples. During analysis, further information / investigation can be sought before a response is defined including whether a CAPA is required. See Figure 1 for an example of a complaint process.

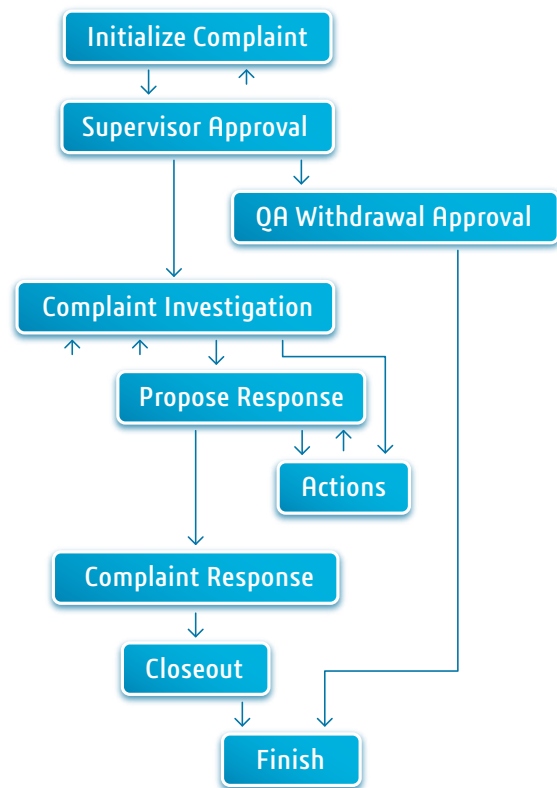


Figure 1. Example of a Complaint Process

## PACKAGE BENEFITS

The Complaint Process Package design enables authorized users to create and contribute to electronic Complaint forms to document the investigation, report and propose resolution actions, and manage the review and approval with 21 CFR Part 11 compliant Electronic Signatures.

The execution of actions is automatically monitored and routed to QA for approval before closure.

All actions are captured in the audit trail. Benefits also include:

- **Availability** - Central common repository for all instances
- **Security** - Forms don't get 'lost in the mail'
- **Legibility** - Electronic rather than hand written forms
- **Accessibility** - Ability to search for trends, previous occurrences, etc.
- **Consistency** - Single repeatable process, generation of consistent output
- **Accountability** - 21 CFR part 11 compliant signatures and audit trail, reports and analysis possible

## Additional Options

In addition to the out-of-the-box elements of this package, clients have the option to purchase further options such as:

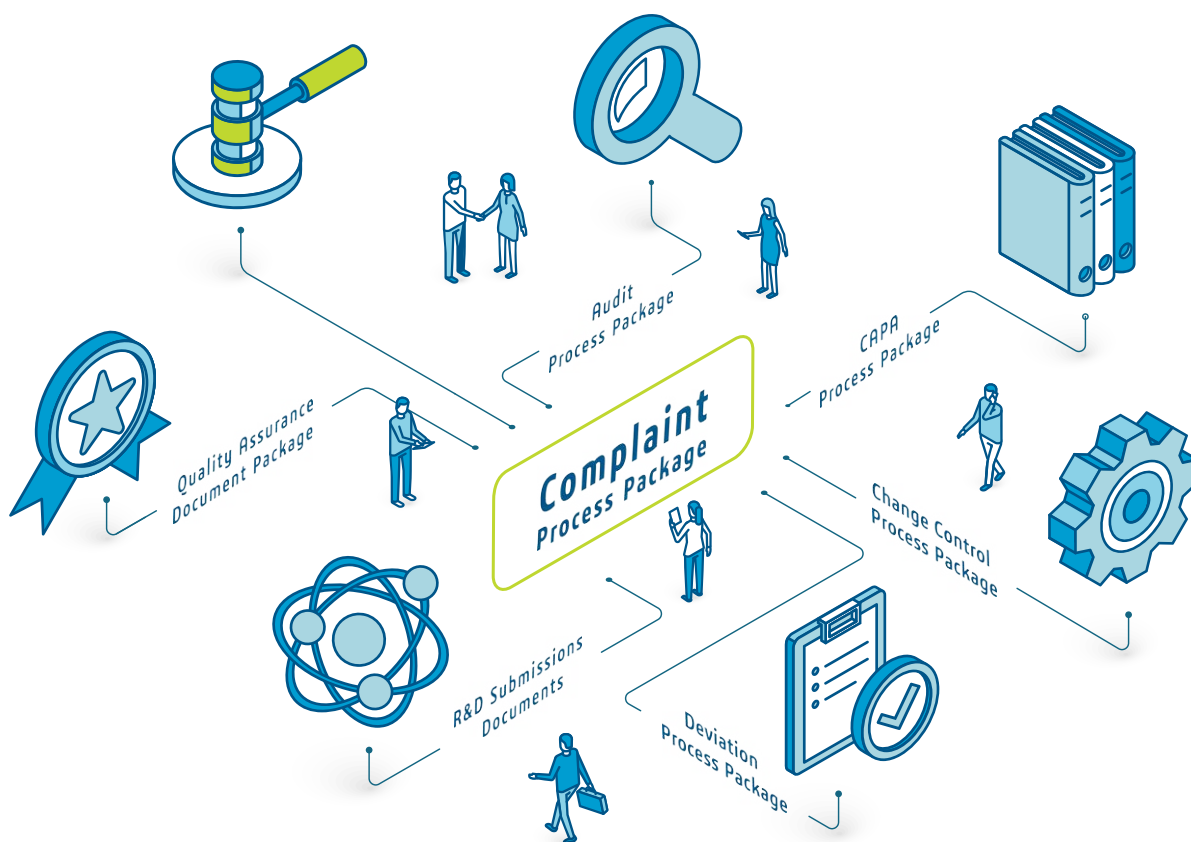
- Additional training days (End User and/or System Administrator)

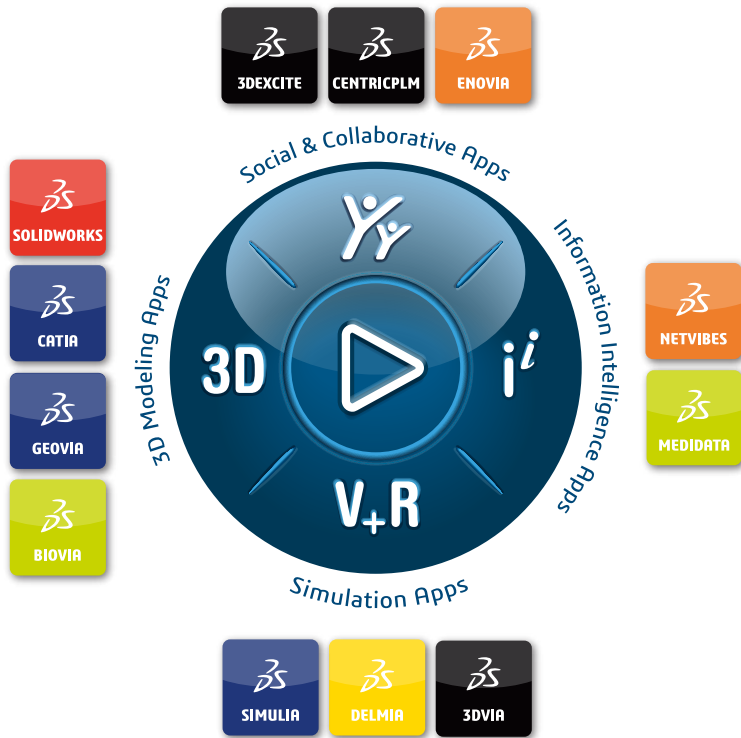
- Additional specific configuration (together with the required documentation, tests, and training)
- Integrations to other systems
- Custom Reports
- Dashboard Reporting tool

## SYSTEM REQUIREMENTS

- 2 servers (Database Server and Application Server) for 2 environments (test environment and production environment)
- Servers can either be physical or virtual hardware
- Detailed guidance on system specifications is available
- ScienceCloud option also available
- Servers can be shared for multiple BIOVIA Packages

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