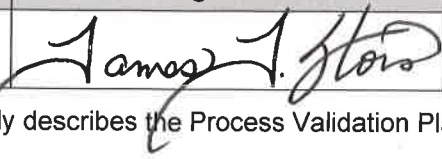


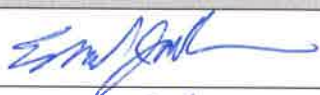
For the Acquity SDS Final Test System – BSM Program

PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer		04 MAR 2020

The "Prepared By" signature denotes that this document accurately describes the Process Validation Planned activities.

REVIEWED BY

Name	Role	Signature	Date
Edward Jackson	Principal Test Engineer		04-MAR-2020
Gayle Gaudreau	Operations Project Manager		05-Mar-2020

The "Reviewed By" signatures denotes agreement with the planned process validation activities.

APPROVED BY

Name	Role	Signature	Date
Megan Marshall	Senior Quality Systems Engineer		04 MAR 2020

The "Approved By" signature denotes that this Process Validation Plan has been approved and is ready for execution.

REVISION HISTORY

VERSION:	01	ORIGINATOR:	James J. Stors	Change ID:	9234533
SUMMARY OF CHANGE: Per the BioBSM Project the SDS tester BSM program shall be updated to Version 2.4 to include the new BioBSM part numbers and Dynamic Leak specifications.					

1.0 Purpose

The purpose of this Process Validation Plan is to provide a detailed Process Validation strategy and to document the deliverables of the TE82943, Acquity SDS Final Test System.

2.0 Background

The Acquity SDS Final Test System is located in NPI, Warranty and Repair, and in the Production Clean Room, at the 34 Maple Street facility, as well as in the Flextronics and Venture manufacturing sites in Singapore.

The Acquity SDS Final Test System is used to perform the final test for the Acquity Solvent Managers. The BSM program is used to test the associated part numbers as defined within 735002010 – Acquity BSM Pump Automated Final Test, Test Specification and Procedure.

Upon completion a Final Test Record is generated and automatically saved to the Sigma Quest Data Archive.

3.0 Scope of the Process Validation Plan

This Process Validation Plan details the planned qualification activities for the Acquity SDS Final Test System – BSM program.

4.0 Abbreviations

Term	Explanation
BioBSM	An inert Binary Solvent Manager pump
BSM	Binary Solvent Manager
EDV	Equipment Design Verification
IQ	Installation Qualification
NPI	New Product Introduction
OQ	Operational Qualification
PQ	Performance Qualification
SAP	Enterprise Resource Planning (ERP) software
SDS	Solvent Delivery System
TMV	Test Method Validation
TSP	Test and Specification Procedure
VP	Validation Plan

5.0 Roles and Responsibilities

Roles	Name	Title	Responsibilities
Project Sponsor	Michael Yelle	Vice President Instrument Product Development	• Ensure appropriate resources based on project activities
Project Sponsor	Mike Budnick	Principal Consulting Project Manager	• Ensure appropriate resources based on project activities
System Owner	Edward Jackson	Principal Test Engineer	• Update the system program • Update system TSP • Review all Process Validation documentation
Validation Engineering	James J. Stors	Senior Test Validation Engineer	• Execute all applicable Process Validation activities • Write all applicable Process Validation documents • Capture/ensure capture of all approved deliverables as specified in 730001835 – Process Validation Procedure for Milford Site
Project Manager	Gayle Gaudreau	Operations Project Manager	• Project management and planning
Quality Assurance	Megan Marshall	Senior Quality Systems Engineer	• Approve all Process Validation documentation

The names/titles listed above are the expected designee at the time of the writing and may change over the course of the Process Validation. Changes of this nature shall require this document to be edited, provided the new designee is from the same Department and has the same role. Other resources may be involved in the Process Validation, as and when required.

6.0 Validation Strategy

The TE82943, Acquity SDS Final Test System – BSM program is a legacy testing program that has previously had a wide range of process validation activities performed, as summarized below:

- A Test Equipment Verification (TEV) of the system/program design as summarized in TE82943-BSM-TEVR
- Installation Qualifications (IQ's) for each individual system (TE82943-1, TE82943-2, TE82943-3, TE82943-4, TE82943-5, TE82943-6, TE82943-7, TE82943-8, TE82943-9, TE82943-11, TE82943-12, TE82943-13, TE82943-14, TE82943-15, TE82943-16, TE82943-17, TE82943-18, TE82943-19, TE82943-20, TE82943-21, TE82943-22, TE82943-23, TE82943-24) as summarized in the associated system IQ Report.

The change being made to the TE82943 BSM program is solely the addition of new BioBSM part numbers, 186015061 and 800000503, and associated Dynamic Leak specification values. The tests performed by the system on the BioBSM units are identical to the testing performed on the existing 186015000, Acquity UPLC I-Class BSM Assembly, with different Dynamic Leak test specifications, as summarized within 735002010, Acquity BSM Pump Automated Final Test, Test and Specification procedure, Version 13.

The testing subroutine within the program, as well as the test record subroutine, are not being modified beyond the specification changes summarized above. The firmware loaded/verified by the system is not being affected by this change/project.

The change is not affecting the design of the system and therefore neither an Equipment Design Verification (EDV) nor a Test Method Validation (TMV) is required.

A partial Installation Qualification consisting of Test Scripts IQ-01, Associated Documentation Verification, IQ-04, Test Software and Instrument Firmware, and IQ-06, Functional Verification, shall be performed for each BSM system in order to verify that the new BioBSM part numbers have been added to the TSP, that the software version defined in the TSP matches the station program, that the new part numbers are able to be tested by the system with no issues, and that the new specifications specific to the BioBSM models are correct. Test Scripts IQ-02, Site Verification, IQ-03, Instrumentation Calibration Verification, and IQ-05, General Safety and Alarms, shall not be re-executed as the change does not affect the results as previously defined within the existing Installation Qualification Reports.

The system performs 100% verification of the critical to quality specifications per the 735002010 – Acquity BSM Pump Automated Final Test, Test Specification and Procedure, and therefore neither an Operational Qualification (OQ) nor a Performance Qualification (PQ) is required.

The following Table provides the expected timeline of the Process Validation activities, including all deliverables. This timeline is subject to change without requiring an update to this Process Validation Plan:

System ID	System Name	Validation Type	Expected Completion
TE82943-1	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020
TE82943-2	Acquity SDS Final Test System – Clean Room	Installation Qualification	April 2020
TE82943-3	Acquity SDS Final Test System - NPI	Installation Qualification	April 2020
TE82943-4	Acquity SDS Final Test System – Clean Room	Installation Qualification	April 2020
TE82943-5	Acquity SDS Final Test System - Refurb	Installation Qualification	April 2020
TE82943-6	Acquity SDS Final Test System – Clean Room	Installation Qualification	April 2020
TE82943-7	Acquity SDS Final Test System - Refurb	Installation Qualification	April 2020
TE82943-8	Acquity SDS Final Test System – Clean Room	Installation Qualification	April 2020
TE82943-9	Acquity SDS Final Test System - NPI	Installation Qualification	April 2020
TE82943-11	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-12	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-13	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-14	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-15	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-16	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-17	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-18	Acquity SDS Final Test System - Flextronics	Installation Qualification	April 2020
TE82943-19	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020
TE82943-20	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020
TE82943-21	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020
TE82943-22	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020
TE82943-23	Acquity SDS Final Test System - NPI	Installation Qualification	April 2020
TE82943-24	Acquity SDS Final Test System – Venture	Installation Qualification	April 2020

7.0 Deliverables

The TE82943, Acquity SDS Final Test System shall be tested in accordance with 730001835 – Process Validation Procedure for Milford Site and will include the following:

Document	System Name	Document Reference	Action/Resource(s)
Operating Procedure	Acquity BSM Pump Automated Final Test TSP	735002155, Version 10/Revision L	• Update System Owner
IQ Reports	TE82943 QSM Stations	TE82943-1-IQR, TE82943-2-IQR, TE82943-3-IQR, TE82943-4-IQR, TE82943-5-IQR, TE82943-6-IQR, TE82943-7-IQR, TE82943-8-IQR, TE82943-9-IQR, TE82943-11-IQR, TE82943-12-IQR, TE82943-13-IQR, TE82943-14-IQR, TE82943-15-IQR, TE82943-16-IQR, TE82943-17-IQR, TE82943-18-IQR, TE82943-19-IQR, TE82943-20-IQR, TE82943-21-IQR, TE82943-22-IQR, TE82943-23-IQR, TE82943-24-IQR	• Create Executor • Review System Owner • Approve Quality Assurance

8.0 Attachments

N/A

9.0 References

The current approved or specified versions of the following documents are referenced within this document:

Document Number	Document Title
730000837	Waters Global Validation Policy
730001835	Process Validation Procedure for Milford Site
735002010	Acquity BSM Pump Automated Final Test TSP

VERIFIED BY

Name	Role	Signature	Date
	Site VMP Coordinator		

The "Verified By" signature denotes that all Process Validation deliverables, as defined within Section 7.0, have been created, performed, reviewed, and/or approved.