



*Compliance Services,  
Setting New Global Standards*

# MyBlueLabel Datasheet

Learn more at [www.mybluelabel.com](http://www.mybluelabel.com)



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## **MyBlueLabel enables Life Science companies to reduce time-to-market**

We have the solution for Quality Management Systems within Pharma, Biotech, and Medtech Industries which opens up new opportunities for companies, stakeholders, Investors, with the purpose to optimize and maintain business critical tasks in go-to-market:

- Regulatory Approval
- ISO Certification
- Inspection / Audits
- Internal Quality Approval
- Prepare for Clinical Trials
- Supplier Management
- Internal Processes

## **Realized client benefits**

Our innovative leading Life Science clients have experienced significant benefits:

- Realized 30x faster implementation than other companies have experienced
- Discovered that the investment was a fraction of general systems
- Achieved fast track ISO, MDR and FDA compliance
- Obtained access to extensive industry knowledge
- Got access to a total "Compliance-as-a-Service" offering



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## MyBlueLabel uniqueness

Our solution is scalable to any size of business in Life Science:

- 18+ years of industry experience
- Pre-validated solution
- Digital, replicable, scalable cloud solution
- Complete Life Science Procedures and templates
- Flexible client adaption
- Business intelligence dashboard

## Selected service clients



## Selected system clients



## Collaborating with Extraordinary Organizations



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## MyBlueLabel Modules



### SPECIFICATION

List all requirements, specification and design, and link them together. This will allow alignment between business, R&D and QA and establish a common frame before building the products.



### RISK

Visualize the Risk Management File will help to communicate Risk to stakeholders. It will guide the organization with key business decisions and optimize resource allocation.



### TRACEABILITY

Traceability from specifications to final verification and validation is essential to communicate full design control. Linked critical to quality process into the matrix will identify the full product life cycle.



### INVENTORY

Inventory Management provides you with an overview of the technical landscape in the entire company.



### DOCUMENT

Document Management gives you and your team the timesaving possibility to create, edit and store all the documented information.



### PROJECT

Project Management helps you organize your project portfolio based on predefined project plan templates.



### CONFIGURATION

Configuration Management provides storage of the code and configuration of the inventories.



### INCIDENT

Incident Management serves as support to your hotline or helpdesk. Categorizing the incident helps trend on issues.



### CHANGE

Change Management gives you and your team the possibility to see all changes made during projects and operations.



### DEVIATION

Deviation Management provides the functionality to create, track, monitor, and close deviations for products and services.



### CAPA

CAPA Management provides you with the template to assign actions to individuals needing to close out Incidents or Deviations.



### KNOWLEDGE

Knowledge Management brings shared information and "lessons learned" into the organization with ease.



### TRAINING

Training Management provides the possibility to assign training based on organization and roles. It tracks the training completion progress throughout the company.



### TEST

Test Management gives you and your team the possibility to author, review, approve and execute testing activities electronically and instantly.



### COMPLAINT

Complaint Handling enables registration and tracking of customer complaints for timely communication to ensure customer satisfaction.

## MyBlueLabel Features

Features ensures fast and intelligent compliance:

- Electronic Signature (Part 11 / Annex 11)
- Business Intelligence Dashboards
- API External Integration

## MyBlueLabel Compliance

System validation support:

- ISO 9001:2015
- ISO 13485:2016
- GAMP5
- FDA 21 CFR Part 11
- EudraLex Annex 11



## MyBlueLabel Data Center Compliance

Microsoft Azure is certified to:

- ISO 9001:2015
- ISO/IEC 27001:2013
- CFR Title 21 Part 11
- GDP

### Company Details

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