

QMex



QMex

Enterprise Quality Management System

<https://bts-tr.com>

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About BTS

- Founded in Istanbul in 2011
 - QMex (Enterprise quality management systems)
 - QMex Workflow (Tailor made digital transformation solutions)
 - Mobile applications
 - Training and Consultancy
- It serves the various sectors with its teams with 30+ qualified employees located in Kolektif House Istanbul and Trakya Teknopark Campus Edirne



Global References

Abbott

Actavis

Alivira Group

Bayer Cropsience

Bayer Health Care

Bremer Pharma

Brenntag

El Kendi

LDM

MS Pharma

Sama AlFayhaa

UPM



Local References

Abdi İbrahim

Ali Raif

Alke

Argis

Arven

Berko

Bilim

Biofarma

Canan Kozmetik

Carolina Pharma

Centurion

Cinnagen

Dem

Deva

Drogsan

Farmatek

Gen İlaç

Gensenta

Genveon

Helba

İlko

Kopaş

Medicavet

Menta Pharma

Neutec

Neutec Inhaler

Nobel

Nukleon

Nuvita

Onko

Orzax

Pharmactive

Pharmavision

Polifarma

Provet

Pulcra

Sanovel

Santa Farma

Turgut İlaç

Turklandbank

Türk İlaç

Vilsan

World Medicine



Istanbul



Istanbul



Edirne



Edirne



BTS – Quality System

- Complies with GMP (Good Manufacturing Practices) and 21 CFR Part 11 requirements
- Designed to comply with ISO 9001:2015
- Complies with CSV (Computerized System Validation) requirements
- Documented in Turkish and English
- BTS Quality Management team uses validated QMex modules
- All quality processes are managed by BTS - QMex Modules



BTS – Quality Policy

- Keeping up with the changing technology
- Improving our employees' qualification in line with the requirements of the industry and technology and to ensure continuous development
- Ensuring customer and employee satisfaction
- To comply with legal regulations, standards and commitments given to customers



What is QMex?

- QMex is a software, with a modular design to manage all quality processes electronically, integrated within its own modules and other electronic business applications, validated according to GAMP in compliance with 21 CFR Part 11 and data integrity 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
- Full inter-modular integration
- Fast document preparation, approval and distribution
- Action tracking and management
- Electronic transaction records in compliance with 21 CFR Part 11 requirements
- Paper and printing material saving
- Time and human resources saving



Manual/Non-Integrated versus Electronic/Integrated QMS

Manual/Non-Integrated QMS	Electronic/Integrated QMS
Intense effort	Management with little effort
Waste of time	Fast and easy
Lack of Accuracy/Precision	Accurate and precise
Repetitive and boring	Efficient and user friendly
Loss of talented people	More productive employees
Increasing errors	Eliminated errors
Difficult reporting	Easy reporting
Retrospective	Proactive and predictable
Difficulty accessing data	Easy and fast access to data
Open to manipulation	Sticks to procedures
Difficulty of auditing	Always ready for auditing



QMex Functions

COMMON FUNCTIONS (1/2)

- Electronic Signature
- System and module based authorization
- LDAP integration
- Audit Trail
- Record history
- Action-based and scheduled notifications
- Personal page: Pending Tasks, Delegated Tasks, Bookmarks
- Dashboard
- Graphical reports
- Trend reports
- Validated reports
- Printer-friendly versions of records
- Configuration screens



QMex Functions

COMMON FUNCTIONS (2/2)

- Multiple file attachments
- Multiple location support
- Multi-language support
- Various reporting and sorting options
- Integration between all QMex modules
- Ready-made services for easy integration with 3rd party softwares
- Related Records screen, which allows viewing related records
- Powerful workflow management
- User-friendly interfaces
- Validation document set



QMex Modules

- Document Management
- Change Control Management
- Non-Conformance Management
- CAPA Management
- Customer Complaint Management
- Training Management
- Work Follow up and Action Management
- MBR Management
- Artwork Management
- Out of Limit Management
- Internal Audits Management
- External Audits Management
- Supplier Audits Management
- Pharmacovigilance Management



QMex Document Management

- Transferring the latest revisions of existing documents to the system, if .pdf (scanned) and .docx (for convenience in revision) are forwarded
- By uploading the documents prepared as .docx on the computer to the system, the conversion of the document into a non-printable .pdf by the system
- Automatic assignment of cover, footer and header of the original document converted to .pdf on the basis of document type by the system
- Option to calculate the document number automatically by the system on the basis of the document type or to be written by user input



QMex Document Management

- User-friendly display and warning of mandatory form fields
- Getting a controlled and traceable print out of an existing document record, making a withdrawal and starting the revision process
- Traceability of revision history and comparison of the original document with the previous revision.
- Document content templates
- Configurable stamp selection
- Document preview feature



QMex Change Control Management

- Grouping of Change Type and Subject selections and creating group action plan
- Definition of a location-specific impact question set
- Ability to manage the change process with more than one license group and variation guide
- Evaluation with special event evaluation follow-up list
- Ensuring that departments can make their own action plans in the action plan of the change process or an action plan is made by the quality assurance department.
- The final decision of the action plan is made by the quality assurance

Change Control Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-00001536 Draft Close

General Information

Impact Assessment

QA Assessment

Actions

Effectiveness Verification

Related Forms

Files

Notes

Correspondences

Record Number:

Date/Time:

Initiated By:

Initiator Department:

Implementation Date:

Closed Date:

N/A-00001536

02/28/2022 12:46:08

Test User 10

Production Planning Department

Change Type:

Change Subject:

Alan

Üretim sahasında değişiklik

Current State:

Requested Change:

Change Reason:

Attention:

Related to Change

Refresh Add Delete Selected



QMex Non-Conformance Management

- Marking the selected batch/series in the deviation record in the ERP
- Parametric impact assessment question set and research checklist
- With the classification function, the Deviation Class can be calculated by the system depending on the effect scale or can be selected by user input.
- Evaluation with special event evaluation follow-up list

Non-Conformance Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-00000032 Draft Close

General Information

Investigations

Impact Assessment

Classification

QA Assessment

Actions

Effectiveness Verification

Related Forms

Files

Notes

Correspondences

Record Number:	Date/Time:	Initiated By:	Initiator Department:	Release Date:	Closed Date:
N/A-00000032	02/28/2022 12:48:17	Test User 10	Production Planning Department		
Occured Date:	Occured Time:	Detected Date:	Detected Time:	Detected Department:	Detected Stage:
Non-Conformance Type:	Possible Deviation Class:				

Non-Conformance Description:

What was expected?:

Possible Root Cause:

Immediate Corrections:



QMex Customer Complaint Management

- Ability to define the impact assessment question set in two different parameters as pre-research and post-research
- Grouping of Complaint Type selections and creating group research templates
- Ability to do adverse effect control for each complaint record
- Recording of similar complaint records without an investigation process
- Sending preliminary reply (internal and external) and reply letter (internal and external) regarding the complaint registration

- Drafts
- All Records
- State
- Initiator Department
- Date
- Authorized User
- Complaint Type
- Complaint Type - Degree
- Complaint Subject
- Complaint Owner
- Complaint Degree
- Complaint Channel
- Root Cause
- Closure Report
- Related Code
- Voided Records
- Graph
- Pharmacovigilance Forms
- Investigations
- User Guide
- Version

Customer Complaint Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-00000271 Draft Close

General Information Complaint Notification Impact Assessment - Before Investigation Investigations Impact Assessment - After Investigation Pharmacovigilance Evaluation CAPA Result Related Forms

Record Number:	Date/Time:	Initiated By:	Initiator Department:	Closed Date:
N/A-00000271	02/28/2022 12:50:32	Test User 10	Production Planning Department	
Complaint Type:	Arrival Date:	Arrival Type:	Receiving Complaint:	Sender Department:
Any samples?:	Samples Number:	Sample Submission Date:	Investigation required?:	Production Site:
Waybill Document Number:	Shipment Date:	Complaint Owner:	Is there a similar complai...	Similar Complaint Number:
			Similar Complaint CAPA Record:	

Complaint Description

	Add Delete
File Definition	File Size Added by

Related Product/Product Group/Batch

Refresh Add Delete Selected	Excel
Type Code Name	Batch Expire Date Missing\Much Adet



QMex CAPA Management

- Determination of workflow roles on the basis of the management system
- Creating CAPA records through customer complaints, internal audit and external audit processes
- Hierarchical action definition and management
- Evaluation with special event evaluation follow-up list
- Action calender



QMex Out of Limit Management

- Ability to manage Instant Detection and Out of Limits processes separately on the same application
- On the basis of laboratory locations, definition of phase questions in the parameter and determination of deadlines
- Automatic calculation of the form number by the system based on the out-of-limit type
- Compulsory process initiation according to the decision made by quality assurance in the finalization process (Change Control, Deviation)

- Drafts
- All Records
- State
- Initiator Department
- Date
- Category
- Out of Limit Type
- Root Cause
- Lab Location
- Authorized User
- Related Code
- Voided Records
- Graph
- Instant Detection Forms
- User Guide
- Version

Out of Limit Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

 Edit  Actions  Save  Cancel  Tools  N/A-00000231  Draft   Close

General Information

Phase I

Assumption Analysis I

Assumption Analysis II

Phase 3 Final and Decision

Related Forms

Files



Notes

Correspondences

Target Date History

Record Number:	Date/Time:	Initiated By:	Initiator Department:	Target Date:	Closed Date:
N/A-00000231	02/28/2022 12:54:12	Test User 10	Production Planning Department		
Lab Location:	Category:	Out of Limit Type:			
Kalite Kontrol					
Company Code:	Company Name:	Analysis Date:	Test Parameter:		
Specification Number:	Specification / Trend Limits:				
Suspicious Analytical Result:	Pending Assessment (Target Date Update):				
Sample Type:	Investigation Subject:				
Analysis Registration Form Number:	Detected Department:				
Attention:					

Related

 Refresh  Add  Delete Selected   Excel

Related

Code	Name	Comment
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QMex MBR Management

- Being able to prepare and print the current documents in a controlled manner as a result of matching the work orders from the ERP
- Automatic assignment of print templates of MBR documents, cover, footer-header information on the basis of document type by the system
- Definition of all data needed in MBR documents from parameters

- Drafts
- All Records
- State
- Material
- User Guide
- Version

MBR Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-00000354 Draft Close

General Information

Other Data Fields

Files

Notes

Correspondences

Record Number:	Date/Time:	Initiated By:	Initiator Department:	Closed Date:	
N/A-00000354	02/28/2022 12:55:56	Test User 10	Production Planning Department		
Work Order Number:	Material Code:	Material Name:	Material Type:	Production Version:	Production Version Description:
Batch Number:	Order Amount:	Order Quantity Unit:			
	0				

Printout Reason:

--

Documents

Add Delete Selected

Document Number Revision Document Type Document Name Document Name (Other Language) State



QMex Artwork Management

- Starting the artwork process with change control action
- Making decisions from sections on the basis of the artwork record.
- Ability to define specification options in parameters based on material type

Artwork Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-0000450 State: Draft Close

General Information Specifications Department Reviews Related Forms Files Notes Correspondences

Record Number: N/A-0000450 Revision Num...: 0 Date/Time: 02/28/2022 12:57:05 Initiated By: Test User 10 Initiator Department: Production Planning Department Effective Date: Closed Date:

Artwork Number: CC Action Number: Artwork Scope: Foreign Trade Type of Material: Leaflet

Material Information

Material Code: Material Name: Former Material Code: Former Material Name: Country:

Product Information

Product Code: Product Name: Product General Code: Product General Name: Product Category:

Current

Current Barcode: Current Design Number: Current Pharma Code:

New

New Packaging Barcode: New Design Number: New Pharma Code:

Company Information

Product Supply Type: Are you going to select Company?: Company Code: Company Name: Company Artwork Number:

Require urgent notification?: Graphic Design File: Is trial necessary?:



QMex Work Follow up and Action Management

- Creating group action plan in parameters
- Monitoring of all work follow-up processes and actions, if any
- Ability to add opening and closing forms for action series to be managed
- Automatic calculation of the form number by the system based on the scope selection
- Scope-based authorization

- Drafts
- All Records
- State
- Initiator Department
- Initiated By
- Authorized User
- Date
- Subject
- Scope
- Graphics
- Voided Records
- Actions
- Scope Templates
- User Guide
- Version

Follow-up Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

Edit Actions Save Cancel Tools

N/A-0000051 Draft

General Information

Actions

Notification Dates

Related Forms

Files

Notes

Correspondences

Record Number:

N/A-0000051

Date/Time:

02/28/2022 12:59:32

Initiated By:

Test User 10

Initiator Department:

Production Planning Department

Closed Date:

Scope:

QA Project

Subject:

Opening Form:

Closure Form:

Work Definition:

Comment

Add Delete

File Definition

File Size

Added by








QMex Training Management

- Working in integration with Document Management
- Obtaining employee and position-based employee training reports
- Ability to make dynamic annual training plan
- Traceability of missing trainings with the needs determination function
- Follow-up of qualification trainings
- Ability to provide self-education and read-understand training
- Viewing team trainings in accordance with the organizational hierarchy
- Management of periodic trainings
- Ability to evaluate and measure the effectiveness of training

Department Training Plan Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

 Edit  Actions  Save  Cancel  Tools N/A-00000036  Draft   Close

General Information Related Forms Files Notes Correspondences







Record Number:	Revision Number:	Date/Time:	Initiated By:	Initiator Department:	Closed Date:
N/A-00000036	0	02/28/2022 13:00:48	Test User 10	Production Planning Department	

Training Year:	Training Month:	Departments:
0		

Attention:

Total Number of Required Attendees:	Total Number of Attendees:	Attendance %:	Successful Attendee:	Success %:
0	0	0.00	0	0.00

Training Plan and Monitoring Table

  Display  Add  Delete Selected  Search Options  Excel

Training Name	Training Category	Training Type	Positions	Other Attendees
---------------	-------------------	---------------	-----------	-----------------



QMex Internal Audits Management

- Ability to make dynamic annual internal audit plan on the basis of scope
- Defining a location-specific internal audit question set
- Ability to create evidence-based corrective and preventive action
- With the classification function, the Finding Class can be calculated by the system depending on the effect scale or selected by user input.
- Ability to associate with the articles of the relevant regulation guide

Internal Audit Form

Location: BTS Bilişim , Merkez Ofis Authorized User: Test User 10

 Edit  Actions  Save  Cancel  Tools   N/A-00000011  Draft   Close

General Information

Findings

Questions

Related Forms

Files

Notes

Correspondences







Delay History

Record Number:	Date/Time:	Initiated By:	Initiator Department:	Closed Date:
N/A-00000011	03/01/2022 14:08:28	Test User 10	Production Planning Department	
Audit Scope:	Audit Year:	Audited Department:	Lead Auditor:	Department Head:
GMP	0			
Planned			Actual	
Start Date:	Start Time:	End Date:	Start Date:	End Date:







Attention:

	 
--	---

Auditors

  		 
Auditor ^	Position	

Audit Attendees

  		 
Audit Attendees ^	Position	



QMex External Audits Management

- Ability to make dynamic annual external audit plan on the basis of scope
- Ability to create evidence-based corrective and preventive action
- Ability to associate with the articles of the relevant regulation guide



QMex Supplier Audits Management

- Ability to make dynamic annual supplier audit plan on the basis of scope
- Definition of a location-specific supplier audit question set
- With the classification function, the Finding Class can be calculated by the system depending on the effect scale or selected by user input.
- Ability to associate with the articles of the relevant regulation guide
- Parametric risk assessment

No data to display

Contact Us



@btstr



@bts_tr



@btsbilisimegitim



info@bts-tr.com



<https://bts-tr.com>

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Thank You...