

**Prospective Software Validation**

Software validation provides documented evidence that software performs as intended. QWXL version 2.2.0.12 has been validated per the protocol established by Busitech and agreed to by its primary customer representatives. Any discrepancies discovered in the validation process that could not be resolved by the product release date will clearly be identified in the validation report and corrected in future versions.

QWXL is a separate program that interfaces with data in Microsoft Excel as an Excel "Add-In". It is called up by highlighting data in rows or columns and clicking on the installed QWXL button on the toolbar. It either uses default targets and limits or reads values preset in the spreadsheet...or allows the user to save values to their spreadsheet once in the program. So in this respect, QWXL is configurable to the customer's application.

The customer may need to do additional software validation (right limits, etc) when QWXL is applied in a regulated application. This additional validation, if needed, is the responsibility of the customer and is typically referred to as a Performance Validation (PQ).

Busitech provides the following validation so that customers can have confidence in Busitech products and comply with their needs to use validated software.

Busitech programming code is proprietary to Busitech and not available for customer review. All code is based on Visual Basic 6, a commercially released Microsoft programming language and fully compatible with Windows 95, 98, 2000, XP and NT.

**Validation Process**

The validation protocol (also known as a test plan) lays out the tests and success criteria required by the validation process. Validation testing is typically organized into 3 steps:

INSTALLATION QUALIFICATION (IQ)	-static checks
OPERATIONAL QUALIFICATION (OQ)	-dynamic testing
PERFORMANCE QUALIFICATION (PQ)	-application verification

Busitech only does IQ and OQ. PQ if necessary is the responsibility of the customer.

The validation report presents the test data relative to success criteria, documents that reviews were completed and notes any discrepancies that were released with notification to customers via the validation report.

The validation process is repeated with each released version. Busitech maintains the right to shorten the validation process or reapply the previous validation when programming changes are known to have not changed specific areas of the program, as is the case with some maintenance releases.

**Prospective Software Validation**

## Validation Protocol

**Installation Qualification (IQ)**

## Objectives and Success Criteria

The installation program provided by Busitech will ensure that

- All the right programs (of the right version) are in the right folders.
- All the Busitech components (dll and ocx) are in the right folders.

## Key risks

- Wrong version files are installed.
- Necessary files are not successfully installed.
- Note: the customer may choose to not use the Busitech install program or the customer may tamper with the files after installation. Changes of this nature are the responsibility of the customer to both control & validate.

## Steps &amp; Checks

1. The software will be installed onto a PC (which does not currently have QWXL installed) using the Busitech install program.
2. All files will be verified (relative to a master file list) as to their presence, location, version number and compile date. Note that user can choose to change the default location and name of the folders.
3. A listing of Busitech installed files will be included in the validation report, showing the version number and compile date of each program.

**Prospective Software Validation****Validation Report****Installation Qualification (IQ)****Objectives and Success Criteria**

The installation program provided by Busitech will ensure that:

All the right programs (of the right version) are in the right folders.

All the Busitech components ( dll and ocx) are in the right folders

**Steps & Checks**

The software will be installed onto a PC (which does not currently have QWXL installed) using the Busitech install program. (Completed by Noel Windle January 5, 2004)

All files will be verified as to their presence (relative to a master file list), location and compile date. (Completed by Noel Windle January 5, 2004)

All programs and files will be verified (relative to a master file list) as to their presence, location, version number and compile date. A listing of Busitech installed programs and files is shown below, showing the version number and compile dates.

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File	MM/DD/YY	Version
<b>Files installed in C:\Busitech\QWXLV2 (default)</b>		
GettingStarted.XLS	04/03/03	Not Applicable
PROCESS.QWD	05/14/99	Not Applicable
PROCESS.QWI	05/14/99	Not Applicable
PROCESS.QWT	05/14/99	Not Applicable
PROCESS.XLS	05/18/99	Not Applicable
QWIMPORT.EXE	01/11/01	2.0
QWREGIST.EXE	03/29/01	1.0
QWXL.CNT	04/17/00	Not Applicable
QWXL.DEP	01/27/00	Not Applicable
QWXL.EXE	11/12/02	2.2.0.12
QWXL.HLP	09/17/02	Not Applicable
QWXL.ICO	05/20/99	Not Applicable
QWXLV2.XLA	02/28/03	Not Applicable
TABLES.INI	12/07/99	Not Applicable
UNWISE.EXE	12/27/96	Not Applicable
INSTALL.LOG (created at install time)		Not Applicable
<b>Files installed in C:\Windows\System</b>		
ASYCFILT.DLL	05/04/01	2.40.4517
COMCAT.DLL	05/04/01	5.0
COMCT332.OCX	05/22/00	6.07.8862
COMDLG32.OCX	05/06/99	6.00.8418
MSCOMCTL.OCX	05/22/00	6.00.8862
MSVBVM60.DLL	05/26/00	6.00.8877
OLEAUT32.DLL	05/04/01	2.40.4517
OLEPRO32.DLL	05/04/01	5.0.4517
STDOLE2.TLB	05/04/01	2.40.4517

Existing files are overwritten only if Date, Time and internal version numbers of the files being installed are newer.

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**Operational Qualification -OQ**

## Objectives and Success Criteria

- All key features of this software will perform as intended.
- All statistics will calculate as intended by Busitech, and be consistent between screens.
- All colors will be consistent throughout the program.
- Calculated Targets & Control Limits will be accurately calculated and drawn.

## Key risks

- Customer receives false signals...wrong or missing alarms, wrong colors or wrong calculated control limits.
- Customer makes incorrect conclusions...inaccurate statistics, color zones or calculated control limits.
- Features do not work properly or as intended.

## Steps &amp; Checks

1. The software will be brought up using a standardized template, database and views designed for the purpose of validation. This is kept constant between QWXL versions to make it easy to identify problems.
2. Busitech has a program called "BenchMark" specifically designed to automatically validate all statistical calculations using a test database. The output from this program will be attached to the validation report.
3. All key functions and features of the software will be checked on each screen manually. Successful completion of these checks (who and when checked) will be confirmed on the validation report.
4. The consistency of alarms and colors will be checked for at least 10 variables between all screens (control, relate, compare). A view is used to test different combinations of calculated targets and limits on the same variables. The consistency of alarms, colors and control limit calculations is confirmed on the validation report (who and when checked).

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**Operational Qualification -IQ**

## Objectives and Success Criteria

- All features of this software will perform as intended.
- All statistics will calculate as intended, and be consistent between screens.
- All colors will be consistent throughout the program.
- Calculated Targets & Control Limits will be accurately calculated and drawn.

## Steps &amp; Checks

- The software will be brought up using a standardized template, database and views designed for the purpose of validation. This is kept constant between QWXL versions to make it easy to identify problems. Busitech has a program specifically designed to automatically validate all statistical calculations using the standardized template and database. See QWXL Statistics Validation Report below.
- All functions and features of the software will be checked on each screen manually. (Completed by Noel Windle August 20, 2002)
- The consistency of alarms and colors will be checked for at least 10 variables between all screens (control, relate, compare). Different combinations of calculated targets and limits on the same variable are tested. The consistency of alarms, colors and control limit calculations is confirmed on the validation report. (Completed by Noel Windle August 20, 2002)

**BenchMark Generated QWXL Statistics Validation Report**

QWXL 2.2.0.12 2004-01-08 16:49:08

Variable	Statistic	Benchmark	Value	Test
C- FFFFFFFF	N	99	99	PASS
C- FFFFFFFF	Tgt_Dev	59.729	59.729	PASS
C- FFFFFFFF	SD	456.346	456.346	PASS
C- FFFFFFFF	Max	2304.83	2304.830	Formating*
C- FFFFFFFF	+4S	2335.114	2335.114	PASS
C- FFFFFFFF	+3S	1878.768	1878.768	PASS
C- FFFFFFFF	Xbar	509.729	509.729	PASS
C- FFFFFFFF	-3S	-859.31	-859.31	PASS
C- FFFFFFFF	-4S	-1315.656	-1315.656	PASS
C- FFFFFFFF	Min	-860.08	-860.080	Formating*
C- FFFFFFFF	Obser_% OSL	6.061	6.061	PASS
C- FFFFFFFF	Obser_PPM OSL	60606	60606	PASS
C- FFFFFFFF	Calc_% OSL	3.29	3.29	PASS
C- FFFFFFFF	Calc_PPM OSL	32900	32900	PASS
C- FFFFFFFF	Cr	1.4	1.4	PASS
C- FFFFFFFF	Tz	0.1	0.1	PASS
C- FFFFFFFF	Cpk	0.7	0.7	PASS
D- CCCCCC	N	99	99	PASS
D- CCCCCC	Tgt_Dev			PASS
D- CCCCCC	SD	456.346	456.346	PASS
D- CCCCCC	Max	2304.83	2304.830	Formating*

Prospective Software Validation				
D- CCCCCC	+4S	2335.114	2335.114	PASS
D- CCCCCC	+3S	1878.768	1878.768	PASS
D- CCCCCC	Xbar	509.729	509.729	PASS
D- CCCCCC	-3S	-859.31	-859.31	PASS
D- CCCCCC	-4S	-1315.656	-1315.656	PASS
D- CCCCCC	Min	-860.08	-860.080	Formating*
D- CCCCCC	Obser_% OSL			PASS
D- CCCCCC	Obser_PPM OSL			PASS
D- CCCCCC	Calc_% OSL			PASS
D- CCCCCC	Calc_PPM OSL			PASS
D- CCCCCC	Cr			PASS
D- CCCCCC	Tz			PASS
D- CCCCCC	Cpk			PASS
E- BBBB	N	99	99	PASS
E- BBBB	Tgt_Dev			PASS
E- BBBB	SD			PASS
E- BBBB	Max			PASS
E- BBBB	+4S			PASS
E- BBBB	+3S			PASS
E- BBBB	Xbar			PASS
E- BBBB	-3S			PASS
E- BBBB	-4S			PASS
E- BBBB	Min			PASS
E- BBBB	Obser_% OSL			PASS
E- BBBB	Obser_PPM OSL			PASS
E- BBBB	Calc_% OSL			PASS
E- BBBB	Calc_PPM OSL			PASS
E- BBBB	Cr			PASS
E- BBBB	Tz			PASS
E- BBBB	Cpk			PASS
F- FFCFCFF	N	99	99	PASS
F- FFCFCFF	Tgt_Dev	59.729	59.729	PASS
F- FFCFCFF	SD	456.346	456.346	PASS
F- FFCFCFF	Max	2304.83	2304.830	Formating*
F- FFCFCFF	+4S	2335.114	2335.114	PASS
F- FFCFCFF	+3S	1878.768	1878.768	PASS
F- FFCFCFF	Xbar	509.729	509.729	PASS
F- FFCFCFF	-3S	-859.31	-859.31	PASS
F- FFCFCFF	-4S	-1315.656	-1315.656	PASS
F- FFCFCFF	Min	-860.08	-860.080	Formating*
F- FFCFCFF	Obser_% OSL	7.071	7.071	PASS
F- FFCFCFF	Obser_PPM OSL	70707	70707	PASS
F- FFCFCFF	Calc_% OSL	14.64	14.64	PASS
F- FFCFCFF	Calc_PPM OSL	146400	146400	PASS
F- FFCFCFF	Cr	1.83	1.83	PASS
F- FFCFCFF	Tz	0.1	0.1	PASS
F- FFCFCFF	Cpk	0.37	0.37	PASS
G- FFFFBBB	N	99	99	PASS
G- FFFFBBB	Tgt_Dev	59.729	59.729	PASS

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G- FFFFBBB	SD	456.346	456.346 PASS
G- FFFFBBB	Max	2304.83	2304.830 Formating*
G- FFFFBBB	+4S	2335.114	2335.114 PASS
G- FFFFBBB	+3S	1878.768	1878.768 PASS
G- FFFFBBB	Xbar	509.729	509.729 PASS
G- FFFFBBB	-3S	-859.31	-859.31 PASS
G- FFFFBBB	-4S	-1315.656	-1315.656 PASS
G- FFFFBBB	Min	-860.08	-860.080 Formating*
G- FFFFBBB	Obser_% OSL	4.04	4.04 PASS
G- FFFFBBB	Obser_PPM OSL	40404	40404 PASS
G- FFFFBBB	Calc_% OSL	1.5	1.5 PASS
G- FFFFBBB	Calc_PPM OSL	15000	15000 PASS
G- FFFFBBB	Cr	1.3	1.3 PASS
G- FFFFBBB	Tz	0.1	0.1 PASS
G- FFFFBBB	Cpk	0.72	0.72 PASS
H- BBBFFFF	N	99	99 PASS
H- BBBFFFF	Tgt_Dev	59.729	59.729 PASS
H- BBBFFFF	SD	456.346	456.346 PASS
H- BBBFFFF	Max	2304.83	2304.830 Formating*
H- BBBFFFF	+4S	2335.114	2335.114 PASS
H- BBBFFFF	+3S	1878.768	1878.768 PASS
H- BBBFFFF	Xbar	509.729	509.729 PASS
H- BBBFFFF	-3S	-859.31	-859.31 PASS
H- BBBFFFF	-4S	-1315.656	-1315.656 PASS
H- BBBFFFF	Min	-860.08	-860.080 Formating*
H- BBBFFFF	Obser_% OSL	2.02	2.02 PASS
H- BBBFFFF	Obser_PPM OSL	20202	20202 PASS
H- BBBFFFF	Calc_% OSL	1.79	1.79 PASS
H- BBBFFFF	Calc_PPM OSL	17900	17900 PASS
H- BBBFFFF	Cr	1.52	1.52 PASS
H- BBBFFFF	Tz	0.1	0.1 PASS
H- BBBFFFF	Cpk	0.7	0.7 PASS
I- CCCCBBB	N	99	99 PASS
I- CCCCBBB	Tgt_Dev		PASS
I- CCCCBBB	SD	456.346	456.346 PASS
I- CCCCBBB	Max	2304.83	2304.830 Formating*
I- CCCCBBB	+4S	2335.114	2335.114 PASS
I- CCCCBBB	+3S	1878.768	1878.768 PASS
I- CCCCBBB	Xbar	509.729	509.729 PASS
I- CCCCBBB	-3S	-859.31	-859.31 PASS
I- CCCCBBB	-4S	-1315.656	-1315.656 PASS
I- CCCCBBB	Min	-860.08	-860.080 Formating*
I- CCCCBBB	Obser_% OSL		PASS
I- CCCCBBB	Obser_PPM OSL		PASS
I- CCCCBBB	Calc_% OSL		PASS
I- CCCCBBB	Calc_PPM OSL		PASS
I- CCCCBBB	Cr		PASS
I- CCCCBBB	Tz		PASS
I- CCCCBBB	Cpk		PASS

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J- BBBCCCC	N	99	99 PASS
J- BBBCCCC	Tgt_Dev		PASS
J- BBBCCCC	SD	456.346	456.346 PASS
J- BBBCCCC	Max	2304.83	2304.830 Formating*
J- BBBCCCC	+4S	2335.114	2335.114 PASS
J- BBBCCCC	+3S	1878.768	1878.768 PASS
J- BBBCCCC	Xbar	509.729	509.729 PASS
J- BBBCCCC	-3S	-859.31	-859.31 PASS
J- BBBCCCC	-4S	-1315.656	-1315.656 PASS
J- BBBCCCC	Min	-860.08	-860.080 Formating*
J- BBBCCCC	Obser_% OSL		PASS
J- BBBCCCC	Obser_PPM OSL		PASS
J- BBBCCCC	Calc_% OSL		PASS
J- BBBCCCC	Calc_PPM OSL		PASS
J- BBBCCCC	Cr		PASS
J- BBBCCCC	Tz		PASS
J- BBBCCCC	Cpk		PASS
K- FFFCFFF	N	99	99 PASS
K- FFFCFFF	Tgt_Dev		PASS
K- FFFCFFF	SD	456.346	456.346 PASS
K- FFFCFFF	Max	2304.83	2304.830 Formating*
K- FFFCFFF	+4S	2335.114	2335.114 PASS
K- FFFCFFF	+3S	1878.768	1878.768 PASS
K- FFFCFFF	Xbar	509.729	509.729 PASS
K- FFFCFFF	-3S	-859.31	-859.31 PASS
K- FFFCFFF	-4S	-1315.656	-1315.656 PASS
K- FFFCFFF	Min	-860.08	-860.080 Formating*
K- FFFCFFF	Obser_% OSL	6.061	6.061 PASS
K- FFFCFFF	Obser_PPM OSL	60606	60606 PASS
K- FFFCFFF	Calc_% OSL	3.29	3.29 PASS
K- FFFCFFF	Calc_PPM OSL	32900	32900 PASS
K- FFFCFFF	Cr	1.4	1.4 PASS
K- FFFCFFF	Tz	0	0 PASS
K- FFFCFFF	Cpk	0.7	0.7 PASS
L- CCCFCCC	N	99	99 PASS
L- CCCFCCC	Tgt_Dev	59.729	59.729 PASS
L- CCCFCCC	SD	456.346	456.346 PASS
L- CCCFCCC	Max	2304.83	2304.830 Formating*
L- CCCFCCC	+4S	2335.114	2335.114 PASS
L- CCCFCCC	+3S	1878.768	1878.768 PASS
L- CCCFCCC	Xbar	509.729	509.729 PASS
L- CCCFCCC	-3S	-859.31	-859.31 PASS
L- CCCFCCC	-4S	-1315.656	-1315.656 PASS
L- CCCFCCC	Min	-860.08	-860.080 Formating*
L- CCCFCCC	Obser_% OSL		PASS
L- CCCFCCC	Obser_PPM OSL		PASS
L- CCCFCCC	Calc_% OSL		PASS
L- CCCFCCC	Calc_PPM OSL		PASS
L- CCCFCCC	Cr		PASS

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L- CCCFCCC	Tz	0.1	0.1 PASS
L- CCCFCCC	Cpk		PASS
M- FCFCFCF	N	99	99 PASS
M- FCFCFCF	Tgt_Dev		PASS
M- FCFCFCF	SD	456.346	456.346 PASS
M- FCFCFCF	Max	2304.83	2304.830 Formating*
M- FCFCFCF	+4S	2335.114	2335.114 PASS
M- FCFCFCF	+3S	1878.768	1878.768 PASS
M- FCFCFCF	Xbar	509.729	509.729 PASS
M- FCFCFCF	-3S	-859.31	-859.31 PASS
M- FCFCFCF	-4S	-1315.656	-1315.656 PASS
M- FCFCFCF	Min	-860.08	-860.080 Formating*
M- FCFCFCF	Obser_% OSL	6.061	6.061 PASS
M- FCFCFCF	Obser_PPM OSL	60606	60606 PASS
M- FCFCFCF	Calc_% OSL	3.29	3.29 PASS
M- FCFCFCF	Calc_PPM OSL	32900	32900 PASS
M- FCFCFCF	Cr	1.4	1.4 PASS
M- FCFCFCF	Tz	0	0 PASS
M- FCFCFCF	Cpk	0.7	0.7 PASS
N- CFCFCFC	N	99	99 PASS
N- CFCFCFC	Tgt_Dev	59.729	59.729 PASS
N- CFCFCFC	SD	456.346	456.346 PASS
N- CFCFCFC	Max	2304.83	2304.830 Formating*
N- CFCFCFC	+4S	2335.114	2335.114 PASS
N- CFCFCFC	+3S	1878.768	1878.768 PASS
N- CFCFCFC	Xbar	509.729	509.729 PASS
N- CFCFCFC	-3S	-859.31	-859.31 PASS
N- CFCFCFC	-4S	-1315.656	-1315.656 PASS
N- CFCFCFC	Min	-860.08	-860.080 Formating*
N- CFCFCFC	Obser_% OSL		PASS
N- CFCFCFC	Obser_PPM OSL		PASS
N- CFCFCFC	Calc_% OSL		PASS
N- CFCFCFC	Calc_PPM OSL		PASS
N- CFCFCFC	Cr		PASS
N- CFCFCFC	Tz	0.1	0.1 PASS
N- CFCFCFC	Cpk		PASS
O- BFFFFFF	N	99	99 PASS
O- BFFFFFF	Tgt_Dev	59.729	59.729 PASS
O- BFFFFFF	SD	456.346	456.346 PASS
O- BFFFFFF	Max	2304.83	2304.830 Formating*
O- BFFFFFF	+4S	2335.114	2335.114 PASS
O- BFFFFFF	+3S	1878.768	1878.768 PASS
O- BFFFFFF	Xbar	509.729	509.729 PASS
O- BFFFFFF	-3S	-859.31	-859.31 PASS
O- BFFFFFF	-4S	-1315.656	-1315.656 PASS
O- BFFFFFF	Min	-860.08	-860.080 Formating*
O- BFFFFFF	Obser_% OSL	2.02	2.02 PASS
O- BFFFFFF	Obser_PPM OSL	20202	20202 PASS
O- BFFFFFF	Calc_% OSL	1.79	1.79 PASS

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O- BFFFFFFF	Calc_PPM OSL	17900	17900 PASS
O- BFFFFFFF	Cr	1.52	1.52 PASS
O- BFFFFFFF	Tz	0.1	0.1 PASS
O- BFFFFFFF	Cpk	0.7	0.7 PASS
P- FBFFFFFF	N	99	99 PASS
P- FBFFFFFF	Tgt_Dev	59.729	59.729 PASS
P- FBFFFFFF	SD	456.346	456.346 PASS
P- FBFFFFFF	Max	2304.83	2304.830 Formating*
P- FBFFFFFF	+4S	2335.114	2335.114 PASS
P- FBFFFFFF	+3S	1878.768	1878.768 PASS
P- FBFFFFFF	Xbar	509.729	509.729 PASS
P- FBFFFFFF	-3S	-859.31	-859.31 PASS
P- FBFFFFFF	-4S	-1315.656	-1315.656 PASS
P- FBFFFFFF	Min	-860.08	-860.080 Formating*
P- FBFFFFFF	Obser_% OSL	6.061	6.061 PASS
P- FBFFFFFF	Obser_PPM OSL	60606	60606 PASS
P- FBFFFFFF	Calc_% OSL	3.29	3.29 PASS
P- FBFFFFFF	Calc_PPM OSL	32900	32900 PASS
P- FBFFFFFF	Cr	1.4	1.4 PASS
P- FBFFFFFF	Tz	0.1	0.1 PASS
P- FBFFFFFF	Cpk	0.7	0.7 PASS
Q- FFBFFFFF	N	99	99 PASS
Q- FFBFFFFF	Tgt_Dev	59.729	59.729 PASS
Q- FFBFFFFF	SD	456.346	456.346 PASS
Q- FFBFFFFF	Max	2304.83	2304.830 Formating*
Q- FFBFFFFF	+4S	2335.114	2335.114 PASS
Q- FFBFFFFF	+3S	1878.768	1878.768 PASS
Q- FFBFFFFF	Xbar	509.729	509.729 PASS
Q- FFBFFFFF	-3S	-859.31	-859.31 PASS
Q- FFBFFFFF	-4S	-1315.656	-1315.656 PASS
Q- FFBFFFFF	Min	-860.08	-860.080 Formating*
Q- FFBFFFFF	Obser_% OSL	6.061	6.061 PASS
Q- FFBFFFFF	Obser_PPM OSL	60606	60606 PASS
Q- FFBFFFFF	Calc_% OSL	3.29	3.29 PASS
Q- FFBFFFFF	Calc_PPM OSL	32900	32900 PASS
Q- FFBFFFFF	Cr	1.4	1.4 PASS
Q- FFBFFFFF	Tz	0.1	0.1 PASS
Q- FFBFFFFF	Cpk	0.7	0.7 PASS
R- FFFBFFFF	N	99	99 PASS
R- FFFBFFFF	Tgt_Dev		PASS
R- FFFBFFFF	SD	456.346	456.346 PASS
R- FFFBFFFF	Max	2304.83	2304.830 Formating*
R- FFFBFFFF	+4S	2335.114	2335.114 PASS
R- FFFBFFFF	+3S	1878.768	1878.768 PASS
R- FFFBFFFF	Xbar	509.729	509.729 PASS
R- FFFBFFFF	-3S	-859.31	-859.31 PASS
R- FFFBFFFF	-4S	-1315.656	-1315.656 PASS
R- FFFBFFFF	Min	-860.08	-860.080 Formating*
R- FFFBFFFF	Obser_% OSL	6.061	6.061 PASS

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R- FFFBFFF	Obser_PPM OSL	60606	60606 PASS
R- FFFBFFF	Calc_% OSL	3.29	3.29 PASS
R- FFFBFFF	Calc_PPM OSL	32900	32900 PASS
R- FFFBFFF	Cr	1.4	1.4 PASS
R- FFFBFFF	Tz	0	0 PASS
R- FFFBFFF	Cpk	0.7	0.7 PASS
S- FFFFBFF	N	99	99 PASS
S- FFFFBFF	Tgt_Dev	59.729	59.729 PASS
S- FFFFBFF	SD	456.346	456.346 PASS
S- FFFFBFF	Max	2304.83	2304.830 Formating*
S- FFFFBFF	+4S	2335.114	2335.114 PASS
S- FFFFBFF	+3S	1878.768	1878.768 PASS
S- FFFFBFF	Xbar	509.729	509.729 PASS
S- FFFFBFF	-3S	-859.31	-859.31 PASS
S- FFFFBFF	-4S	-1315.656	-1315.656 PASS
S- FFFFBFF	Min	-860.08	-860.080 Formating*
S- FFFFBFF	Obser_% OSL	6.061	6.061 PASS
S- FFFFBFF	Obser_PPM OSL	60606	60606 PASS
S- FFFFBFF	Calc_% OSL	3.29	3.29 PASS
S- FFFFBFF	Calc_PPM OSL	32900	32900 PASS
S- FFFFBFF	Cr	1.4	1.4 PASS
S- FFFFBFF	Tz	0.1	0.1 PASS
S- FFFFBFF	Cpk	0.7	0.7 PASS
T- FFFFFBF	N	99	99 PASS
T- FFFFFBF	Tgt_Dev	59.729	59.729 PASS
T- FFFFFBF	SD	456.346	456.346 PASS
T- FFFFFBF	Max	2304.83	2304.830 Formating*
T- FFFFFBF	+4S	2335.114	2335.114 PASS
T- FFFFFBF	+3S	1878.768	1878.768 PASS
T- FFFFFBF	Xbar	509.729	509.729 PASS
T- FFFFFBF	-3S	-859.31	-859.31 PASS
T- FFFFFBF	-4S	-1315.656	-1315.656 PASS
T- FFFFFBF	Min	-860.08	-860.080 Formating*
T- FFFFFBF	Obser_% OSL	6.061	6.061 PASS
T- FFFFFBF	Obser_PPM OSL	60606	60606 PASS
T- FFFFFBF	Calc_% OSL	3.29	3.29 PASS
T- FFFFFBF	Calc_PPM OSL	32900	32900 PASS
T- FFFFFBF	Cr	1.4	1.4 PASS
T- FFFFFBF	Tz	0.1	0.1 PASS
T- FFFFFBF	Cpk	0.7	0.7 PASS
U- FFFFFFB	N	99	99 PASS
U- FFFFFFB	Tgt_Dev	59.729	59.729 PASS
U- FFFFFFB	SD	456.346	456.346 PASS
U- FFFFFFB	Max	2304.83	2304.830 Formating*
U- FFFFFFB	+4S	2335.114	2335.114 PASS
U- FFFFFFB	+3S	1878.768	1878.768 PASS
U- FFFFFFB	Xbar	509.729	509.729 PASS
U- FFFFFFB	-3S	-859.31	-859.31 PASS
U- FFFFFFB	-4S	-1315.656	-1315.656 PASS

Prospective Software Validation			
U- FFFFFFFB	Min	-860.08	-860.080 Formating*
U- FFFFFFFB	Obser_% OSL	4.04	4.04 PASS
U- FFFFFFFB	Obser_PPM OSL	40404	40404 PASS
U- FFFFFFFB	Calc_% OSL	1.5	1.5 PASS
U- FFFFFFFB	Calc_PPM OSL	15000	15000 PASS
U- FFFFFFFB	Cr	1.3	1.3 PASS
U- FFFFFFFB	Tz	0.1	0.1 PASS
U- FFFFFFFB	Cpk	0.72	0.72 PASS
V- SD=0 Value=USL	N	100	100 PASS
V- SD=0 Value=USL	Tgt_Dev	1050	1050.0 Formating*
V- SD=0 Value=USL	SD	0	0.0 Formating*
V- SD=0 Value=USL	Max	1500	1500.0 Formating*
V- SD=0 Value=USL	+4S	1500	1500.0 Formating*
V- SD=0 Value=USL	+3S	1500	1500.0 Formating*
V- SD=0 Value=USL	Xbar	1500	1500.0 Formating*
V- SD=0 Value=USL	-3S	1500	1500.0 Formating*
V- SD=0 Value=USL	-4S	1500	1500.0 Formating*
V- SD=0 Value=USL	Min	1500	1500.0 Formating*
V- SD=0 Value=USL	Obser_% OSL	0	0 PASS
V- SD=0 Value=USL	Obser_PPM OSL	0	0 PASS
V- SD=0 Value=USL	Calc_% OSL		PASS
V- SD=0 Value=USL	Calc_PPM OSL		PASS
V- SD=0 Value=USL	Cr	0	0 PASS
V- SD=0 Value=USL	Tz	1	1 PASS
V- SD=0 Value=USL	Cpk		PASS
W- SD=0 Value=UCL	N	100	100 PASS
W- SD=0 Value=UCL	Tgt_Dev	549	549.0 Formating*
W- SD=0 Value=UCL	SD	0	0.0 Formating*
W- SD=0 Value=UCL	Max	999	999.0 Formating*
W- SD=0 Value=UCL	+4S	999	999.0 Formating*
W- SD=0 Value=UCL	+3S	999	999.0 Formating*
W- SD=0 Value=UCL	Xbar	999	999.0 Formating*
W- SD=0 Value=UCL	-3S	999	999.0 Formating*
W- SD=0 Value=UCL	-4S	999	999.0 Formating*
W- SD=0 Value=UCL	Min	999	999.0 Formating*
W- SD=0 Value=UCL	Obser_% OSL	0	0 PASS
W- SD=0 Value=UCL	Obser_PPM OSL	0	0 PASS
W- SD=0 Value=UCL	Calc_% OSL		PASS
W- SD=0 Value=UCL	Calc_PPM OSL		PASS
W- SD=0 Value=UCL	Cr	0	0 PASS
W- SD=0 Value=UCL	Tz	1	1 PASS
W- SD=0 Value=UCL	Cpk		PASS
X- SD=0 Above TGT	N	100	100 PASS
X- SD=0 Above TGT	Tgt_Dev	250.09	250.09 PASS
X- SD=0 Above TGT	SD	0	0 PASS
X- SD=0 Above TGT	Max	700.09	700.090 Formating*
X- SD=0 Above TGT	+4S	700.09	700.09 PASS
X- SD=0 Above TGT	+3S	700.09	700.09 PASS
X- SD=0 Above TGT	Xbar	700.09	700.09 PASS

Prospective Software Validation				
X- SD=0 Above TGT	-3S	700.09	700.09	PASS
X- SD=0 Above TGT	-4S	700.09	700.09	PASS
X- SD=0 Above TGT	Min	700.09	700.090	Formating*
X- SD=0 Above TGT	Obser_% OSL	0	0	PASS
X- SD=0 Above TGT	Obser_PPM OSL	0	0	PASS
X- SD=0 Above TGT	Calc_% OSL			PASS
X- SD=0 Above TGT	Calc_PPM OSL			PASS
X- SD=0 Above TGT	Cr	0	0	PASS
X- SD=0 Above TGT	Tz	1	1	PASS
X- SD=0 Above TGT	Cpk			PASS
Y- SD=0 Value=TGT	N	100	100	PASS
Y- SD=0 Value=TGT	Tgt_Dev	0	0.0	Formating*
Y- SD=0 Value=TGT	SD	0	0.0	Formating*
Y- SD=0 Value=TGT	Max	450	450.0	Formating*
Y- SD=0 Value=TGT	+4S	450	450.0	Formating*
Y- SD=0 Value=TGT	+3S	450	450.0	Formating*
Y- SD=0 Value=TGT	Xbar	450	450.0	Formating*
Y- SD=0 Value=TGT	-3S	450	450.0	Formating*
Y- SD=0 Value=TGT	-4S	450	450.0	Formating*
Y- SD=0 Value=TGT	Min	450	450.0	Formating*
Y- SD=0 Value=TGT	Obser_% OSL	0	0	PASS
Y- SD=0 Value=TGT	Obser_PPM OSL	0	0	PASS
Y- SD=0 Value=TGT	Calc_% OSL			PASS
Y- SD=0 Value=TGT	Calc_PPM OSL			PASS
Y- SD=0 Value=TGT	Cr	0	0	PASS
Y- SD=0 Value=TGT	Tz	0	0	PASS
Y- SD=0 Value=TGT	Cpk			PASS
Z- SD=0 Below TGT	N	100	100	PASS
Z- SD=0 Below TGT	Tgt_Dev	-250.09	-250.09	PASS
Z- SD=0 Below TGT	SD	0	0	PASS
Z- SD=0 Below TGT	Max	199.91	199.910	Formating*
Z- SD=0 Below TGT	+4S	199.91	199.91	PASS
Z- SD=0 Below TGT	+3S	199.91	199.91	PASS
Z- SD=0 Below TGT	Xbar	199.91	199.91	PASS
Z- SD=0 Below TGT	-3S	199.91	199.91	PASS
Z- SD=0 Below TGT	-4S	199.91	199.91	PASS
Z- SD=0 Below TGT	Min	199.91	199.910	Formating*
Z- SD=0 Below TGT	Obser_% OSL	0	0	PASS
Z- SD=0 Below TGT	Obser_PPM OSL	0	0	PASS
Z- SD=0 Below TGT	Calc_% OSL			PASS
Z- SD=0 Below TGT	Calc_PPM OSL			PASS
Z- SD=0 Below TGT	Cr	0	0	PASS
Z- SD=0 Below TGT	Tz	-1	-1	PASS
Z- SD=0 Below TGT	Cpk			PASS
AA- SD=0 Value=LCL	N	100	100	PASS
AA- SD=0 Value=LCL	Tgt_Dev	-450	-450.0	Formating*
AA- SD=0 Value=LCL	SD	0	0.0	Formating*
AA- SD=0 Value=LCL	Max	0	0.0	Formating*
AA- SD=0 Value=LCL	+4S	0	0.0	Formating*

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AA- SD=0 Value=LCL	+3S	0	0.0 Formating*
AA- SD=0 Value=LCL	Xbar	0	0.0 Formating*
AA- SD=0 Value=LCL	-3S	0	0.0 Formating*
AA- SD=0 Value=LCL	-4S	0	0.0 Formating*
AA- SD=0 Value=LCL	Min	0	0.0 Formating*
AA- SD=0 Value=LCL	Obser_% OSL	0	0 PASS
AA- SD=0 Value=LCL	Obser_PPM OSL	0	0 PASS
AA- SD=0 Value=LCL	Calc_% OSL		PASS
AA- SD=0 Value=LCL	Calc_PPM OSL		PASS
AA- SD=0 Value=LCL	Cr	0	0 PASS
AA- SD=0 Value=LCL	Tz	-1	-1 PASS
AA- SD=0 Value=LCL	Cpk		PASS
AB- SD=0 Value=LSL	N	100	100 PASS
AB- SD=0 Value=LSL	Tgt_Dev	-900	-900.0 Formating*
AB- SD=0 Value=LSL	SD	0	0.0 Formating*
AB- SD=0 Value=LSL	Max	-450	-450.0 Formating*
AB- SD=0 Value=LSL	+4S	-450	-450.0 Formating*
AB- SD=0 Value=LSL	+3S	-450	-450.0 Formating*
AB- SD=0 Value=LSL	Xbar	-450	-450.0 Formating*
AB- SD=0 Value=LSL	-3S	-450	-450.0 Formating*
AB- SD=0 Value=LSL	-4S	-450	-450.0 Formating*
AB- SD=0 Value=LSL	Min	-450	-450.0 Formating*
AB- SD=0 Value=LSL	Obser_% OSL	0	0 PASS
AB- SD=0 Value=LSL	Obser_PPM OSL	0	0 PASS
AB- SD=0 Value=LSL	Calc_% OSL		PASS
AB- SD=0 Value=LSL	Calc_PPM OSL		PASS
AB- SD=0 Value=LSL	Cr	0	0 PASS
AB- SD=0 Value=LSL	Tz	-1	-1 PASS
AB- SD=0 Value=LSL	Cpk		PASS
AC- SD=0 Calc Limits	N	100	100 PASS
AC- SD=0 Calc Limits	Tgt_Dev		PASS
AC- SD=0 Calc Limits	SD	0	0 PASS
AC- SD=0 Calc Limits	Max	1499.99	1499.990 Formating*
AC- SD=0 Calc Limits	+4S	1499.99	1499.99 PASS
AC- SD=0 Calc Limits	+3S	1499.99	1499.99 PASS
AC- SD=0 Calc Limits	Xbar	1499.99	1499.99 PASS
AC- SD=0 Calc Limits	-3S	1499.99	1499.99 PASS
AC- SD=0 Calc Limits	-4S	1499.99	1499.99 PASS
AC- SD=0 Calc Limits	Min	1499.99	1499.990 Formating*
AC- SD=0 Calc Limits	Obser_% OSL		PASS
AC- SD=0 Calc Limits	Obser_PPM OSL		PASS
AC- SD=0 Calc Limits	Calc_% OSL		PASS
AC- SD=0 Calc Limits	Calc_PPM OSL		PASS
AC- SD=0 Calc Limits	Cr		PASS
AC- SD=0 Calc Limits	Tz		PASS
AC- SD=0 Calc Limits	Cpk		PASS

**Pass: 372 Fail: 0 Formating\*\*: 87**

**Note\*:** All Formating warnings due to insignificant trailing zeroes

<b>Prospective Software Validation</b>
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**Known Issues with This Release**

QWXL addresses all issues which have been reported since the last version of QWXL was submitted for SEWP Certification.

The purpose of listing known discrepancies here is to ensure that:

- a) The customer understands these discrepancies and properly considers them in their application
- b) Busitech has documentation on current version discrepancies that will be addressed prior to the next release.

Here are the known discrepancies that will be fixed in the next version of QWXL:

No known discrepancies

<b>Prospective Software Validation</b>
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**Performance Qualification –PQ** - not applicable or by Customer if needed.

QWXL version 2.2.0.12 has been properly tested and checked as per the validation protocol. All results match success criteria. All known issues have been identified and communicated to Busitech technical resources to be resolved by the next release.

Validated by:



Noel Windle  
Busitech Validation Leader

We indicate that we have reviewed the information and concur with the indicated decision to consider QWXL version 2.2.0.12 IQ/OQ validated. We have also reviewed this with our key customer contacts for their acceptance.



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Ray St Denis  
Busitech  
Technical Director