METTLER TOLEDO

Validation Manual		
Volume 1		
FormWeigh.Net v1 and higher		
ME-21`901`220		

CSV Pac - Computer System Validation



Content

1.	Purpose and amendments	December 2, 2004
2.	Non-disclosure Agreement	
3.	Organization and Validation	
3.1	Background Information Mettler-Toledo	February 2003
3.2	Validation Phases FormWeigh.Net	January 25, 2005
4.	Quality Management	
4.1	Certification of Vendor Checklist	December 13, 2004
4.2	21 CFR Part 11 Compliance Assessment	December 23, 2004
5.	Software Development Documentation Plan	
5.1	Sales, Development and Support Procedure	January 31, 2005
5.2	Software Development Process	April 22, 2004
5.3	SOP – Configuration Management	July 27, 2004
5.4	Configuration Management (Template)	
6.	Software Development Specification	
6.1	SOP – Document Management	July 02, 2003
6.2	User Requirements Specification (Template)	
6.3	Functional Specification (Template)	
6.4	SOP – Guideline for General Review	July 27, 2004
6.5	General Review Item (Template)	
7.	Quality Syle Guide and Procedure	
7.1	SOP – Object Pascal Code Style Guide	July 27, 2004
7.2	SOP – Code Review Guidelines and Checklists	October 26, 2004
8.	Test Documentation and Release Notes	
8.1	SOP – Test Management	July 27, 2004
8.2	Test Protocol (Example)	December 22, 2004
8.3	SOP – Error Management	January 24, 2005
8.4	Relese Note (Template)	
9.	Certificates	
9.1	ISO 9001:2000/ ISO 14000:1996 Certificate MT	June 04, 2004