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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

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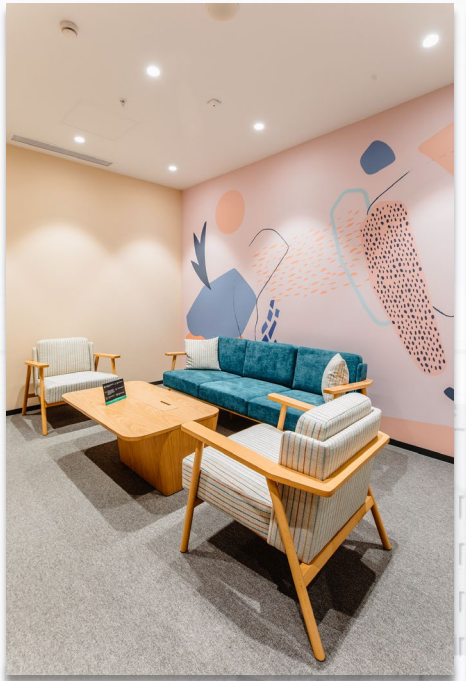


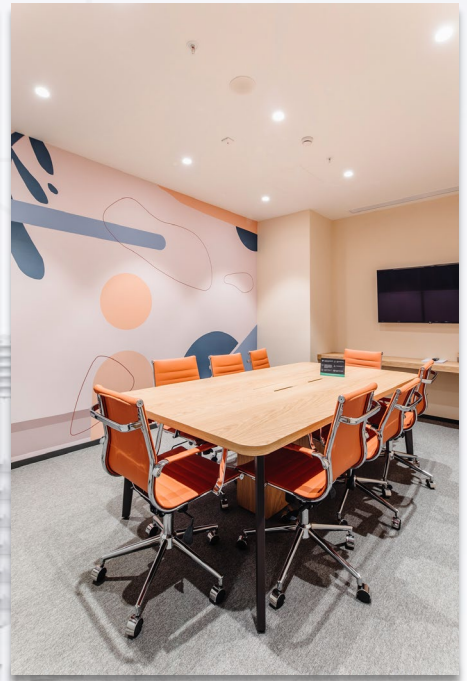

İstanbul

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Edirne

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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

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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.

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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

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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

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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

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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

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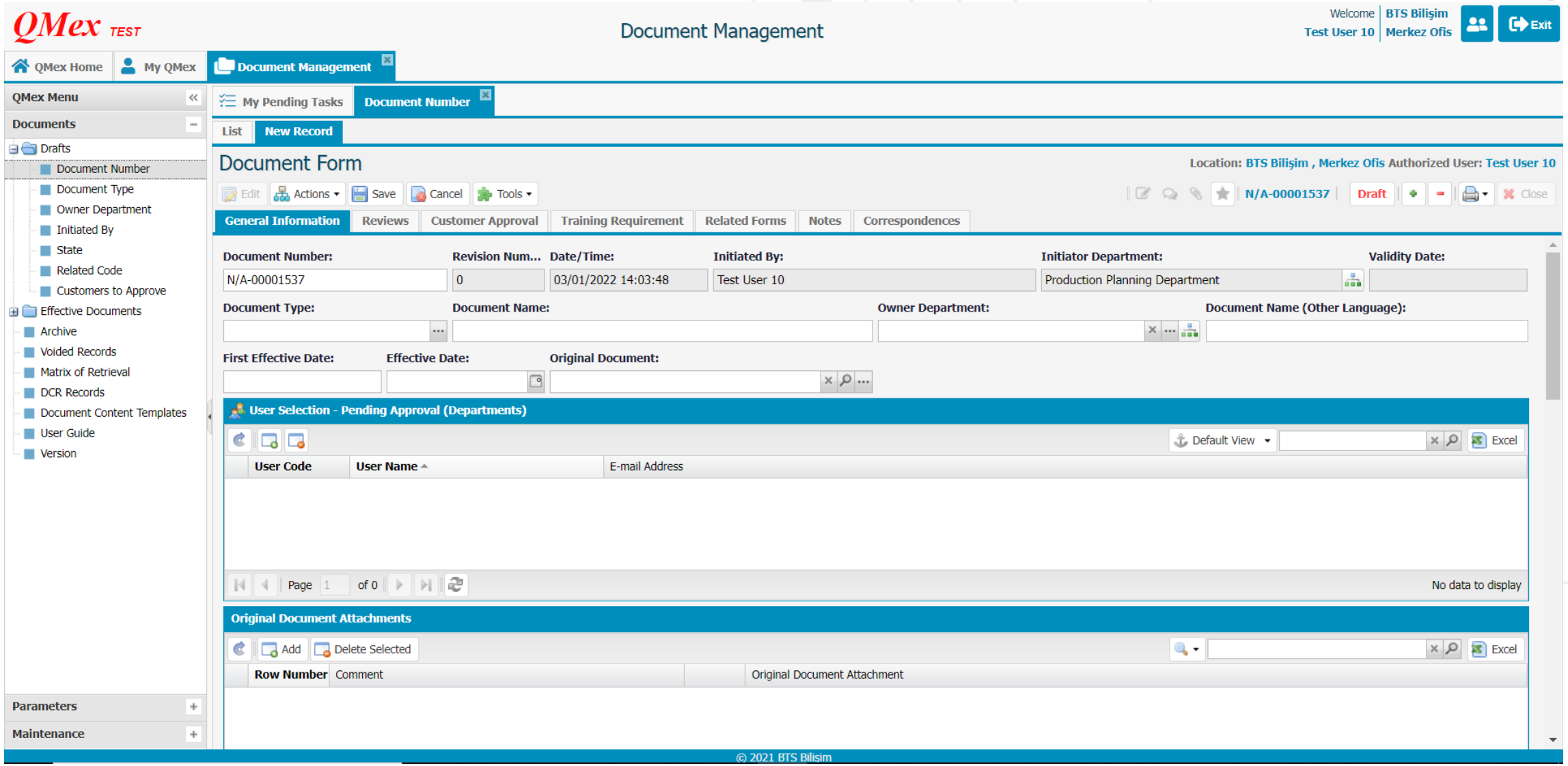

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QMex Change Control Management

- 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

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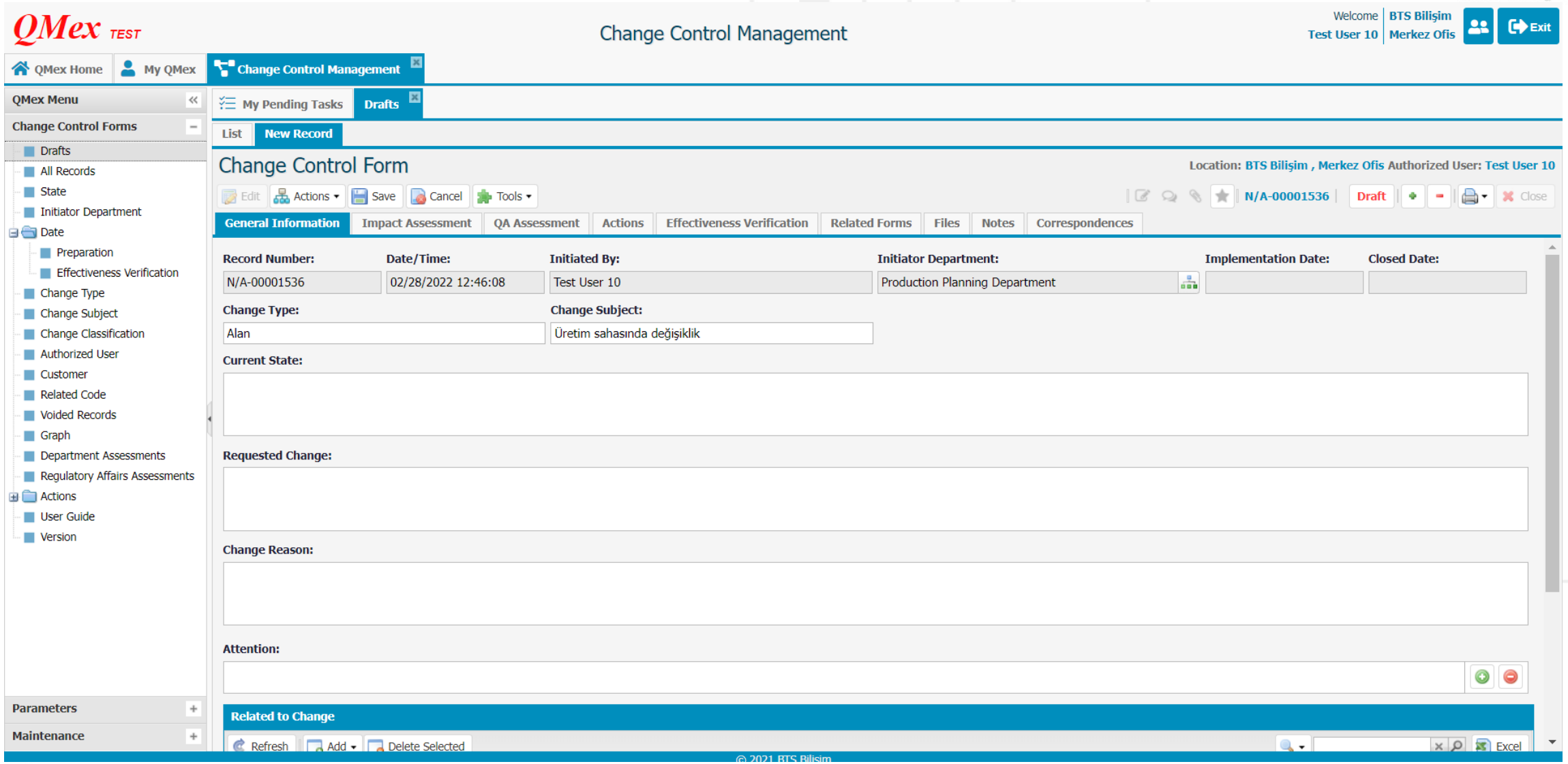

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QMex Non-Conformance Management

- 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

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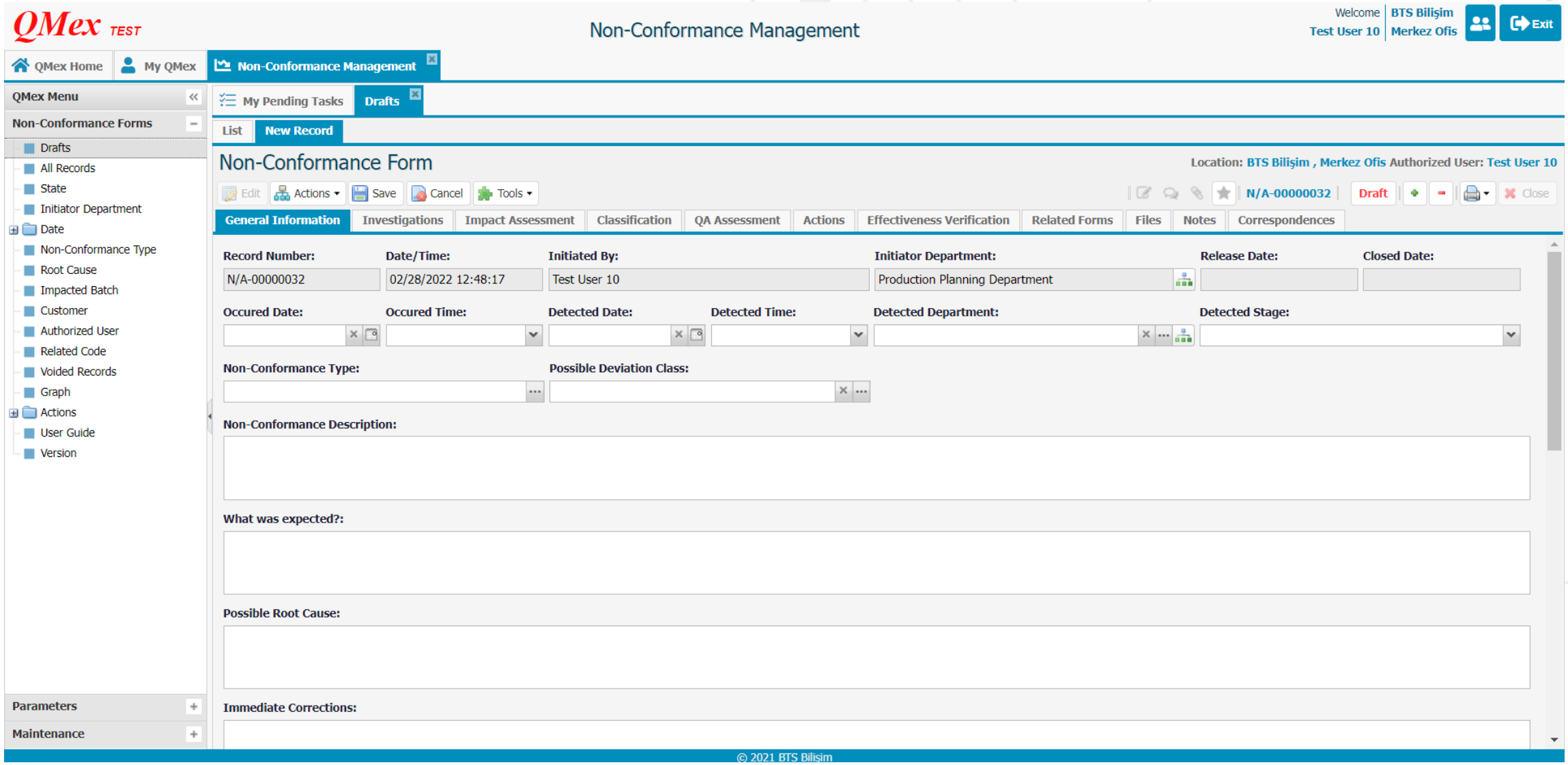

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QMex Customer Complaint Management

- 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

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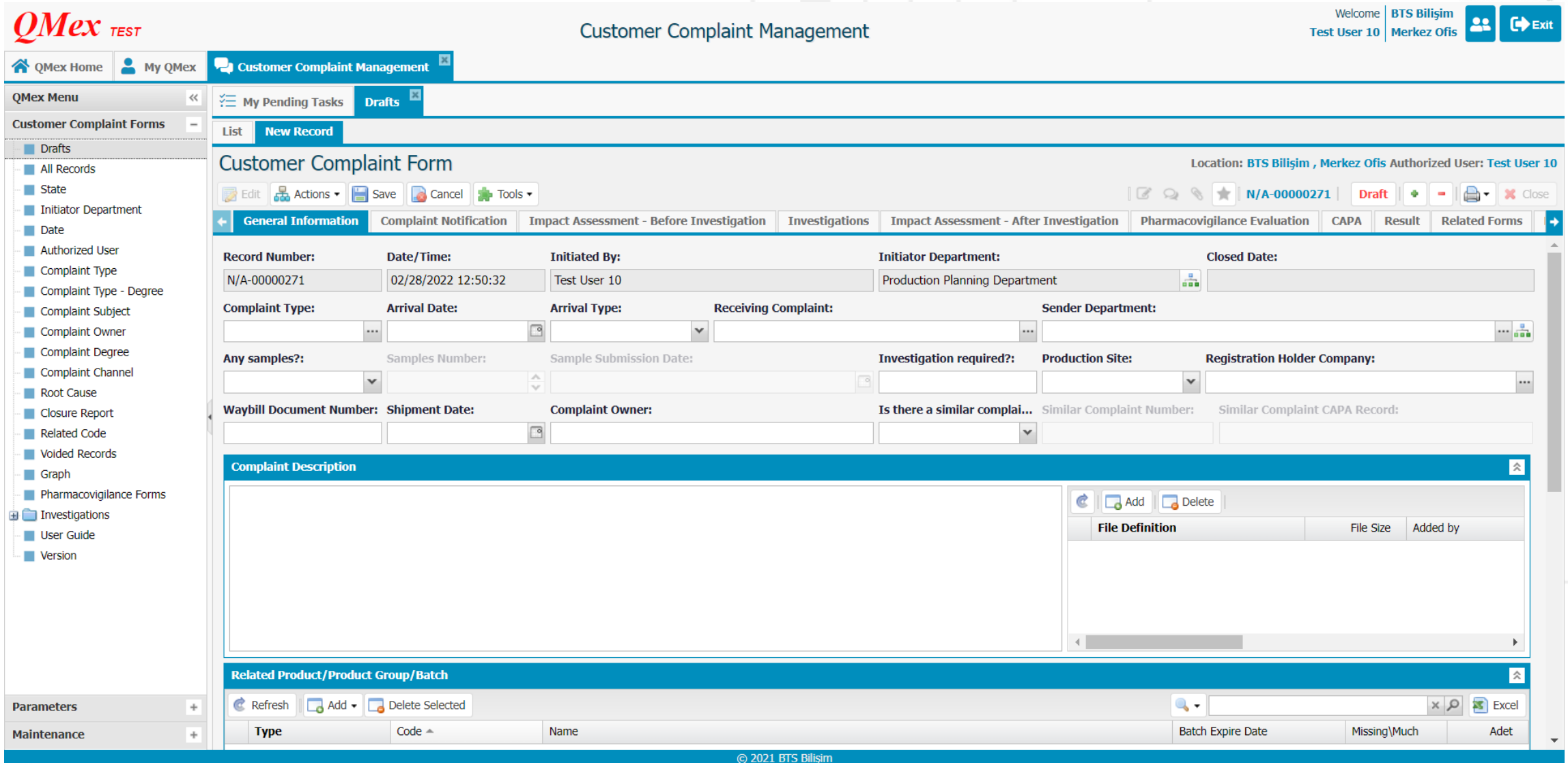

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QMex CAPA Management

- 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

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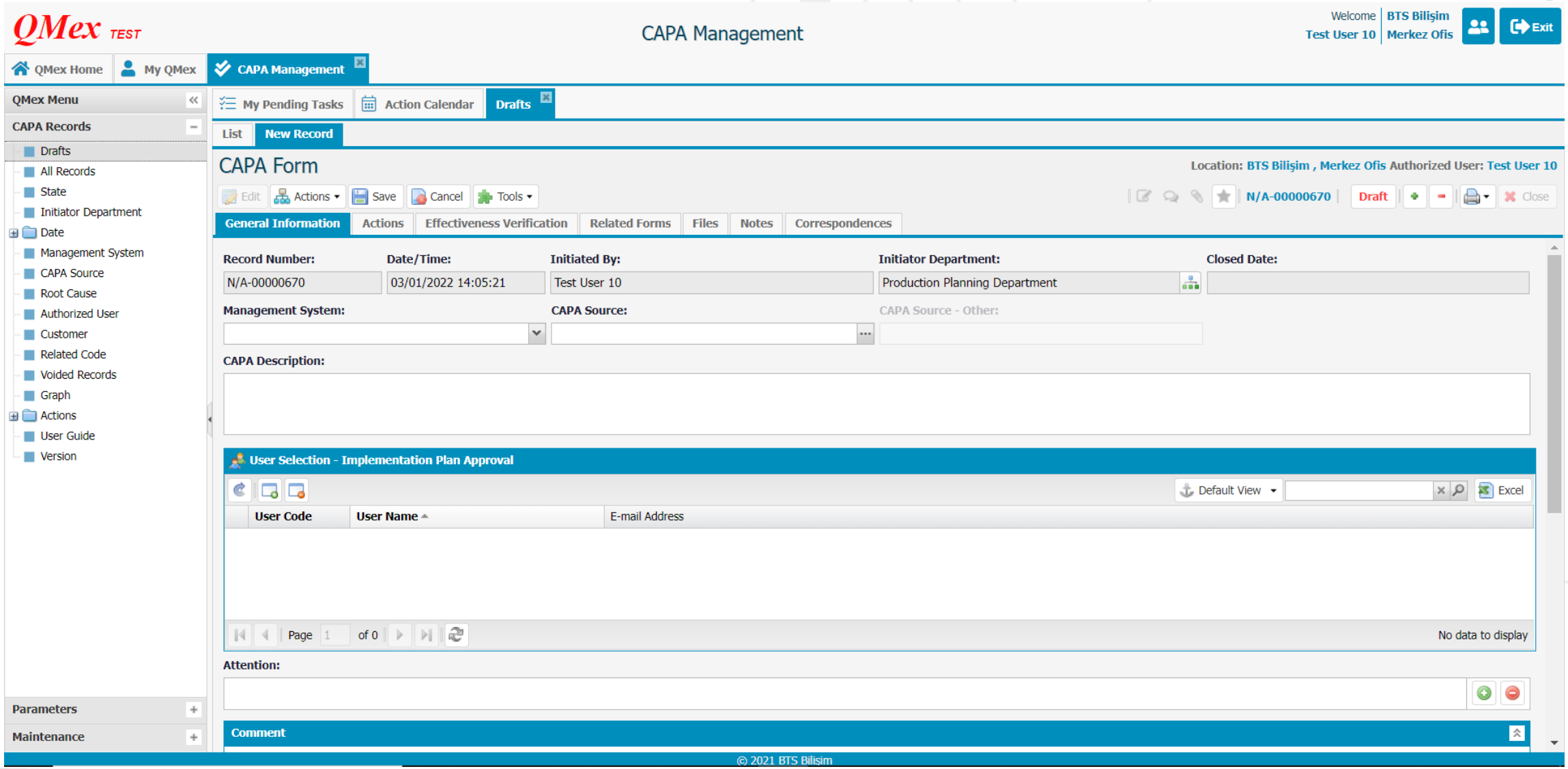

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QMex Out of Limit Management

- 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)

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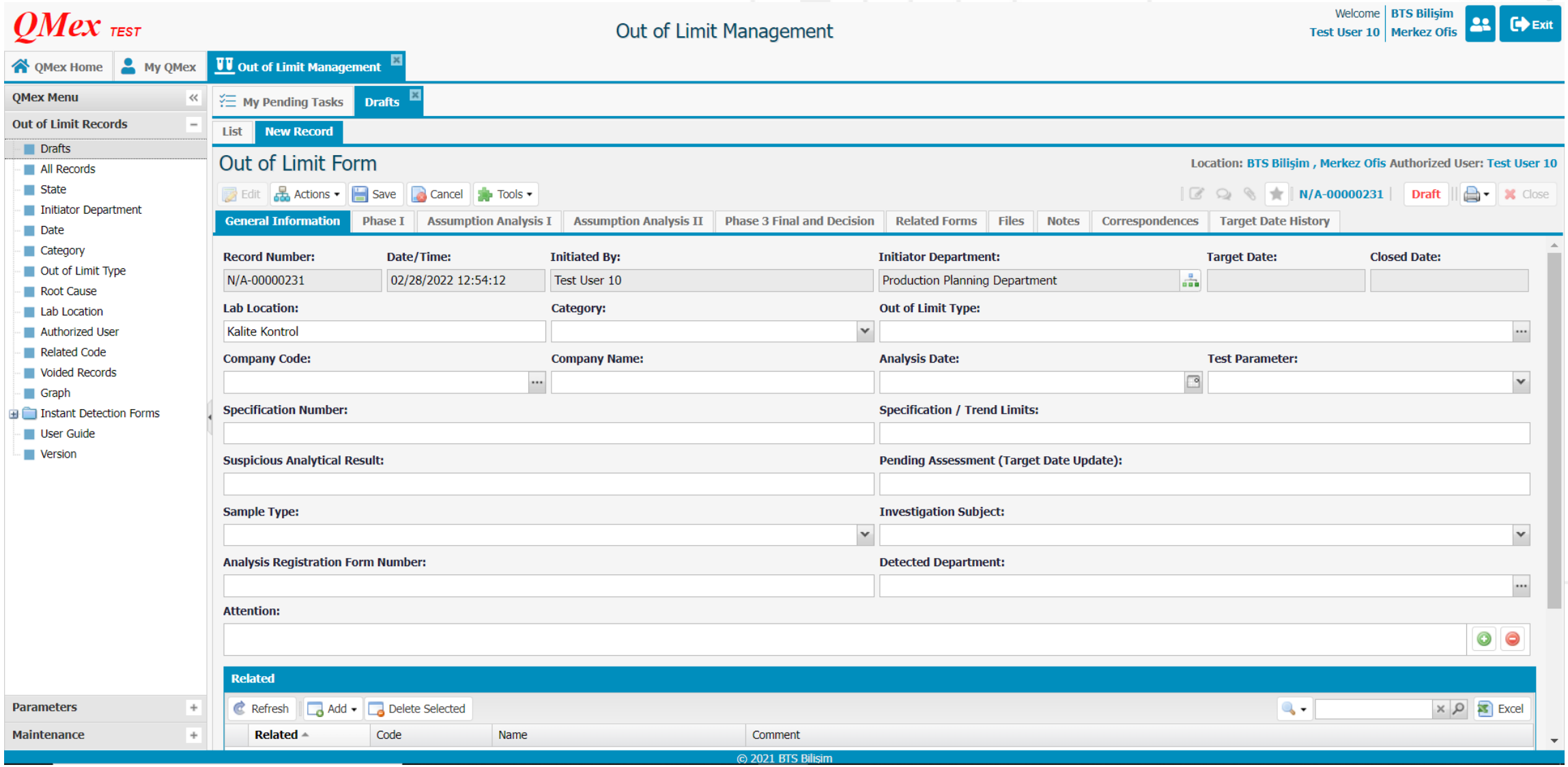

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QMex MBR Management

- 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

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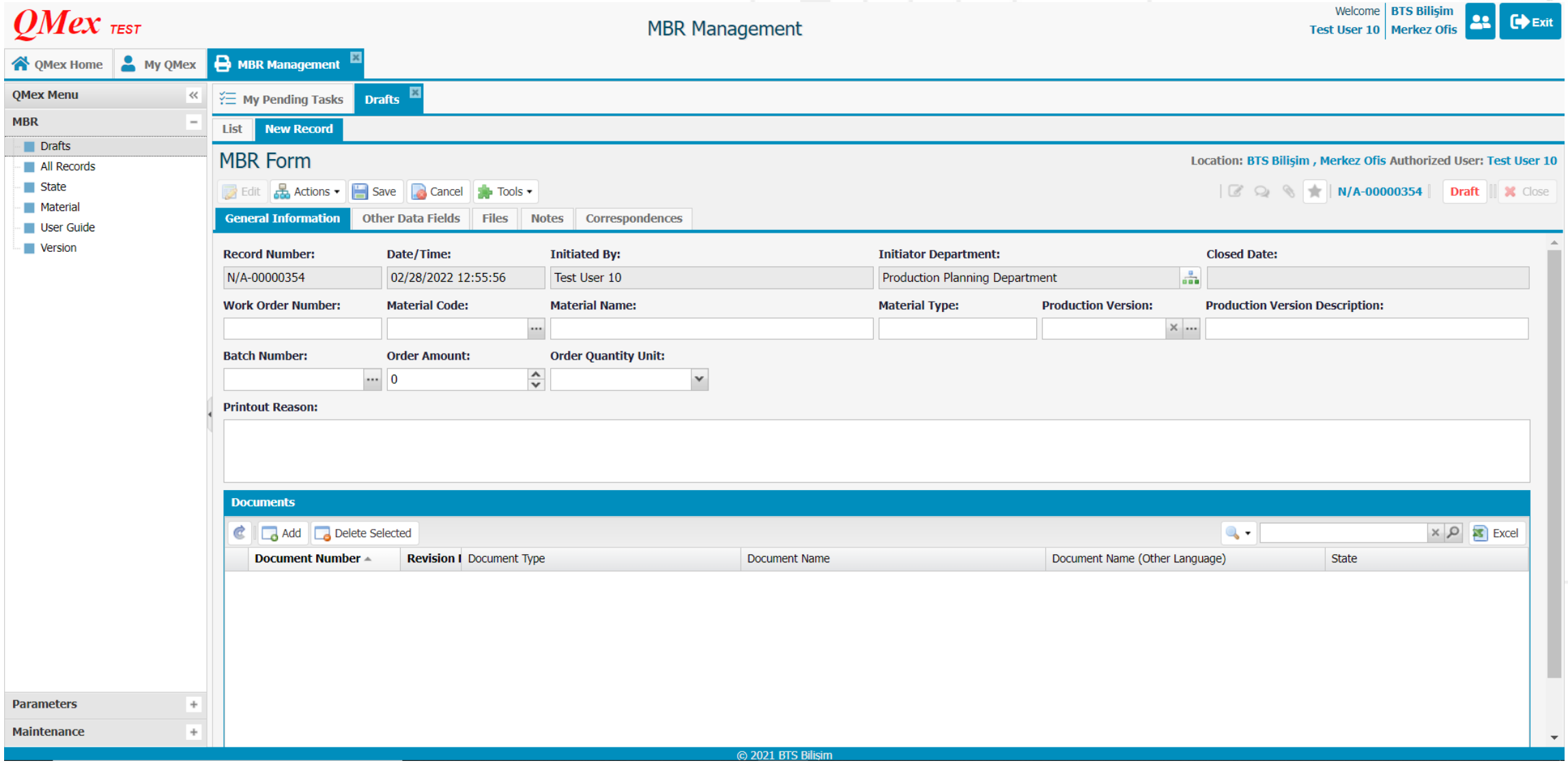

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QMex Artwork Management

- 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

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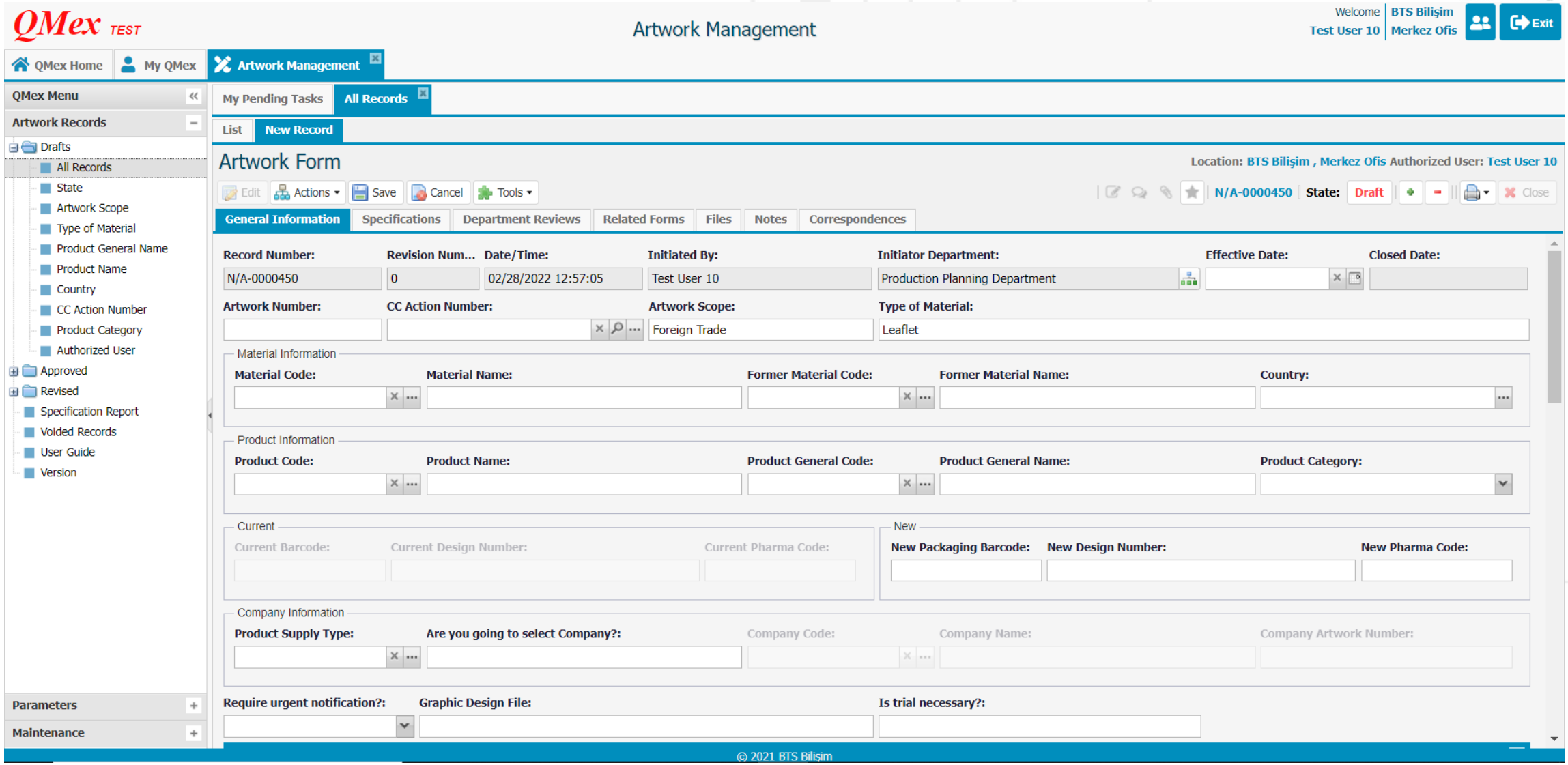

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QMex Work Follow up and Action Management

- 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

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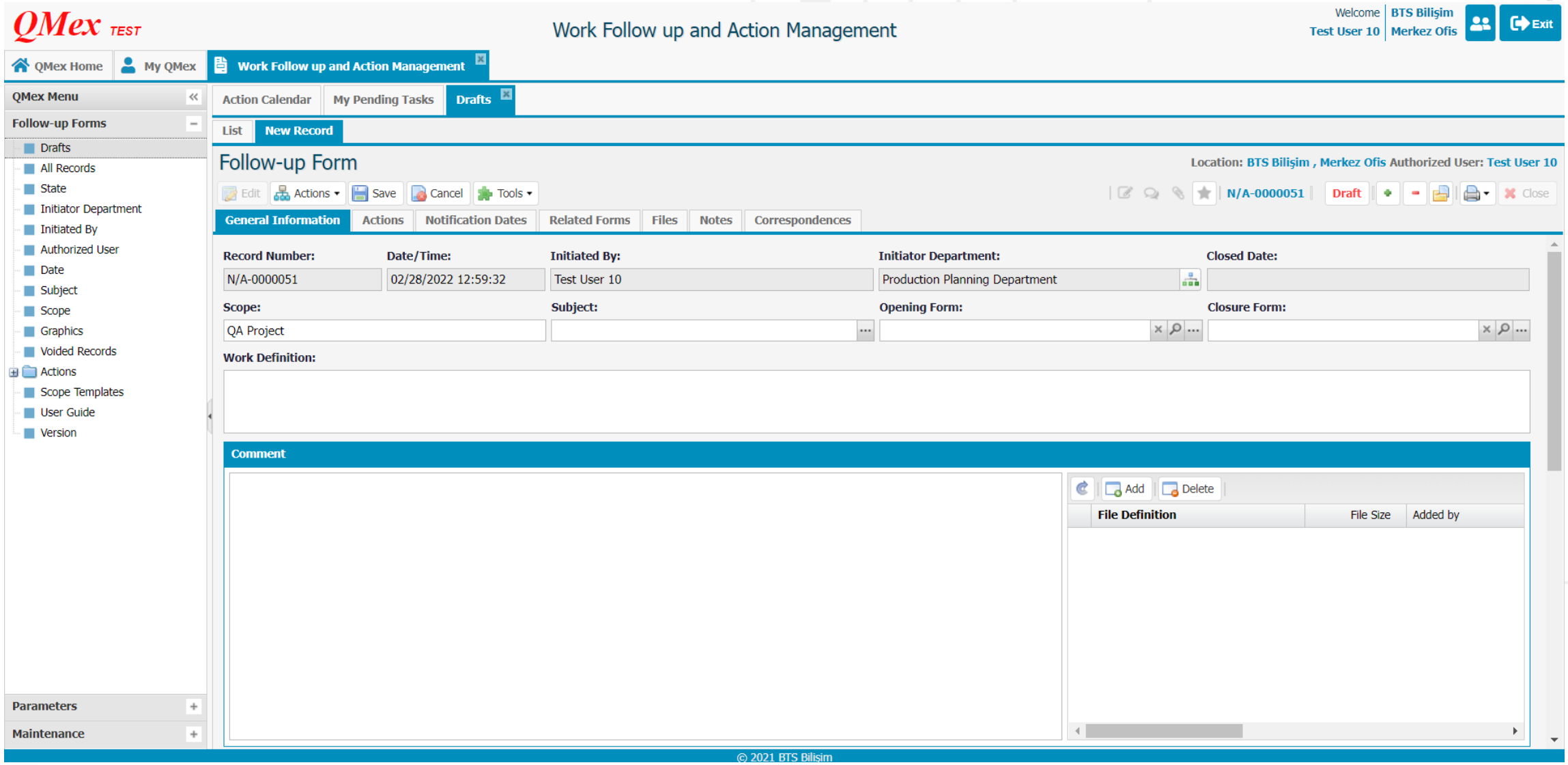

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QMex Training Management

- 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

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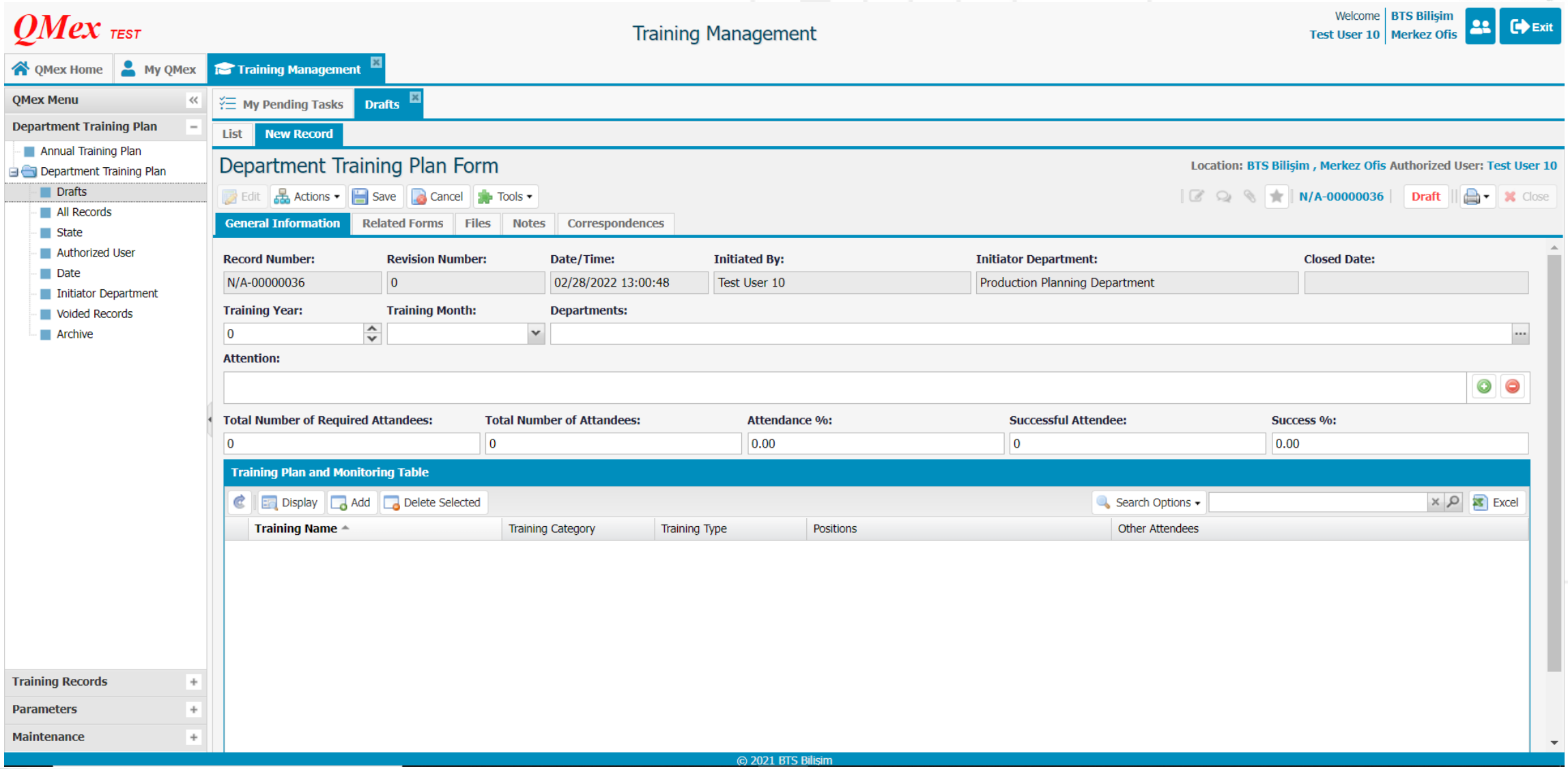

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QMex Internal Audits Management

- 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

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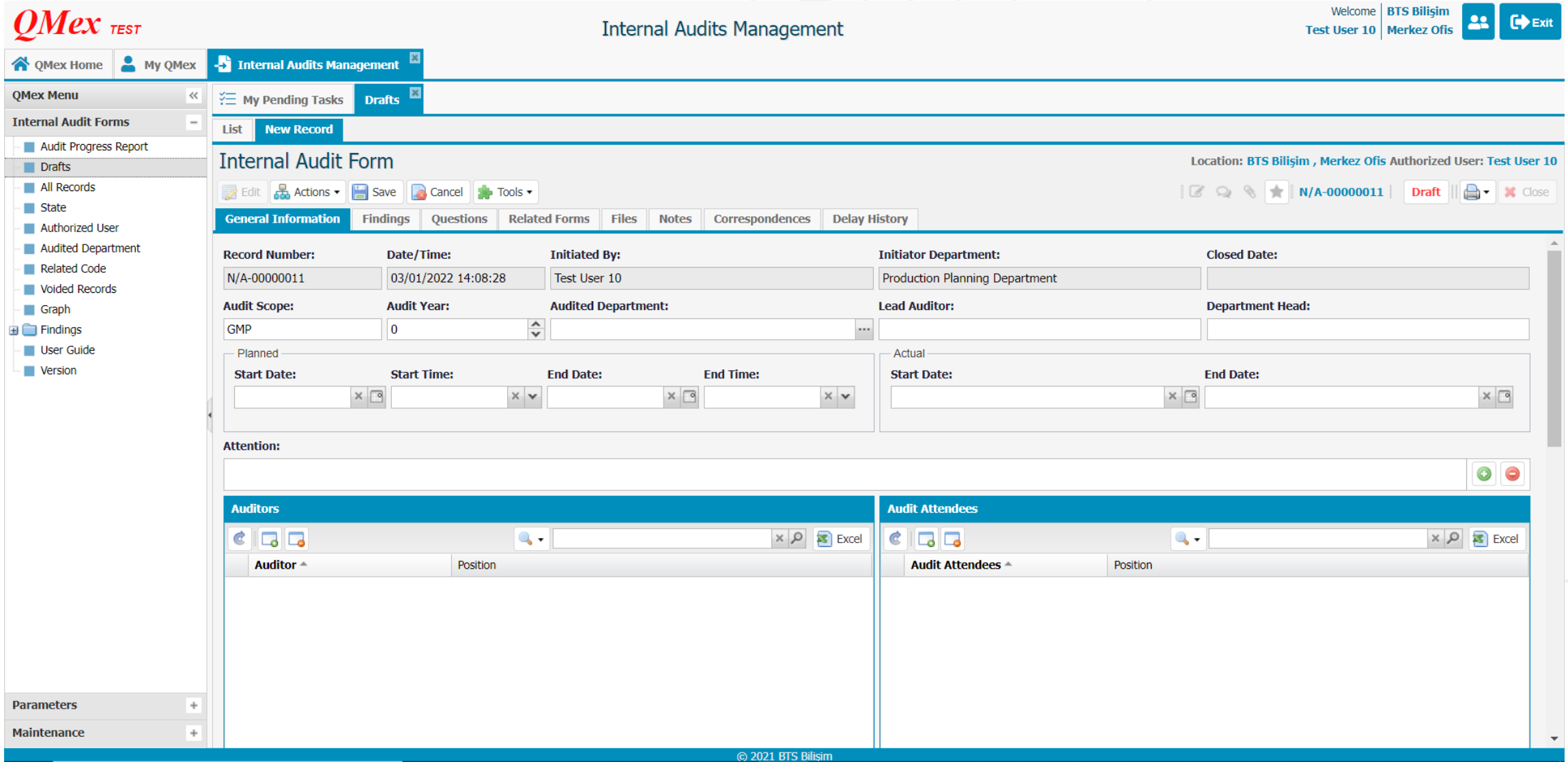

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QMex External Audits Management

- 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

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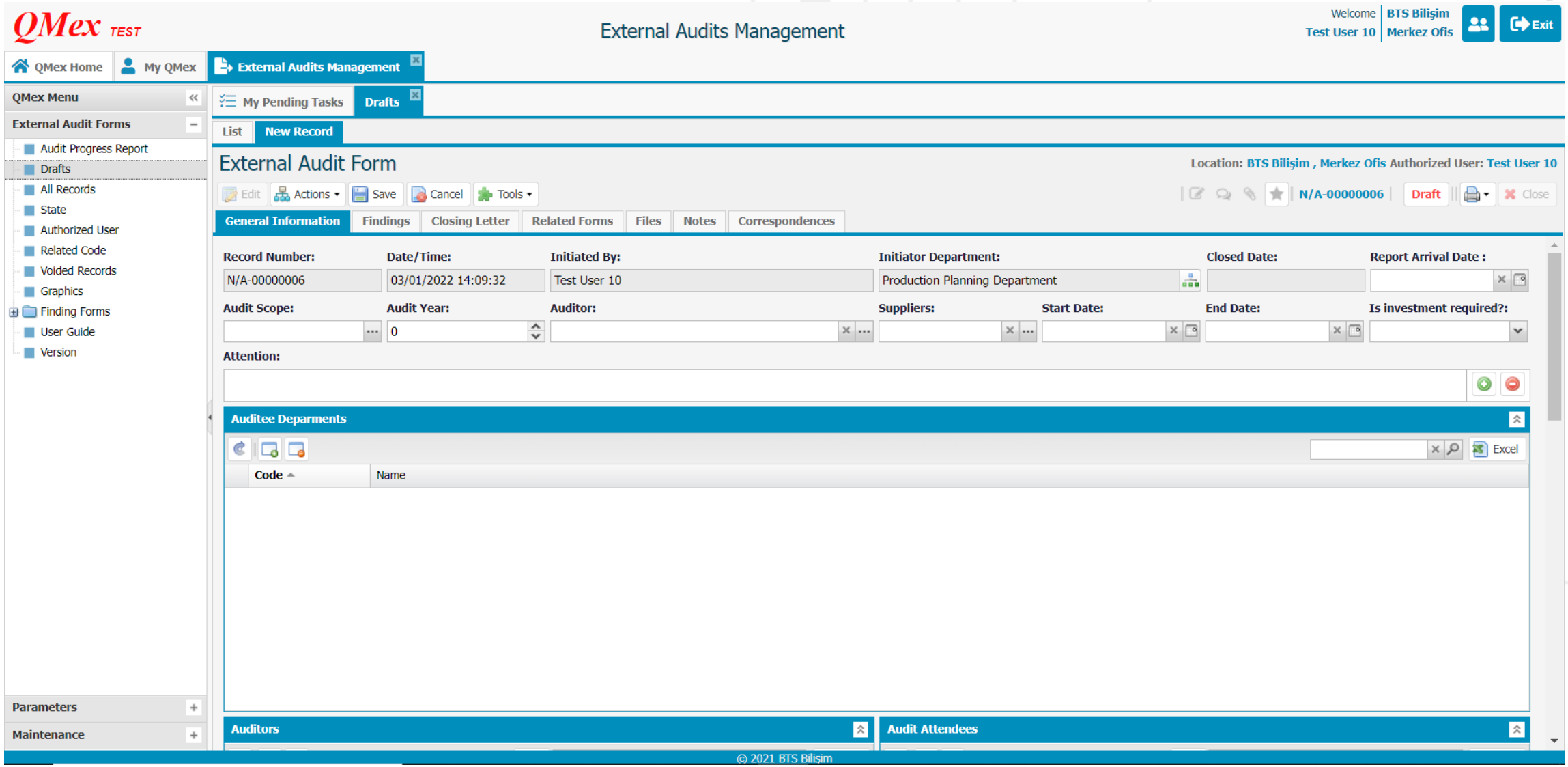

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QMex Supplier Audits Management

- 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

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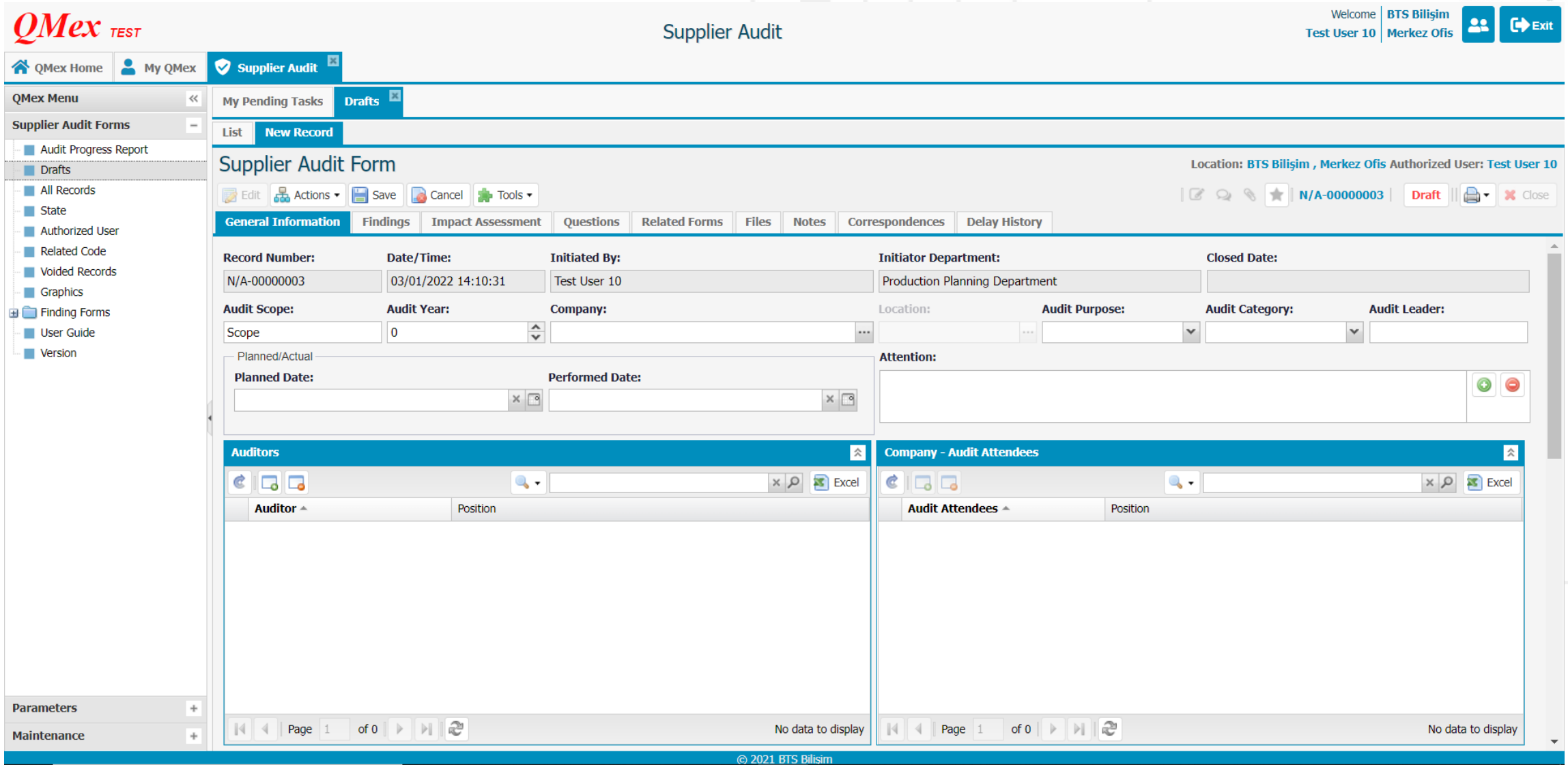

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Thank You...