

# GDT Portal

## Global Decision Tracking for Product Labeling

Determine how well your organization is complying with content of labeling standards.  
Ensure your global and local regulatory teams work together.



### Top Features

- Web Application
- Global Access
- Enterprise Reporting
- Enterprise Audit Trail
- SOP Enforcement
- Risk Mitigation
- System Alerts
- Legacy System Integration

### Function

GDT Portal is a web-based application that provides decision tracking, reporting, and data entry for pharmaceutical companies. GDT Portal can support unlimited country locations, milestones, and users. In addition, the application can be customized to interface with other systems to limit redundant data entry.

### Central Repository

The GDT Portal repository allows for tracking of country labeling modifications based on global labeling decisions. Headquarters level decisions are tracked based on core labeling associations to country labeling. Countries that market associated products are immediately alerted to any and all updates pertaining to their associated products.

### Milestones

GDT Portal milestones are configurable. The unique standard operating procedures of each pharmaceutical company can be configured so that processes are tracked based on design.

### Timelines

The duration between milestones is defined based on the priority, scope, and origin associated to a decision. Organizations can define one-to-many priorities and daily durations of any length.

### Audit Trail

All modifications are captured by user name and date. Additionally, GDT Portal captures content values before and after an update. This feature provides the basis for GDT Portal's audit trail functionality.

### Multiple Delivery Models

GDT Portal can be hosted internally by your organization or companies can subscribe to the hosted Software-as-a-Service (SaaS) application. The SaaS model provides immediate global access with no software to purchase or install.

### Dashboard

The dashboard feature provides a snapshot of each decisions current status. Users are immediately informed of the decisions current status and alerted to any over-due items. Each decision in the dashboard also provides links for managing the decision.

### Reporting

GDT Portal provides multiple preconfigured reports that detail decision status, country progress, product status, and delayed decisions.



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# Features

## Minimum Server Technical Requirements

- Microsoft Windows Server 2003 SP 3 or greater
- IIS version 6 or greater
- Microsoft Word 2003 or greater
- 4.0 GHz Processor (Minimum)
- 4.0 GB RAM (Minimum)
- 100 GB Storage (Minimum)
- Windows SQL Server 2005
- .Net Framework 3.5

## Decision Management

- Decision content capture
- Grouping of one-to-many decisions to a tracking item
- Priority assignment
- Origin identification
- Tracking item assignment based on country / product mapping
- Centralized procedure functionality
- Global team notes

## Tracking Item Management

- Tracking of multiple milestones for each country
- Country specific notes at the tracking number and milestone level
- Country exclusions
- Current status identification
- Final milestone identification

## Risk Mitigation

- Field level audit trail functionality
- Country specific timeline and performance measurements
- Policy and timeline enforcement

## Milestones and Timelines

- Configurable milestones
- Configurable timeline by priority, scope, and origin
- Final milestone identification

## E-Mail

- Automated e-Mail task notification
- E-Mail alerts for past due items
- Scheduled e-Mail of static reports

## County Configuration

- Product mapping
- E-Mail notification
- Regional grouping
- Final milestone identification

## Administration

- User management
- E-Mail notification management
- Role based access and security
- Country based access
- Priority configuration
- Product management

## Reports

- Dashboard
- Current Status
- Overdue Decisions
- Average Days
- Tracking Number
- Country Performance