QDMS | bimser

QDMS *for* PHARMA

A Regulation-Compliant, Validated Quality Management System

Tailored for the Pharmaceutical Industry

QDMS for Pharma is a validated digital quality management solution specifically designed for the pharmaceutical, biotechnology, and medical device industries. It is fully compliant with GxP requirements and enables organizations to manage their quality processes in a reliable, digital, and auditable way.

Built on the Bimser QDMS platform, QDMS for Pharma complies with international standards such as **ISO 13485, FDA 21 CFR Part 11**, and **GMP Annex 11**, ensuring secure, compliant, and traceable quality management processes.

Purpose of QDMS for Pharma

- Full compliance with regulatory and quality standards
- Always audit-ready infrastructure
- Prevention of manual errors and document complexity
- Traceability, measurability, and reliability across all processes

What Makes QDMS for Pharma Different

- Ready-to-use, validated, and approved document set
- Globally accepted validation assurance
- Fast implementation with cost-efficient project structure
- Integrated quality management with a comprehensive module scope

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REGULATORY COMPLIANCE, **AUDIT-READY AT ALL TIMES!**

Advantages in the Validation Process

- Significant time savings during implementation
- Ability to focus solely on organization-specific configurations during validation
- Complete compliance with a reliable and approved document set

Technical Features and Integrations

- QDMS Mobile App
- User-Friendly Interface
- Bulk Data Import
- Active Directory Integration
- Multi-Language Support
- API and Pre-Built Service Support
- Role-Based Authorization
- Advanced Reporting & Dashboards
- Email and SMS Notifications
- Delay Alerts and Reminder System

Why Choose QDMS for Pharma?

- ✔ Approved validation document set
- ✔ Comprehensive module coverage
- ✔ Compliance with global standards
- ✔ Strong local support backed by Bimser expertise
- ✔ Fast and cost-efficient implementation

Core Modules of QDMS for Pharma

- Document Management
- Corrective and Preventive Actions (CAPA)
- Action Management & Management Review
- External Customer Complaints
- Audit Management
- Equipment Management
- Incident Reporting
- Change Management
- Deviation Management
- Training Planning
- Supplier Evaluation

Business Value Delivered by QDMS for Pharma

Strategic Benefits

- Full readiness for audits
- Reduced compliance risks
- Increased quality and efficiency through digital transformation

Operational Benefits

- Up to **40% time savings**
- **50% reduction** in error rates
- Document integrity and full traceability
- **30% increase** in operational efficiency

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