TECHNOLOGY & BUSINESS SOLUTIONS

"Define-Achieve-Maintain"

Software Solution for Pharmaceutical Company

QUALITY COMPLIANCE

Providing IT Solutions Since 2005

www.tecbsl.com
pharma.tecbsl.com

Technology and Business Solutions Ltd. (TBS) have developed and implemented IT solutions in Quality Compliance, Marketing and Sales for the pharmaceutical industry. Our solution includes Design, Coding/Testing, Documentation, Training End-Users, Deployment and Maintenance Support.

Our rich experience in this sector has given us a unique insight and domain expertise not only to implement similar systems, but also confident we can provide world class solutions in other areas.

PQC (Pharmaceutical Quality Compliance)

Pharmaceutical companies are regularly subjected to tremendous financial pressure to produce products. A delay in releasing a batch of drug is not only costly but also consumes additional resources in the company. It is therefore crucial that analytical data be collected, compiled, and submitted in a timely, accurate and reliable but secure manner.

The PQC application is a centralized web based information management system for Pharmaceutical QC / QA to store batch analytical result, manufacturing information, and to track, monitors analytical / manufacturing data in a secure manner. The system supports the management of analytical result data of raw material, packaging material, water, finished product and stability of products.

The main functionality of PQC is to track a batch life cycle from manufacturing to batch release. The system enables the printing of reports like Certificate of Analysis (COA), trend analysis and other reports.

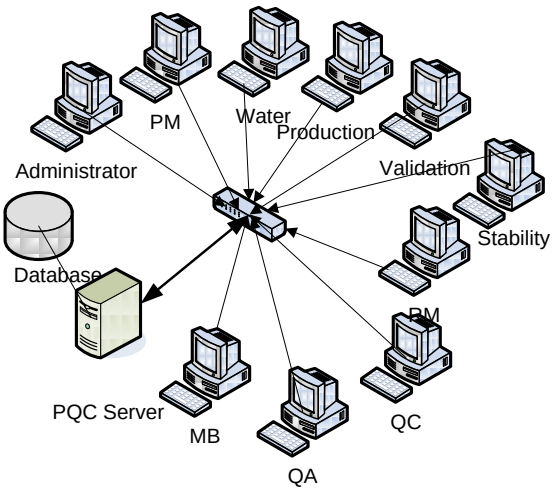
Benefits and Advantages

- ✓ Enhance Productivity and Efficiency
- ✓ Improve Reliability & Accuracy of QC Process
- ✓ Faster Report Generation including APR
- ✓ Comply with Regulatory Requirements
- ✓ Centralized Analytical Information Repository
- ✓ Faster Analysis of Analytical Data
- ✓ Secured and Consistent Approval Process
- ✓ Storage of QC, QA & Manufacturing Data
- ✓ Patient Risk Reduction

Guidelines and Standards

- ✓ GMP, EU GMP Annex 11, EU GMP Part 11, 21 CFR Part-11 and ICH Guideline
  - Computerized System
  - Electronic Record, Data & Data Storage
  - Accuracy Check
  - Audit Trails
  - Change and Configuration Management
  - Security
  - Electronic Signature
  - Print outs
  - Batch Release

System Overview



Modules

- ✓ Product
  - Solid & Liquid Product
- ✓ Raw Material (RM)
  - API & Excepients
- ✓ Packaging Material (PM)
  - Primary & Secondary PM
- ✓ Water
  - Boiler, Steel Mass, Purified, WFI, Tank, Feed, Softener etc
- ✓ Stability
  - Development, Marketed & New Product

Batch Processing Steps

- ✓ Batch Testing (Test & Specification) by QC & MB
- ✓ Batch Approval (Approve & Reject)
- ✓ Product Authorization
- ✓ COA for Every Step of a Batch

Roles

- ✓ Super Administrator
- ✓ Administrator by Modules
- ✓ Analyst (QC & MB) by Modules
- ✓ Approver (QC & MB) by Modules
- ✓ Authorizer (QC & MB) by Modules
- ✓ Quality Assurance
- ✓ Production
- ✓ Data Entry Operator

Features and Functionality

- ✓ Master Data
  - Items (Product, Raw Material, Packaging Material, Water) Management
  - Specification Management for All Items
  - Shelf Life, Equipment and Others
  - Analyst, Approver & Authorizer
- ✓ Batch Entry
- ✓ QC & MB Analytical Result Entry & Approval
- ✓ QA Observation Entry
- ✓ Validation of Products
- ✓ Authorization for Finished Products
- ✓ Raw Material Audit
- ✓ Email Notifications
- ✓ Alert for Out of Specification
- ✓ Certificate of Analysis (COA)
- ✓ Automatic Stability Schedule Generation
- ✓ Stability Analytical Data Entry and Approval
- ✓ Printing Facility
- ✓ Rich Searching Features / Advance Search
- ✓ Browser Compatibility: IE6+, Firefox 3.5+

Product Stability

- ✓ Generate Schedule
- ✓ Frequency Testing
- ✓ Approval for Each Step
- ✓ Authorization for Final Step
- ✓ Storage Stability Result

Stakeholders

- ✓ Production
- ✓ Quality Assurance (QA)
- ✓ Quality Compliance (QC)
- ✓ Validation
- ✓ Stability
- ✓ Raw Material (RM)
- ✓ Packaging Material (PM)
- ✓ Microbiology (MB)
- ✓ Water

Security

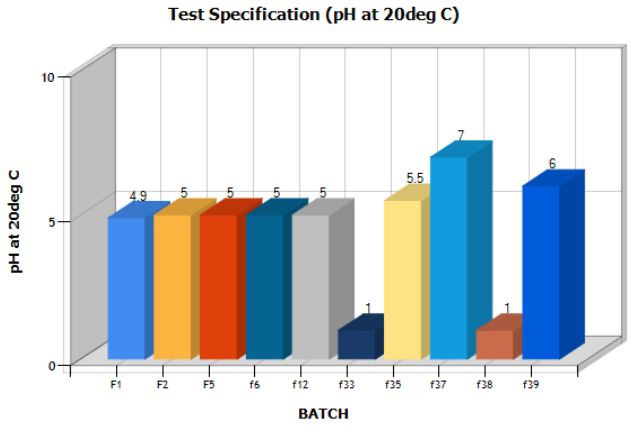
- ✓ User Management
- ✓ Active Directory Login
- ✓ Roles & Privilege Management
- ✓ Privilege for Edit & Update
- ✓ Track Login & Logout
- ✓ Audit Trail
- ✓ Session Timeout

Reports

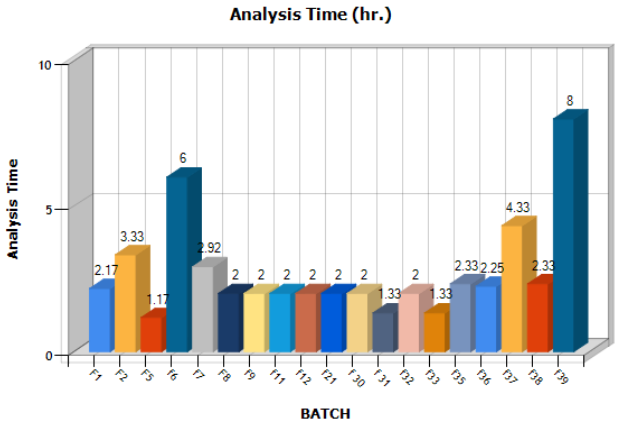
- ✓ In House Reports by Modules, Departments & Steps
- ✓ Basic Data Reports for Products (Manufacturing Data)
- ✓ Certificate of Analysis (COA)
- ✓ APR (Annual Product Review) for:
  - Analytical and Manufacturing Data
- ✓ APR by Modules
  - Products
  - Raw Material
  - Packaging Material
  - Water
- ✓ Graphical Reports of Trend Analysis
- ✓ Analysis Time for QC, MB
- ✓ Individual Specification by Items & Modules
- ✓ QO Cycle Time & Yield Percentage for Product

Graphical Reports

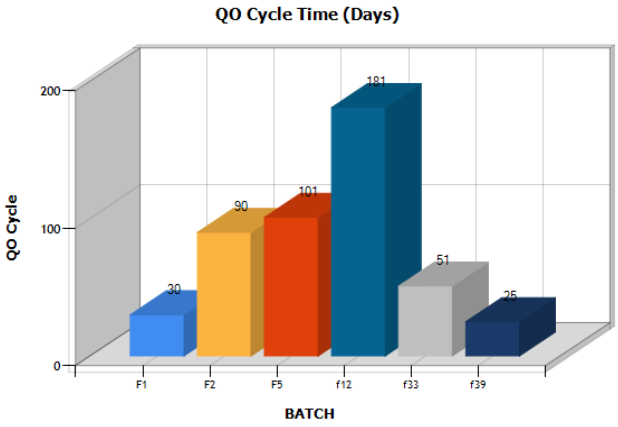
APR: Trend Analysis for pH



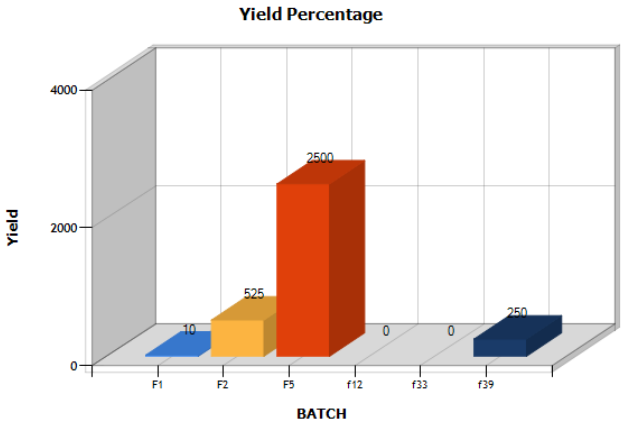
APR: Trend Analysis for Analysis Time



APR: Trend Analysis for QO Cycle Time



APR: Trend Analysis for Yield Percentage



Platform & Technology: ASP .NET 3.5 SP1, MS Chart, C#, CSS, JavaScript, IIS,SQL Server, JQuery, Ajax

Company Background

TBS was formed by industry professionals with worldwide experience in Information Technology Our main focus and goal is to make organizations in the private and public sector more productive, efficient and profitable by leveraging technology and processes, by offering world class solutions in the following areas:

Core Areas

- ✓ System and Software Development
- ✓ Software Quality Assurance & Testing
- ✓ Business Process Improvement (BPI)
- ✓ Monitoring and Evaluation (M & E)
- ✓ Independent Validation & Verification (IV&V)

Ancillary Areas

- ✓ Digital Archiving and QC
- ✓ Capacity Building & Training
- ✓ Infrastructure Development
- ✓ MIS Backup Support & Maintenance
- ✓ Technical and Business Documentation
- ✓ Management and Logistic Support

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