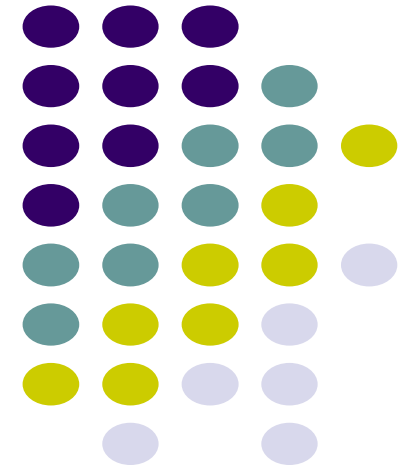




PeP11 LabCal

A system that provides 21 CFR Part 11 controls (open and Closed) to spreadsheet and Word data with electronic signature.





PeP11 Features

- Clients
- Our Edge
- Easy to Use
- 21 CFR Part 11 Compliant
- Implementation Support (Validation & Training)
- Contact Information

Clients





OUR EDGE

- Encrypted Electronic Records
- Complies with Global Regulations for Electronic Record and Electronic Signature
- Auto Restore Database
- No Access to spreadsheet or word file
- Paper Copy **NOT** Required
- Unlimited Forms (Templates) and Data Files

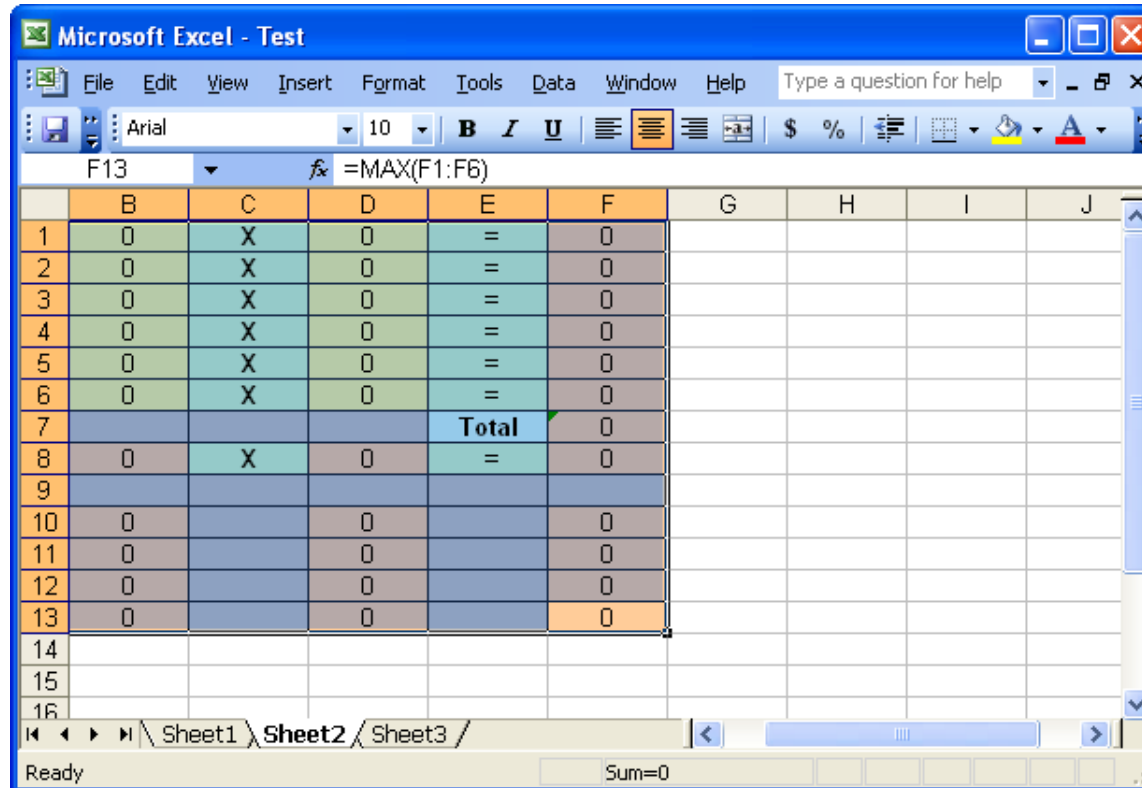


OUR EDGE

- No Change in Company's processes
- Easy to Follow Audit Trail
- Provide comprehensive process control to avoid human errors
- Work as MS Excel or Word
 - Eliminates need of expensive technical personnel to add additional forms and maintain data.
- Easy to Use

Easy to Use

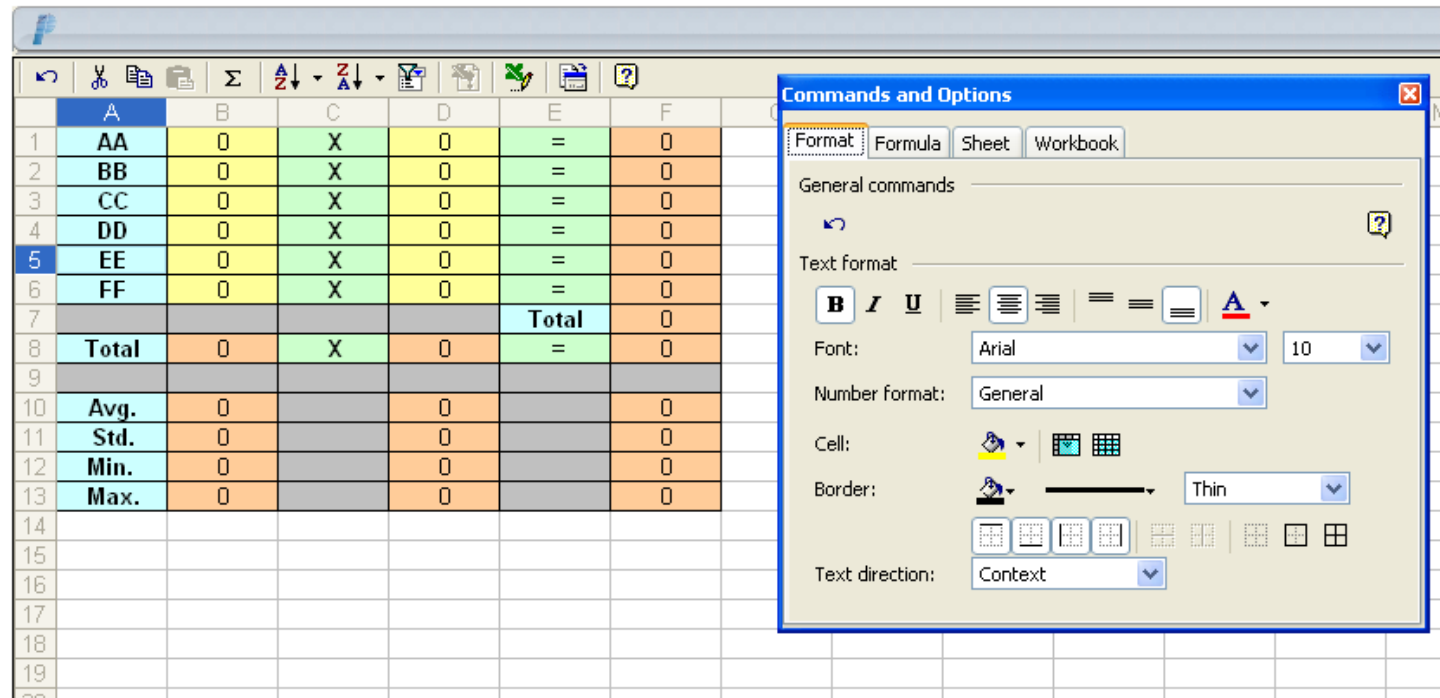
- Copy spreadsheet

A screenshot of a Microsoft Excel spreadsheet titled "Microsoft Excel - Test". The spreadsheet shows a table with columns B through F and rows 1 through 13. The formula bar shows the formula =MAX(F1:F6) in cell F13. The status bar at the bottom shows "Ready" and "Sum=0".

	B	C	D	E	F	G	H	I	J
1	0	X	0	=	0				
2	0	X	0	=	0				
3	0	X	0	=	0				
4	0	X	0	=	0				
5	0	X	0	=	0				
6	0	X	0	=	0				
7				Total	0				
8	0	X	0	=	0				
9									
10	0		0		0				
11	0		0		0				
12	0		0		0				
13	0		0		0				

Easy to Use

- Paste to PeP11 LabCal



The screenshot displays a spreadsheet application window. The spreadsheet contains a table with columns A through F and rows 1 through 13. The data is as follows:

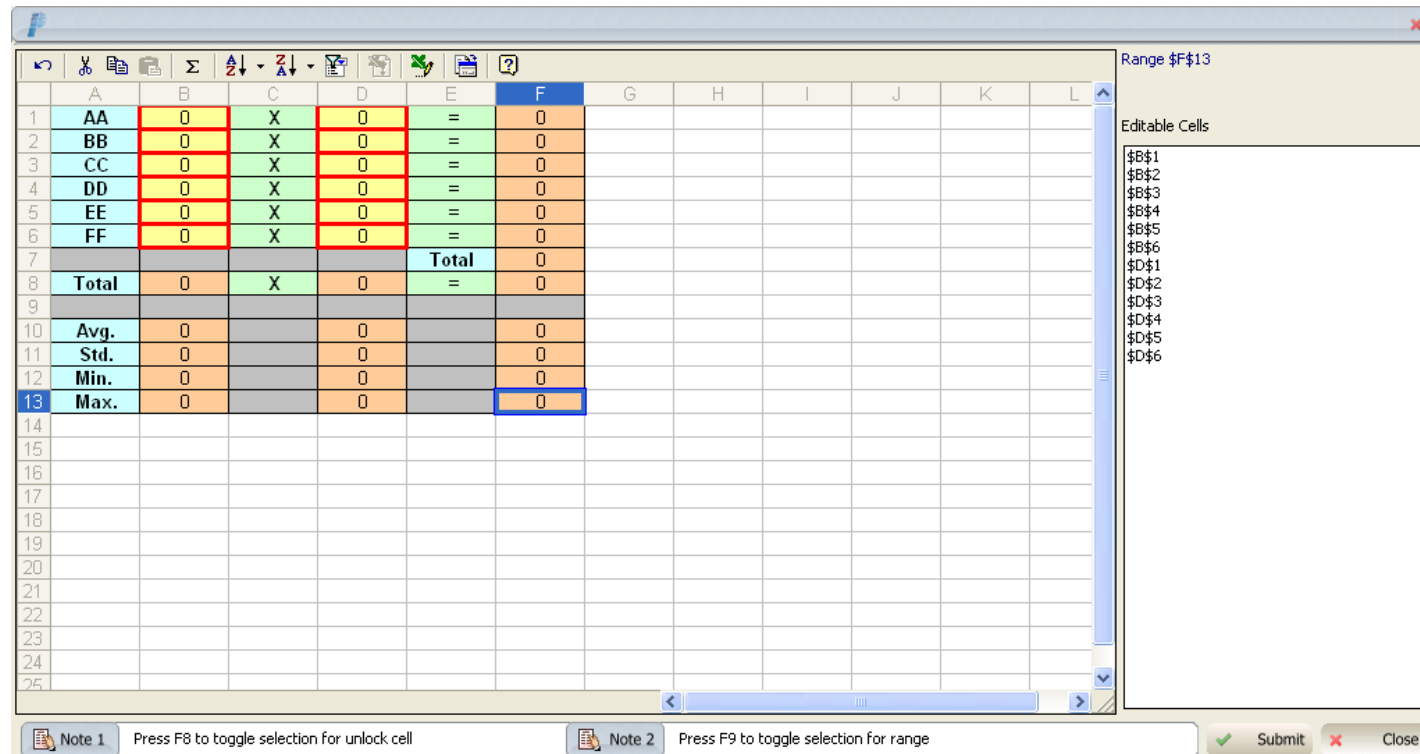
	A	B	C	D	E	F
1	AA	0	X	0	=	0
2	BB	0	X	0	=	0
3	CC	0	X	0	=	0
4	DD	0	X	0	=	0
5	EE	0	X	0	=	0
6	FF	0	X	0	=	0
7					Total	0
8	Total	0	X	0	=	0
9						
10	Avg.	0		0		0
11	Std.	0		0		0
12	Min.	0		0		0
13	Max.	0		0		0

Overlaid on the right side of the spreadsheet is a 'Commands and Options' dialog box. The dialog has tabs for 'Format', 'Formula', 'Sheet', and 'Workbook'. The 'Format' tab is active. It contains the following options:

- General commands: A refresh icon and a help icon.
- Text format: Bold (B), Italic (I), Underline (U), text alignment (left, center, right, justified), bullet point, and font color (A).
- Font: Arial, size 10.
- Number format: General.
- Cell: A dropdown menu and a grid icon.
- Border: A dropdown menu set to 'Thin' and a grid icon.
- Text direction: Context.

Easy to Use

- Secure Cell and Print Range



	A	B	C	D	E	F	G	H	I	J	K	L
1	AA	0	X	0	=	0						
2	BB	0	X	0	=	0						
3	CC	0	X	0	=	0						
4	DD	0	X	0	=	0						
5	EE	0	X	0	=	0						
6	FF	0	X	0	=	0						
7					Total	0						
8	Total	0	X	0	=	0						
9												
10	Avg.	0		0		0						
11	Std.	0		0		0						
12	Min.	0		0		0						
13	Max.	0		0		0						

Range \$F\$13

Editable Cells

\$B\$1
\$B\$2
\$B\$3
\$B\$4
\$B\$5
\$B\$6
\$D\$1
\$D\$2
\$D\$3
\$D\$4
\$D\$5
\$D\$6

Note 1 Press F8 to toggle selection for unlock cell

Note 2 Press F9 to toggle selection for range

Submit Close



21 CFR Part 11 Compliance

- **21 CFR Part 11 Requirements**
 - Closed and Open System Controls
 - Secure Computer Generated Time Stamped Audit Trail (Cell Level)
 - Authority Checks
 - Validation
 - Secure Record
 - Backup, Archive, and Restore
 - Encrypted Electronic Record in Transition (Open System)
 - Electronic Signature



PART11 COMPONENTS

- **Closed and Open System Controls**
 - Secure Computer Generated Time Stamped Audit Trail (Cell Level)

Folder - Form - File Details

Folder Name:	PeP11\DT Folder	
User ID	Super User	Date - Time Created: Aug 1, 2007 1:48 pm
Form Name:	DT Form 2	
User ID	System	Date - Time Created: Aug 1, 2007 5:16 pm
Data File Name:	DT Data File 02	
User ID	User	Date - Time Created: Aug 1, 2007 7:01 pm

Session Details

Session ID	9	Session Created Date-Time Aug 1, 2007 7:00 pm
User ID	User	

Cell Details

Cell Address	Old Data	New Data	Modified Date - Time
\$B\$1	0	1	Aug 1, 2007 7:01 pm
\$B\$2	0	1	Aug 1, 2007 7:01 pm



Audit Trail

Session Details

Session ID 9 Session Created Date-Time Aug 1, 2007 7:00 pm
User ID User

Cell Details

Cell Address	Old Data	New Data	Modified Date - Time
\$B\$1	0	1	Aug 1, 2007 7:01 pm
\$B\$2	0	1	Aug 1, 2007 7:01 pm
\$B\$3	0	13	Aug 1, 2007 7:01 pm
\$B\$4	0	33	Aug 1, 2007 7:01 pm
\$B\$5	0	44	Aug 1, 2007 7:01 pm
\$B\$6	0	4	Aug 1, 2007 7:01 pm
\$B\$7	0	4	Aug 1, 2007 7:01 pm
\$B\$8	0	6	Aug 1, 2007 7:01 pm
\$B\$9	0	8	Aug 1, 2007 7:01 pm
\$B\$10	0	9	Aug 1, 2007 7:01 pm

e - Signature Details

Meaning	User ID	Note	e - Signature Date - Time
Saved	User	Save	Aug 1, 2007 7:01 pm



Audit Trail

e - Signature Details

Meaning	User ID	Note	e - Signature Date - Time
Checked	System Administrator	Check	Aug 1, 2007 7:05 pm

Session Details

Session ID	12	Session Created Date-Time	Aug 1, 2007 7:05 pm
User ID	System Administrator		

Cell Details

Cell Address	Old Data	New Data	Modified Date - Time

e - Signature Details

Meaning	User ID	Note	e - Signature Date - Time
Reviewed	QA	Reviewed	Aug 1, 2007 7:06 pm

Session Details

Session ID	13	Session Created Date-Time	Aug 1, 2007 7:06 pm
User ID	User		

Cell Details

Cell Address	Old Data	New Data	Modified Date - Time

e - Signature Details

Meaning	User ID	Note	e - Signature Date - Time
Approved	Super User	Approve	Aug 1, 2007 7:07 pm



PART 11 COMPONENTS

- **Authority Checks**

- Data file cannot be created unless the form/template is approved.
- Approval Work flow.

Save Discard Submit Print Close Form Name - PVS US Form 01	Checked By Check	Reviewed By None	Approved By None	Modified By None
---	---------------------	---------------------	---------------------	---------------------



PART 11 COMPONENTS

- **Validation**

- Validation package includes User Requirements Specification (URS), Functional Specification (FS), Design Specification (DS), Traceability Matrix, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and 21 CFR Part 11 assessment.

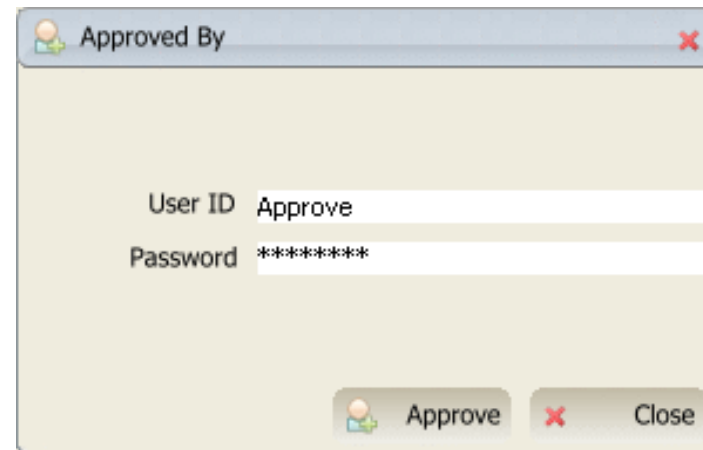


PART 11 COMPONENTS

- **Secure Record**
 - Encrypted Electronic Records with 128-bit AES technology
- **Backup, Archive, and Restore**
 - Daily Back-up
 - Restore automatically from the last back-up
- Encrypted Electronic Record in Transition (Open System) - with 128-bit AES technology

PART 11 COMPONENTS

- **Electronic Signature**
 - Linked to electronic record
 - Two components - User ID and Password

A screenshot of a software dialog box titled "Approved By". The dialog box has a light beige background and a grey title bar with a red close button. It contains two input fields: "User ID" with the text "Approve" and "Password" with "*****". At the bottom, there are two buttons: "Approve" with a person icon and "Close" with a red 'X' icon.

Approved By

User ID Approve

Password *****

Approve Close



Implementation Support

- **Implementation and Support Personnel**
- **PeP11 LabCal Version 1.0 Validation Ppackage**
 - Validation package includes User Requirements Specification (URS), Functional Specification (FS), Design Specification (DS), Traceability Matrix, Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).



Implementation Support

- **Training Program**

- PurnVed Solutions offers a comprehensive training program. This includes an overview of PeP11 LabCal, discussion of all functional aspects of the system, and 21 CFR Part 11 controls, along with hands on training.



adpt@adptllc.com

www.adptllc.com

1.856.580.3869