Manage Your Quality at World Standards

QMex

BTS
business ▸ technology ▸ solution

http://www.bts-tr.com

QMex

What is *QMex* ?

QMex is a workflow management software, with a modular design to manage all quality processes electronically, integrated within its own modules and other electronic business applications, validated according to 21 CFR Part 11 requirements, it is accessed via web browsers and facilitates compliance with regulatory requirements.

QMex Benefits

Process analysis, consultancy and process improvement opportunities

Information traceability and security

Transparency and ease of auditing

Effortless reporting

Integration with other legacy systems (SAP, CRM, LIMS, etc.)

Full inter-modular integration

Fast document preparation, approval and distribution

Monitoring timely and correct realization of activities

Validation

Electronic records in compliance with 21 CFR Part 11 requirements

Paper and printing material saving

Time and Human Resources saving

Regulatory Requirements

FDA: American Food and Drug Administration

EMA: European Medicines Agency (European Union agency for the evaluation of medicinal products)

GMP: Good Manufacturing Practices

GDP: Good Documentation Practices

GLP: Good Laboratory Practices

ISO 9001:2008 Quality Management System

ISO 14001: Environmental Management System

ISO 222716: Good Manufacturing Practices for Cosmetics

ISO 27001: Information Security Management System

OHSAS 18001: Occupational Health and Safety Management System

ISO 22000: HACCP Food Safety Management System

BRC: Food Technical Standard

Q

QMex Modules

Document Management System

This module contains all organizational documents with multiple approval mechanisms, which undergo simultaneous review by different departments and are controlled distributed and revised following approval (Quality Manual, Site Master File, Quality Agreement, SOP, Procedure, Job Description, Form, List, Instruction, MBR, Test Method, Specifications, etc.). This module has following functions;

e-form where document cover information and other keywords required for reporting are stored
attaching the main document prepared in MS Word
attached documents associated with the main document
review and approval (electronic workflow & electronic approval)
converting the approved document to non-printable pdf format
converting the approved document to printable pdf format
(only by designated users)
distribution (by e-mail)
information on distribution points stored in the system
revision management (electronic workflow & electronic approval)
MBR (Master Batch Record) preparation
standard reports
MS excel reports
graphic reports
audit trail
automatic notification and tracking mechanisms
full integration with other QMex modules
delegation
mobile device support
online help

Our ISO 9001 Quality Certificate


SGS

Belge TR14/001962

BTS BİLİŞİM EĞİTİM VE DANIŞMANLIK HİZMETLERİ LTD. ŞTİ.

Fahrettin Kerim Gökay Caddesi Emek Apt. Kat:5 Daire:12 No:126, 34724, Feneryolu / Kadıköy – İstanbul, Türkiye

Yönetim Sistemi

ISO 9001:2008

İş uygulamaları yazılımları ve IT projeleri danışmanlık hizmetleri, yazılım ürünleri satışı; GMP, GLP, QMS eğitim, danışmanlık ve tedarikçi denetim hizmetleri

Bu belge, takip tetkiklerinin başarılı bir şekilde sonuçlanması koşuluyla 09/09/2014 tarihinden 08/09/2017 tarihine kadar geçerlidir.
Yeniden belgelendirme tetkikinin 25/08/2017 tarihinden önce gerçekleştirilmesi gerekmektedir.
Yayın 1 09/09/2014 tarihinden itibaren belgelidir

Onaylayan

UKAS MANAGEMENT SYSTEMS

0008

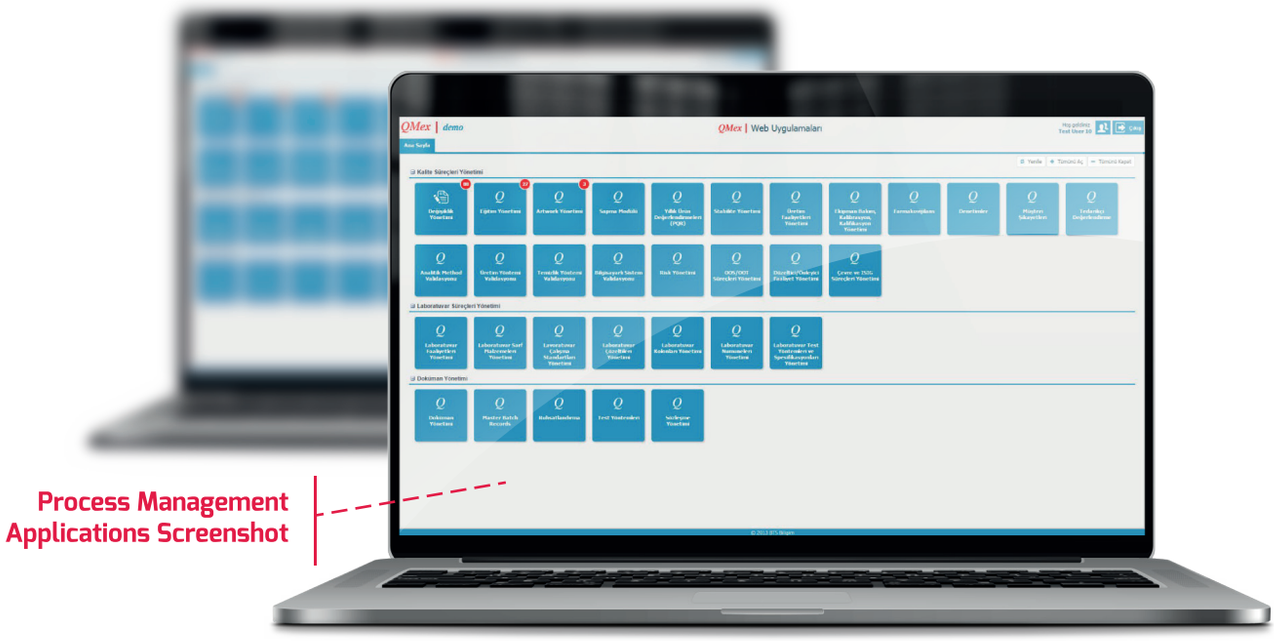
SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

Sayfa 1 / 1

SGS

QMex

Process Management Applications



1. Change Control
2. **Training Management**
3. Artwork Management
4. **Quality Nonconformance and Deviation Management**
5. Product Quality Review (PQR)
6. **Stability Management**
7. Production Activities Management
8. **Equipment Maintenance, Calibration. Qualification Management**
9. Pharmacovigilance
10. **Audits (Internal, External, Supplier)**
11. Customer Complaints Management
12. **Supplier Qualification**
13. Analytical Method Validation
14. **Production Method Validation**
15. Cleaning Method Validation
16. **Computerized Systems Validation**

All QMex modules contain following functions;

e-forms simultaneously filled and processed by different departments

document attachment (pdf, docx, xlsx, jpeg, png, etc.)

review and approval (electronic workflow & electronic approval)

distribution (by e-mail)

revision management (electronic workflow & electronic approval)

standard reports

MS excel reports

pdf reports

audit trail

automatic notification and tracking mechanisms

full integration with other QMex modules

integration with legacy software

delegation

mobile device support

online help

QMex

QMex Advantages

- Process consultancy, analysis and improvement services within the scope of the Project
- Easy adaptation to business processes and customizability
- 21 CFR Part 11 compliant validation set availability
- Support for validation processes
- Fast and traceable Help-Desk support
- Server based unlimited user license
- Easy implementation, training and user-friendly operation
- Easy access via web browser
- Cloud based alternative
- Multiple IT platform support
- Multiple language support
- Full integration between QMex modules
- Easy integration with other legacy systems
- Minimum IT resource and support requirement
- Environmental responsibility (paper and printing material saving)

Decreasing

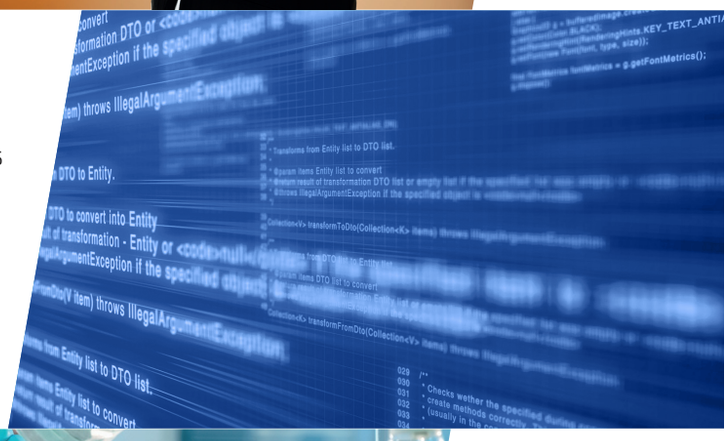
Product Deviation
Document Copying
Printed Documents
Archive Area
Personnel Quality Risk
Job Safety and Environmental Risk
Decision Making Time
Time

Increasing

Synchronized Quality Operations
Traceability
Transparency
Speed and Quality of Information Retrieval
Performance Reporting
System Quality
Operational Performance
Compliance with Regulatory Requirements
Corporate Reputation

Which Organizations Should Use *QMex*?

- Pharmaceutical Manufacturers, Importers, Sales and Marketing Companies
- **Biotechnology Manufacturers, Sales and Marketing Companies**
- Medical Device Manufacturers, Sales and Marketing Companies
- **Food Manufacturers, Distributors, Sales and Marketing Companies**
- Pharmaceutical Distribution Warehouses
- **Chemicals Manufacturers, Sales and Marketing Companies**
- Laboratories
- **Veterinary, Cosmetics and Dietary Supplement Manufacturers, Sales and Marketing Companies**
- Banks
- **General Manufacturing Companies**
- Public Organizations
- **High Tech Manufacturers, Sales and Marketing Companies**
- Automotive Manufacturers, Sales and Marketing Companies
- **Energy Producing Companies**
- All Organizations with a Quality System



Quality Management Processes Risk Assessment Chart

				RISK ASSESSMENT					RISK MITIGATION ACTIVITIES	
Item No	Item Description	GMP Critical Y/N	Business Critical Y/N	Risk Scenario	Risk Impact	Risk Probability	Probability of Risk Detection	Risk Level	Traditional Approach	Suggested Data Integrity Compliant Approach
1	Documentation is required for all different management systems applied within the organization. (GMP, ISO 9001, ISO 14001, BRC, ISO 27001, HACCP, etc.)	Y	Y	Preparing separate documents with similar contents for each management system.	Medium	High	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
2	Organizational Quality Management System documents must be reviewed and approved by respective department responsibles and be up to date.	Y	Y	Unapproved, not reviewed documents or old revisions of documents being in use	Medium	High	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
3	Organizational training plans must be in place. Deviations in training plans must be traceable. Trainings for newly recruited or newly appointed personnel must be completed in time and comprehensively. It must be ensured that documents prepared within Quality System scope such as SOP, Procedure, Instruction, etc. are put into effect after their trainings are completed. Effectiveness of all trainings must be evaluated and reported.	Y	Y	Inefficient planning and tracking of trainings. Improper/inadequate training for personnel with position changes. Quality System documents put into effect without completing required trainings. Inadequate tracking of absent participants' trainings. Missing training evaluation reports.	High	Medium	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
4	All deviations directly impacting product quality must be tracked effectively and root cause analysis and preventive actions must be realized.	Y	Y	Inefficient tracking of deviations in manual systems, repeating deviations in similar issues, deviations not being closed in time, presence of open deviations for products released for sale.	High	High	Medium	1	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
5	All changes directly impacting product quality must be tracked effectively and change actions must be completed by respective responsible persons.	Y	Y	Change Control forms being lost in interdepartmental approval process. Monetary loss arising from inefficient management of changes (e.g., new product) requiring great number of actions and simultaneous processing by different departments.	High	High	Medium	1	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
6	All CAPA actions and customer complaints tracked must be processed, closed and documented in time.	Y	Y	CAPA's are not tracked effectively. CAPA's are not closed in time. Customer complaints are not processed in time and company reputation suffers.	High	High	Medium	1	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
7	In order to determine product expiry dates, stability activities in compliance with ICH Q1, must be performed and reported comprehensively and in time.	Y	Y	Insufficient planning of stability studies, missing stability sample analysis, stability reports not presented in time	High	High	Medium	1	Employing increased number of personnel in operational workforce	Analysis for improvement of existing stability management processes, implementation and routine usage of **Caliber LIMS** system
8	Periodic reports must be prepared regarding product quality assessment and certain product related Critical Process Parameters (CPP) must be monitored by instant graphics when required.	Y	Y	Annual Product Review reports not produced in time. No applications to graphically demonstrate multiple parameters.	Medium	High	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of existing quality processes, implementation and routine usage of QMex system
9	Production processes should be documented in sync with production and all Critical Process Parameters (CPP) should be monitored on batch basis. When required CPP's should be statistically documented.	Y	Y	Manual systems do not allow simultaneous documentation. Critical Process Parameters are not traceable. CPP's are not statistically evaluated.	Medium	High	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of existing production documentation processes, implementation and routine usage of QMex system
10	All supporting processes used in Quality Control Laboratories to verify product quality must be documented and traceable in accordance with GLP requirements.	Y	Y	Quality Control Laboratory processes are not effectively documented and not traceable due to manual monitoring.	High	High	High	2	Employing increased number of personnel in operational workforce	Analysis for improvement of quality control processes, implementation and routine usage of **Caliber LIMS** system
11	As part of Quality Management Processes departments within the company and suppliers with an impact on product quality must be audited in time and audit actions must be ensured to be completed in time. 3rd party audit actions must be completed in time and correctly.	Y	Y	Audits are not performed according to plans. Audit actions are not tracked.	High	High	Medium	1	Employing increased number of personnel in operational workforce	Analysis for improvement of audit processes, implementation and routine usage of QMex system
12	As part of Quality Management Processes risk analysis should be performed and reported according to ICH Q9 when required.	Y	Y	As part of Quality Management Processes risk analysis should be performed and reported according to ICH Q9 when required.	High	High	Medium	1	Hiring personnel skilled and trained in Quality Risk Management	Increasing detail level of risk management SOP's and increasing trainings
13	Key Performance Indicators (KPI) determined in Quality Management Processes assessment must be quantified and reported.	Y	Y	Manually tracked processes' KPI's cannot be quantified.	High	High	Medium	1	Employing increased number of personnel in operational workforce	Implementation and routine usage of QMex system to gather automated data for KPI management
14	All documents and data within Quality Management Processes scope must be traceable, readily accessible and stored securely.	Y	Y	Quality Management Process data are not traceable and readily accessible and are not stored securely.	High	High	Low	1	Password protected documents	Implementation and routine usage of QMex system to able to define various electronic approval mechanisms

Low Risk

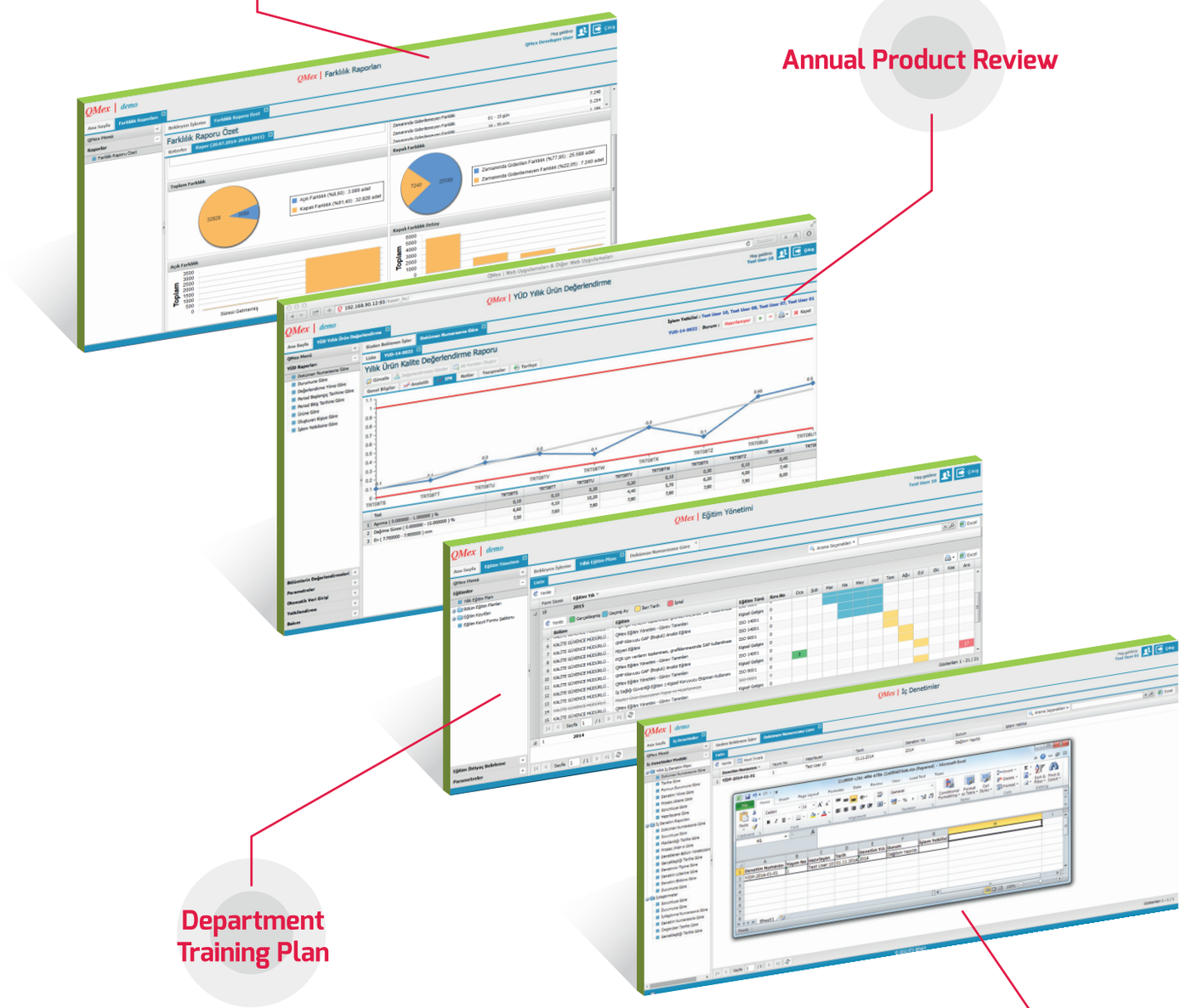
Medium Risk

High Risk

QMex Screenshots

Graphic Reporting Interface

Annual Product Review



Department Training Plan

Internal Audits

QMex

http://www.bts-tr.com

Our References

- Abbott
- Ali Raif
- Abdi İbrahim
- Actavis
- Amgen
- Arven
- Bayer Pharmaceuticals
- Bayer Crop Science
- Biofarma
- Brenntag
- Centurion
- Deva
- İlko
- Mustafa Nevzat
- Neutec
- Nobel
- Onko Koçsel
- Pharmavision
- Pharmactive
- Santa Farma
- Sanovel
- VSY Biotechnology
- World Medicine
- Vilsan

Address:
Feneryolu Mah. Fahrettin Gökay Cad.
Emek Apt. No:126/12 Kadıköy - İstanbul

T: +90 216 566 00 50
F: +90 216 566 00 51

info@bts-tr.com

/company/bts---business-technology-solution

/bts_tr

/btstr

BTS
business ▸ technology ▸ solution