

## Optional software for CLASS-Agent CLASS-Agent Report



The CLASS-Agent Report is software that creates reports based on Excel's report templates and analysis results registered in the CLASS-Agent database. The Excel, though widely used for creating reports, lacks audit trail, security and electronic signature functions mandatory for the compliance with FDA 21 CFR Part 11. CLASS-Agent Report allows the use of Excel in an environment satisfying the Part 11 requirements by providing the features of Audit Trail, Security and Electronic Signature.

### **Simple system creation**

Report templates can be created quickly by re-using existing Excel worksheets. Created templates are easily saved to the database for secure management using the registration tool. This reduces the workload before the system can be operated after introduction.

### **Easier report generation**

Reports are generated automatically simply by selecting analysis data and report templates registered in the CLASS-Agent database. No manual input is required, saving effort for report generation and checking.

### **Automatic generation of PDF files**

A PDF file is generated automatically at the same time an Excel report file is created. The excellent portability of PDF files is effective for electronic report transfer.

### **Automatic database registration**

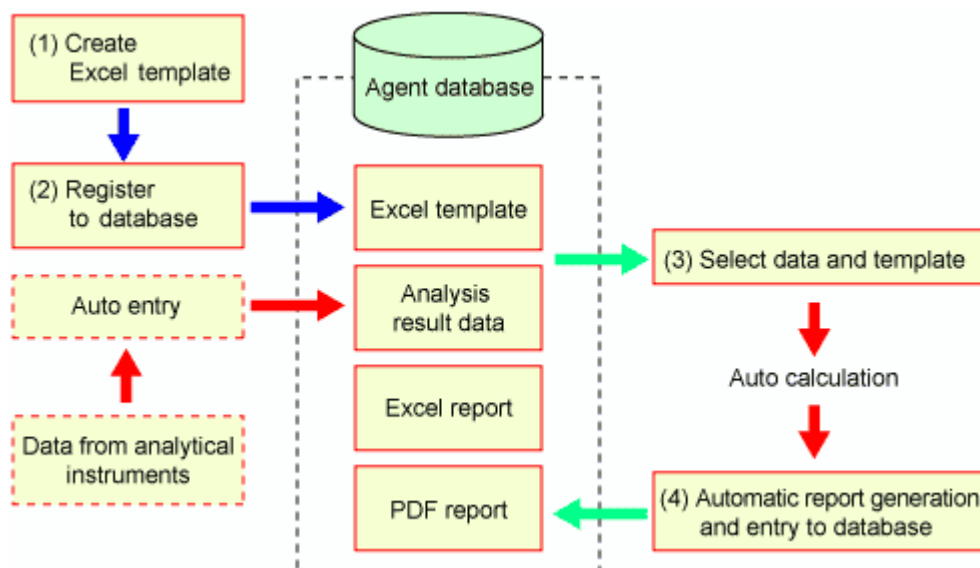
Created reports are automatically saved in the database for secure storage. Required reports and analysis data can be easily found and recalled using the associated information that is automatically registered simultaneously.

### **Electronic signature-compatible**

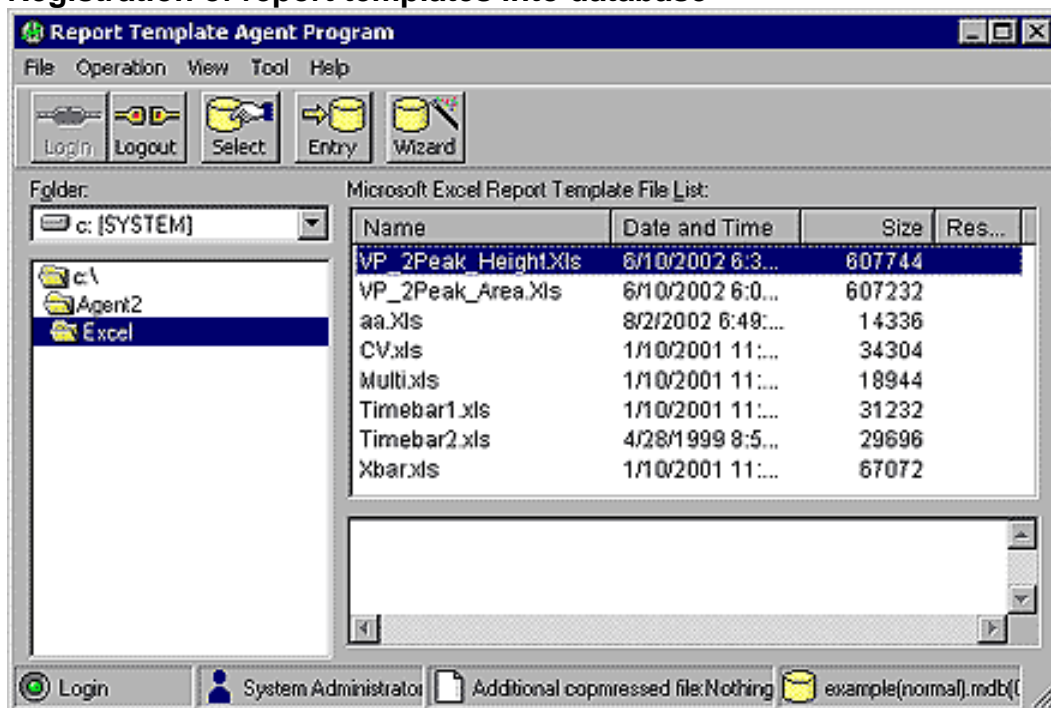
Electronic signatures can be applied to reports using standard functions of CLASS-Agent Manager

### **Unified operation for all analytical instruments**

From the data once registered by CLASS-Agent, you can create reports for any analytical instruments in a same operation.



## Registration of report templates into database



## Example of report

The screenshot displays a software application window titled 'LABS Agent Manager Ver. 2.1'. The main window contains a table with columns: Sample name, Data process type, Instrument name, Reg. date, Approval, Reviewer, Date Reviewed, and Approved by. Below this, an 'Adobe Acrobat' window is open, displaying an 'Area Report' for file 'MICRON10206110070.10.PDF'. The report includes a table with columns: Data file name, Sample ID, Time acquired, Val. No., Peak # (Peak), Area, Height, Area (%) and a summary section for Average, Standard Deviation, and Coefficient of Variation (%).

Sample name	Data process type	Instrument name	Reg. date	Approval	Reviewer	Date Reviewed	Approved by
40	PAC	Port1	1999/05/21 20:00:15+0900	Uncollected			
41	PAC	Port1	1999/05/21 20:00:17+0900	Uncollected			
42	PAC	Port1	1999/05/21 20:00:19+0900	Uncollected			
43	Wilson STD	LCTD-1	1999/05/21 19:39:25+0900	Uncollected			
44	Wilson STD	LCTD-1	1999/05/21 19:39:26+0900	Uncollected			
45	Wilson STD	LCTD-1	1999/05/21 19:39:19+0900	Uncollected			
46	VP	Instrument1	1999/05/21 19:17:32+0900	Uncollected			
47	VP	Instrument1	1999/05/21 19:17:35+0900	Uncollected			

Area Report					
File Name	Instrument Name	Date acquired	Operator	Method file	Sequence file
MICRON10206110070.10.PDF	Instrument1	2003/02/22	System Administrator	Micron.vp.method.MICRON10206110070.10.PDF	

Data file name	Sample ID	Time acquired	Val. No.	Peak # (Peak)	Area	Height	Area (%)	Time	Height	Area (%)	Height (%)
Micron_035.vp.col	Micron_365	15:01:35	0	5.005	31156	31156	4.581	18050	1.293394110		
Micron_036.vp.col	Micron_364	15:02:38	0	3	12360	4.581	4.581	3357	1.90454860		
Micron_037.vp.col	Micron_311	15:04:41	0	3.005	48320	4.581	4.581	28643	1.29744710		
Micron_038.vp.col	Micron_311	15:05:14	0	3.005	48399	4.581	4.581	3315	1.26180620		
Micron_039.vp.col	Micron_365	15:04:42	0	3.005	48350	4.581	4.581	35248	1.29252420		
Micron_039.vp.col	Micron_365	15:05:29	0	3.005	54430	4.581	4.581	14821	1.26329110		
Micron_037.vp.col	Micron_367	15:00:44	0	3.005	33519	4.581	4.581	72673	1.29348950		
Micron_031.vp.col	Micron_361	14:17:54	0	3	48352	4.581	4.581	33679	1.29424370		
Average	-	-	-	-	3.005	31156.20	4.5812	4871	1.26175940		
Standard Deviation	-	-	-	-	0.0317323	5478.4425	3.3044415	4216	0.3315754		
Coefficient of Variation (%)	-	-	-	-	0.1251809	16.0430110	0.1318138	38.4753193	3.78884430		

## Operation Requirements

For Agent Report operation, the following products are required

1. CLASS-Agent Manager Ver. 2.1 or later
2. Microsoft Excel 2000
3. Adobe Acrobat 5.0