



# Deviations Management System

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# 1. Deviations Management

## 1.1. Introduction

### 1.1.1. Platform – Windows SharePoint Services

The Deviations Management system is a web application based on a Windows SharePoint Services 3 (WSS3) platform. WSS3 is a .NET based web application tool which comes for free with Windows 2003 / 2008 Server software. It requires integration with existing MS SQL Server 2000 / 2005 / 2008 database servers.

It integrates with existing Windows Authentication mechanisms such as Active Directory, and provides permissions / security using standard Authentication mechanisms.

Although WSS3 offers various functions, a description of these functions is beyond the scope of this document. For further information on what advantages Windows SharePoint Services offers, please enquire with Computime Ltd.

## 1.2. Deviations Management

The Deviations Management system allows the tracking of any Deviations from normal processes. The system allows the inputting information related to a specific deviation, and what Corrective Actions have been taken to mitigate the effects of the deviation.

Deviation information recorded includes the following (fields are customisable as necessary):

- Deviation No (autonumber)
- Product Name (selectable list of products)
- Batch No
- Manufacturing Stage (selectable list of stages)
- Responsible Person
- Quality Control Responsible Person
- Description
- Deviation Type (selectable list of types)
- Time Deviation Stopped Process
- Status (selectable list of statuses)
- Month Deviation Occurred
- Date Deviation Occurred

Correction Actions information recorded includes the following (fields are customisable as necessary):

- Deviation No (relation to Deviations)
- Corrective Action Title

## Deviations Management

- Corrective Action Description

The above database structure creates a relation between Deviations and Corrective Actions. The system also audits who has created the Deviation and Corrective Action entries.

Each list features a number of views. A view is simply a list of items in the Deviations / Corrective Actions list (or a combination of both), sorted by specific fields and possibly filtered by specific criteria

The following views are available by default, though others can be customised as required:

- High Priority Deviations
- Expiring Deviations
- Deviations Grouped by Responsible Person
- Specific Deviation and All Corrective Actions related to it

Besides these, sorting / filtering can be done ad hoc by each user using the system.

The Homepage brings together most components and links required to operate the Deviations Management Solution at a basic level.

Deviation No.	Product Name	Batch No.	Target Date of Completion	Manufacturing Stage	Abbreviation	Deviation Type	Status	Month Deviation Occurred	Description
DEV2008/0001	Loratadine 10mg	F09315 111	31/10/2008	PACKAGING	ROGUE	Minor	C	January	XYZ ...
DEV2008/0002	Ramipril 2.5mg Capsules	F09406	18/10/2008	CAPSULE FILLING	DOCUMENTATION	Minor	C	November	XYZ
DEV2008/0003	Paroxetine 20mg	S21702	01/02/2009	COMPRESSION	PRODUCT SPECIFIC ISSUES	Major	IP	January	XYZ
DEV2008/0004	Ramipril 10mg Tablets	F09632	17/10/2008	PACKAGING	MISSED TEST	Major	C	January	XYZ
DEV2008/0005	Glimesipride 4mg	S22362	28/10/2008	GRANULATION	EQUIPMENT	Minor	C	February	XYZ
DEV2008/0006	Mirtazapine Orodispersable 15mg	S22080	02/10/2008	DRY BLENDING	DOCUMENTATION	Major	C	February	XYZ
DEV2008/0007	Sertraline 50mg	F09408	01/09/2008	PACKAGING	MACHINE SETTING	Minor	C	February	XYZ
DEV2008/0008	Terbinafine 250mg	F09356	14/10/2008	PACKAGING	DOCUMENTATION	Minor	C	April	XYZ
DEV2008/0010	Ciprofloxacin 250mg	F09354	10/11/2008	PACKAGING	ROGUE	Minor	C	January	XYZ
DEV2008/0011	Lisinopril / HCT 20/12.5mg	F09565	05/12/2008	PACKAGING	EQUIPMENT	Minor	IP	March	XYZ
DEV2008/0012	Ramipril 5mg Tablets	S22111	21/11/2008	IN-PROCESS	EQUIPMENT	Major	C	July	XYZ
DEV2008/0021	test item 1	t1	12/12/2008	CAPSULE FILLING	MISSED TEST	Minor	IP	Merch	ABC
DEV2008/0022	test item 2	t2	07/07/2008	DRY BLENDING	MISSED TEST	Minor	C	April	ABC
DEV2008/0023	TEST ITEM 3	T13	25/11/2008	GRANULATION	PROCEDURES	Minor	C	August	abc
DEV2008/0024	TEST ITEM 4	T14	11/11/2008	IN-PROCESS	PRODUCT SPECIFIC ISSUES	Major	IP	January	abc
DEV2008/0025	TEST ITEM 5	T15	05/02/2008	COATING	ROGUE	Major	IP	February	ABC
DEV2008/0026	TEST ITEM 6	T16	22/03/2008	DISPENSING	PACKMAT	Major	C	March	abc
DEV2008/0027	TEST ITEM 7	T17	16/08/2008	QC	UTILITIES	Minor	C	May	ABC
DEV2008/0028	test item 8	t8	03/01/2008	GRANULATION	DOCUMENTATION	Minor	C	December	abc

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### **1.2.1. Deviations Preview**

There's a small view on the homepage that allows users to view the most important fields of the latest deviations. A bulb can be found near each deviation, where a green bulb marks "Complete", and a yellow bulb marks "In Progress".

### **1.2.2. Reports**

This will launch the reporting module, which will be explained at a later stage.

### 1.3. Deviations List

Deviations are stored as a custom list. This list can be accessed by selecting it from the navigation bar on the left.

#### 1.3.1. Adding a Deviation

The screenshot shows a web application interface for adding a new deviation. The form is titled 'Deviations: New Item' and includes the following fields:

- Deviation No.: WILL BE AUTOMATICALLY FILLED IN LATER
- Product Name: [Text Input]
- Batch No.: [Text Input]
- Compression/Coating No.: [Text Input]
- Manufacturing Stage: CAPSULE FILLING (Dropdown)
- Abbreviation: (None) (Dropdown)
- Responsible Person: [Text Input]
- QC Responsible Person: [Text Input]
- Description: [Rich Text Editor]
- Deviation Type: (None) (Dropdown)
- Target Date of Completion: [Date Picker]
- Date of Completion: [Date Picker]
- Interval for finalization of Deviations: (None) (Dropdown)
- Time deviation stopped process (minutes): [Text Input]
- Status: (None) (Dropdown)
- Month Deviation Occured: [Dropdown]
- Date Deviation Occured: [Date Picker]

A new deviation can be added to the Deviations list by clicking **New** → **New Item**. This loads a form with all the details necessary to describe a new deviation. While most fields aren't required, it is an encouraged practice that the user fills as many as possible, to help make the item as distinguishable as can be.

- > The Autonumbering System  
Deviations have an identification number, called a **Deviation Number**, automatically assigned to them. The number is based on the year and the item's number in the list. This number is saved to the deviation shortly after the user creates it.

#### 1.3.2. Modifying a Deviation

A deviation can be modified by finding the deviation in the list and opening it. Selecting **Edit Item** in the next window will allow the user to edit any fields pertaining to the deviation.

Alternately, a user can select to edit the deviation form the drop-down menu by its **Deviation Number**.

### 1.3.3. Sorting Deviations

The deviations list can be sorted by clicking any field header (i.e. field name), and selecting the way the list is to be sorted/filtered.

NOTE that from the web part on the homepage, Deviations can only be sorted by Deviation Number.

### 1.3.4. Filtering

Filtering can be performed on the list by selecting a field header and picking a value with which to filter the data. For example, to show all deviations of **Deviation Type** 'Major', the value 'Major' must be selected as shown below:

The screenshot shows a table titled 'Deviations' with the following columns: Deviation No., Product Name, Batch No., Target Date of Completion, Manufacturing Stage, Abbreviation, Deviation Type, and Cons. The table contains four rows of data. A dropdown menu is open over the 'Deviation Type' column, showing options: Ascending, Descending, Clear Filter from Deviation Type (Empty), Major (selected), and Minor. The 'Major' option is highlighted in blue.

Deviation No.	Product Name	Batch No.	Target Date of Completion	Manufacturing Stage	Abbreviation	Deviation Type	Cons
DEV2008/0001	Loratadine 10mg	F09315 111	31/10/2008	PACKAGING			0
DEV2008/0002	Ramipril 2.5mg Capsules	F09406	18/10/2008	CAPSULE FILLING			0
DEV2008/0003	Paroxetine 20mg	S21702	01/02/2009	COMPRESSION			0
DEV2008/0004	Ramipril 10mg Tablets	F09632	17/10/2008	PACKAGING	MISSED TEST	Major	0

NOTE that information can also be filtered, sorted, grouped and displayed by creating and using different **views**. These can be created by administrators, but used by all.

## 1.4. Supporting Lists

### 1.4.1. Deviation Types

Users of a sufficiently qualified security level will be allowed to create, modify and delete any **Deviation Types** for use in the **Deviations** list.

Note that deleting **Deviation Types** that are currently in use will simply blank their fields in the **Deviations** list.

### 1.4.2. Abbreviations

Users of a sufficiently qualified security level will be allowed to create, modify and delete any **Abbreviations** for use in the **Deviations** list.

Note that deleting **Abbreviations** that are currently in use will simply blank their fields in the **Deviations** list.

### 1.4.3. Manufacturing Stages

Users of a sufficiently qualified security level will be allowed to create, modify and delete any **Manufacturing Stages** for use in the **Deviations** list.

Note that deleting **Manufacturing Stages** that are currently in use will simply blank their fields in the **Deviations** list.

### 1.4.4. Statuses

Users of a sufficiently qualified security level will be allowed to create, modify and delete any **Statuses** for use in the **Deviations** list.

Note that deleting **Statuses** that are currently in use will simply blank their fields in the **Deviations** list. Furthermore, any new **Statuses** created will not have matching coloured icons (as was the case with "Complete" and "In Progress").

## 1.5. Corrective Actions

A **Corrective Action** may be created from the **Corrective Actions** list, accessible from the Quick Launch Navigation (Refer to **1.1.4**). Once viewing the **Corrective Actions** list, a user can view, create and even modify (depending on the user's access rights) **Corrective Actions**. Since **Corrective Actions** depend on **Deviations**, the user will have to select a **Deviation** from the list based on their **Deviation Number**.

Corrective Actions can also be created directly from the portal's homepage by clicking on **Create a New Corrective Action** in the **Actions** list to the right.

> [Corrective Action](#) > [New Item](#)

### Corrective Action: New Item

OK Cancel

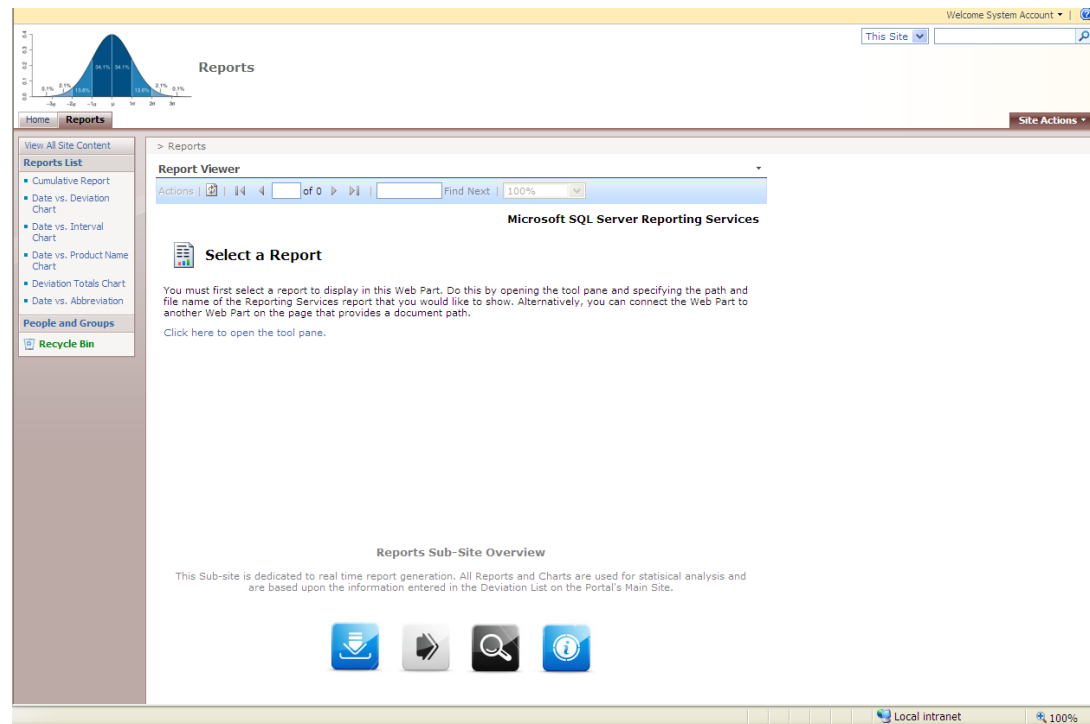
Attach File \* indicates a required field

Deviation	<input type="text"/>
Corrective Action Title *	(None) DEV2008/0001 DEV2008/0002 DEV2008/0003 DEV2008/0004 DEV2008/0005 DEV2008/0006 DEV2008/0007
Corrective Action Description	

Display lookup values

OK Cancel

## 2. Reports



The **Reports** page allows for the creation of six kinds of reports:

- > Cumulative Report
- > Date vs. Abbreviation Chart
- > Date vs. Deviation Chart
- > Date vs. Interval Chart
- > Date vs. Product Name Chart
- > Deviation Totals Chart

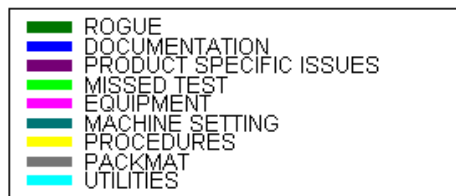
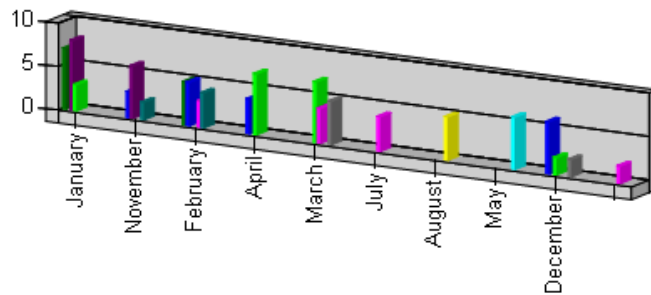
All reports can be exported from the portal to a variety of formats, allowing them to be published and viewed externally.

Other reports can be created as necessary, both by Computime, or following training by the client.

## 2.1. Cumulative Report

This report adds all different **abbreviations** and their appearances over the months.

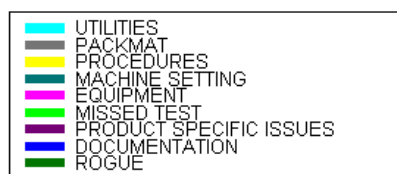
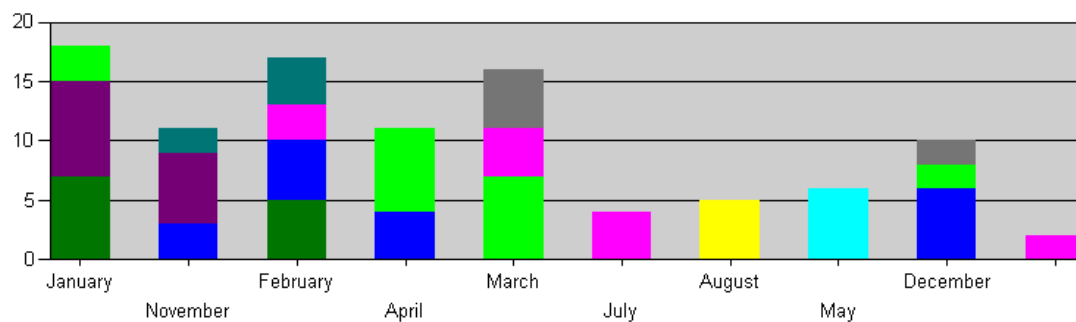
### Cumulative Chart



## 2.2. Date vs. Abbreviations Report

This report lists the different abbreviations used per month.

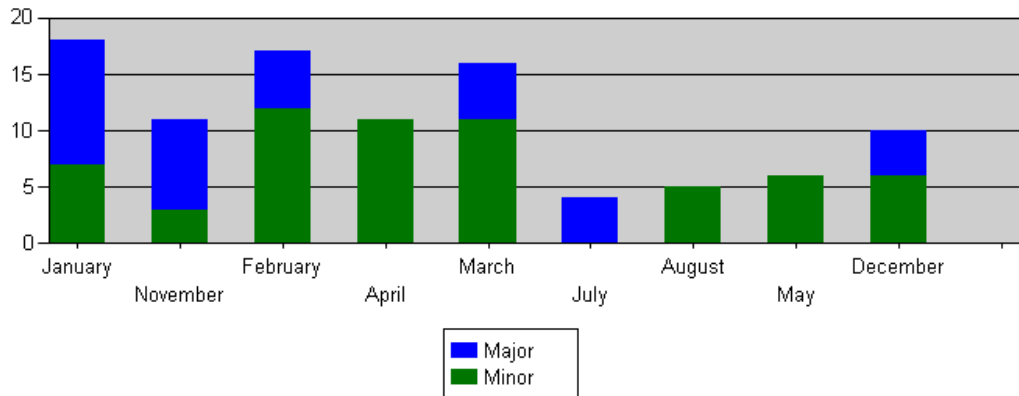
### Date vs Abbreviation Chart



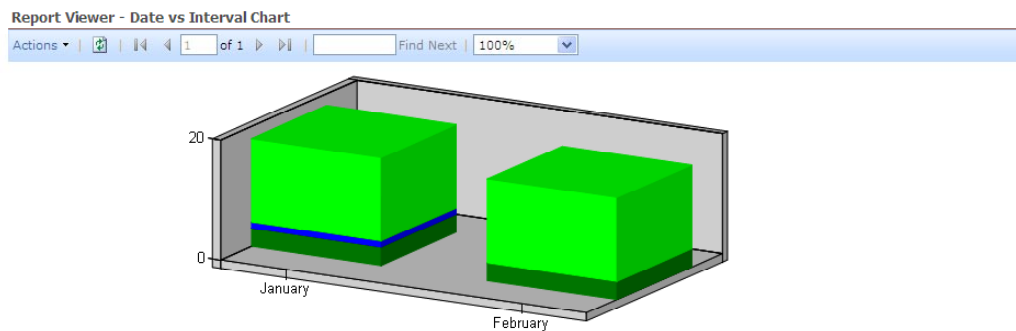
### 2.3. Date vs. Deviation Types Report

This report lists the occurrences of all deviation types over a given year.

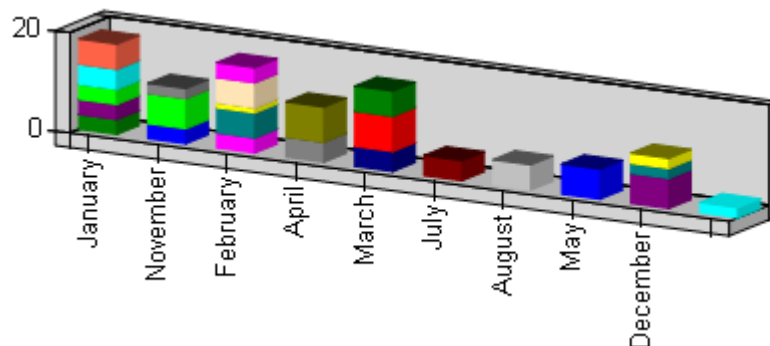
#### Date vs Deviation Type Chart



### 2.4. Date vs. Interval Report



### 2.5. Date vs. Product Name Report



This report lists all product deviations per month for a year.

### **3. Generic Functionality**

The Deviations Management System has been designed to be both simple to use and flexible in terms of customisation.

#### **3.1. Fields in Deviations / Corrective Actions list**

Field names and any additional fields can be created by Administrative users of the system. Items in drop down lists can also be customised as necessary to suit the needs of the client.

#### **3.2. Views customisation**

Views of each list can be created as necessary. If users require a specific view of the information in a list e.g. deviations which will be expiring in the next 7 days, these can be created easily

#### **3.3. Attachments**

The system allows documents or other attachments to be attached to any item in a list (Deviation / Corrective Action). Areas can also be created to provide additional documents such as documentation, help files, images, etc. These can either be generic, or specific to particular deviations.

#### **3.4. Permissions**

The system is flexible in terms on permissions. Users can have Administrative rights (be able to customise the system), Contribute rights (can input new information into lists), or Read Only rights. Combination of rights is also possible, e.g. Read Only on Deviations, Contribute on Corrective Actions.

#### **3.5. Export**

Items in a list can easily be exported to Excel. Reports can be exported to a number of formats including CSV, PDF.

#### **3.6. Notifications**

System allows a user to subscribe to an alerting mechanism i.e. sends an email when a particular list has been updated, or send an email when an item I have created has been updated.