

Table of Contents

1. Subject	2
2. Purpose	3
3. Scope	3
4. Definitions & Abbreviations	3
5. Roles & Responsibilities	4
6. References / Related Documents	6
7. Forms and Records	8
8. Health & Safety	8
9. Description of Procedure	9
9.1. Phases and Milestones	9
9.2. Design Reviews	9
9.3. Deliverables and Tailoring	11
9.4. Separations Instrument Project Deliverables and Product Information	12
9.5. Mass Spectrometry Instrument Project Deliverables and Product Information	13
10. Appendices / Attachments	14

Title: Waters Instrument Development Procedure

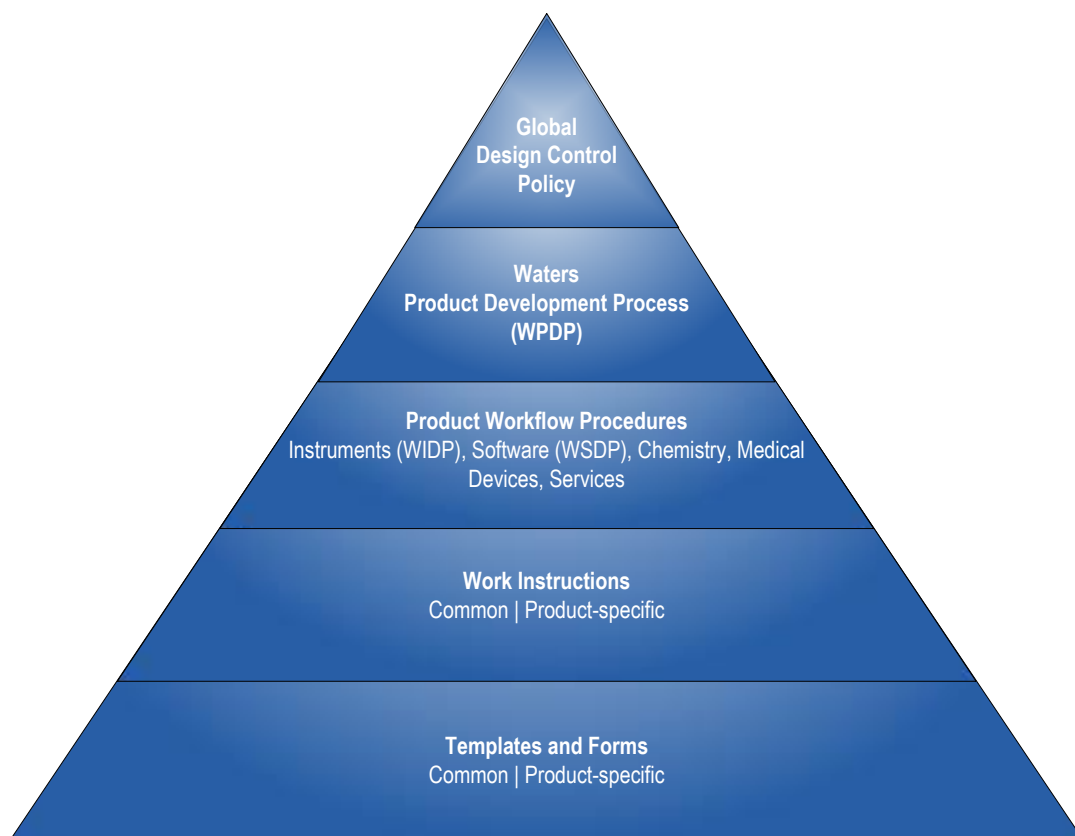
Document No: 730001286

Version No: 01

Page 2 of 14

1. SUBJECT

This subject of this document is the Waters Instrument Development Procedure (WIDP) which is a Product Workflow Procedure under the Waters Product Development Process (WPDP). This structure is illustrated below.



WPDP: The Waters Product Development Process content and structure is intended to provide the framework for consistency in approach for all Waters product development.

WIDP: The Waters Instrument Development Procedure builds upon the core WPDP to include more specific details required for the design and development of instrument products.

2. PURPOSE

The purpose of this document is to describe the procedure for developing instrument products within the Waters Product Development Process (730000985).

3. SCOPE

The scope of this procedure is all instruments developed by Waters, including instrument control software and instrument related accessories.

4. DEFINITIONS & ABBREVIATIONS

See 730001140 WPDP Glossary of Terms.

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 4 of 14

5. ROLES & RESPONSIBILITIES

- 5.1.** This listing of roles and responsibilities is intended to cover the general case of an instrument development effort to be used as a guide. It can be tailored according to project scope and local practices using the Design and Development plan. It is recognized and accepted that there can be differences in practice between development sites resulting in role, process, and template differences.

Refer to the following diagrams for more detailed deliverable information by role and phase:

- Section 9.4 (Separations Instrument Project Deliverables and Product Information).
- Section 9.5 (Mass Spectrometry Instrument Project Deliverables and Product Information).

Roles	Responsibilities
Product Management	Develop and manage business plans and marketing activities. Determine and document marketing requirements and user requirements working collaboratively with Subject Matter Experts, Product Development, and Project Management. Represent the customer perspective and needs to the project team. Prepare and present the Concept Phase Gate. Review the business plan and risk to the project objectives at each phase gate to facilitate the decision whether to continue or not. Work collaboratively with Commercialization Management to support development of a commercialization plan and manage product commercialization activities.
Technical Communications	Develop and manage end user documentation, including specification sheets, online help, qualification, release notes and user guides.
Project Management	Manage the overall product development process and deliverables, in line with the procedure detailed within this document, and in collaboration with a cross functional project team. Create and manage the overall Design and Development Plan, which will detail and justify any deviation from the standard process. Manage and be responsible for the project expense budget. Prepare and present Phase Gates, facilitate Design Reviews, and provide management reports / reviews where appropriate.
Systems Engineering	Determine and document system / product requirements & specifications, working collaboratively with Product Management, Product Development, and Project Management. Integration of sub-systems and accountability for all design verification activities ensuring that reports provide a comprehensive and complete set of records through a traceability document. Work collaboratively with other business functions to aid management and commercialization activities.

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 5 of 14

Roles	Responsibilities
Mechanical Engineering	Develop, document and manage the mechanical design of the product and bill of material. Work collaboratively with other functions to achieve the best product architecture and implementation.
Electrical Engineering	Develop, document and manage the electrical and electronic design of the product. Work collaboratively with other functions to achieve the best product architecture and implementation.
Software Engineering	Develop, document, and manage the software for the product. Work collaboratively with other team members to achieve the best product architecture and implementation.
Compliance Engineering	Work with the development team to provide guidance and interpretation of regulations impacting the project/product. Develop and manage a compliance plan. Compile and maintain the product Technical File and Risk Management File. Manage compliance testing and interface with external compliance organizations.
Evaluation	Develop and manage the product evaluation activities required to support product development, including verification and validation.
New Product Introduction or New Product Operations	Develop and manage the product build and delivery activities required to support product development, evaluation, and order fulfillment. Ensure the production process and documentation is complete and capable of routinely and sustainably producing product of acceptable quality before transferring to full scale production.
Product Assurance	Develop and manage product assurance activities and deliverables, including plans and test reports. Ensure design and production processes are appropriate and in use to effectively and consistently produce a high quality product.
Reliability Engineering	Develop and manage the product reliability evaluation activities and deliverables required to support the product development including verification and validation.
Global Service Support	Develop and manage the product service and support activities required to install, maintain and repair the product.
Quality (including Technical Product Management)	Support development of project deliverables including previous product analysis, risk management, and post release customer complaints. Develop and manage quality metrics. Manage and resolve technical product issues.
Regulatory Affairs	Manage Regulatory activities in support of IVD products.
Finance	Administer, report and review project budgets and participate in product costing.

6. REFERENCES / RELATED DOCUMENTS

Procedure and Template Documents

Doc No:	Document Title
	General Process
730001095	Global Design Control Policy
730000985	Waters Product Development Process
730001140	WPDP Glossary of Terms
730001756	Phase Gate Review Process
730001098	WPDP Phase Gate Review Certificate
730001276	WPDP Product Release Certificate
	Design Input and Quality
730000993	WPDP Design Input Procedure
730001236	WPDP Market Requirements Procedure
730001254	WPDP Market Requirements Template
730001100	WPDP User Requirements Template
730001957	WIDP Product Requirements Template
730000992	WPDP Previous Product Analysis Procedure
730001206	WPDP Previous Product Analysis Template
730002898	Regulatory Strategy Template (for IVD product only)
	Management, Development and Evaluation
730000990	WPDP Design and Development Plan Procedure
730001099	WPDP Design and Development Plan Template
730000996	WPDP Design Review Procedure
730001283	WPDP Design Review Meeting Minutes Template
730001532	Instrument Regulatory Compliance Checklist
730000710	Creating and Maintaining Technical Files
730000768	Template, Technical File
730000991	WPDP Design History File Index Procedure
730000942	WPDP Design History File Index Template
730000995	WPDP Design Verification Procedure
730000997	WPDP Design Validation Procedure
730000989	WPDP Traceability Matrix Procedure

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 7 of 14

Doc No:	Document Title
730001102	WPDP Traceability Matrix Template
730000999	WPDP Post Release Evaluation Procedure
730001199	WPDP Post Release Evaluation (Process) Template
730001284	WPDP Post Release Review (Product) Template
730000555	Requests for Beta Units - Finance
	Risk Management
730000362MP	RM: Risk Management Process
	Operations
730001235	WPDP Design Transfer Checklist
730000680	Device Master Record Policy
	Technical Communications
WAT000245MP	Customer Documentation Management Process
730000784	Tech Comm Documentation Plan Template
	Service
730000563	Template, GSS New Product Introduction Plan

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 8 of 14

Separations Specific Procedure and Template Documents

Doc No:	Document Title
730000566	Template, Mechanical Design Plan
730000560	Template, Electronic Design Plan
730000939	Engineering Report Procedure
730000940	Engineering Report Template
WAT077824SO	Development Engineering Change
WAT077822SO	Production Engineering Change
WAT000230MP	New Product Intro Process – Milford Ops

Mass Spectrometry Specific Procedure and Template Documents

Doc No:	Document Title
26180	Mechanical Design Process
32415	Electronics Design Process (System)
42030	Supplier Audit Procedure – Quality
10273	Software Design Process
45219	Reliability Engineering Plan
49032	Prototype Transfer Checklist

7. FORMS AND RECORDS

Doc No:	Document Title
Not Applicable	Not Applicable

8. HEALTH & SAFETY

No Health & Safety specific considerations

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

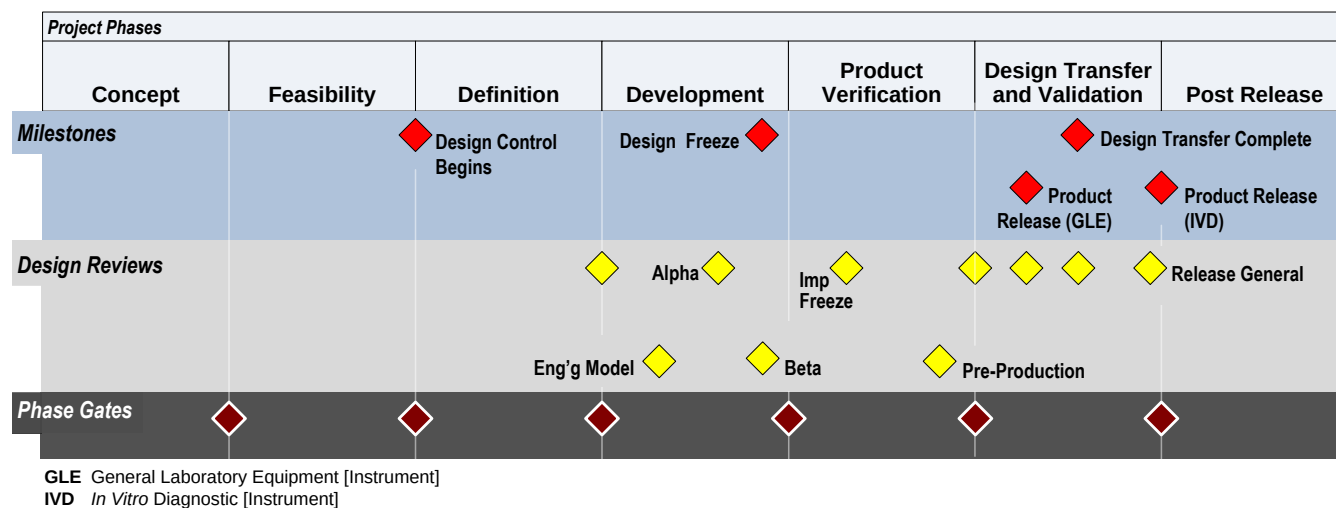
Page 9 of 14

9. DESCRIPTION OF PROCEDURE

9.1. Phases and Milestones

The Waters Instrument Development Procedure consists of a series of phases, phase gates, design reviews and milestones, as defined in the Waters Product Development Process (730000985). Additional milestones are included in the WIDP for various iterations of design builds. This is illustrated below.

Note: This is a representation of a typical project. Each project may be tailored and the specific milestones, design reviews and phase gates are to be documented in the Design and Development plan.



9.2. Design Reviews

Once Design Control has begun, Design Reviews (procedure 730000996) are required as indicated in the Design & Development Plan (procedure 730000990). Design reviews can take the form of pre-phase gate reviews of required deliverables or be focused technical reviews of specific design elements.

Typical WIDP Design Reviews are listed below.

Design Review	Phase	Objective	Review Focus
Design Input	Definition	To ensure that all User Requirements and Product Requirements are completely defined, fully understood and traceable	User Requirements Product Requirements Traceability Matrix
Engineering Model	Development	To ensure that a subset of the critical performance criteria, as defined in the test Plan, Product Requirements and Traceability Matrix, have been met on one or more Engineering	Product Requirements Verification Plan Traceability Matrix Engineering Model Verification

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 10 of 14

Design Review	Phase	Objective	Review Focus
		models of the instrument	Summary Report
Alpha Performance	Development	To ensure that the critical functional, performance and other criteria, as defined in the Test Plan, Product Requirements and Traceability Matrix, have been met on one or more Alpha models of the instrument	Test Plan Product Requirements Traceability Matrix Alpha Verification Summary Report
Design Freeze	Development	To ensure that designs are stable enough to release to Beta, thus enabling the build of Beta models of the instrument. Design docs and SAP BOM release to BE status via an Engineering Change Request.	Subassembly designs Drawings Packaging designs
Implementation Freeze	Product Verification	To assess readiness for full evaluation to begin – design activity complete to spec and Beta units ready – exceptions reviewed and risk assessed. Ensure that test cases exist for all requirements to be verified. Document risk assessment where there are exceptions	Verification test cases Traceability matrix Beta data report
Release to PP	Product Verification	To ensure that the designs are stable enough to release to PP, thus enabling the build of PP models of the instrument. Design docs and SAP BOM release to PP status via an Engineering Change Request.	Product Requirements Traceability Matrix Reliability Reports Beta Verification Summary Report
Design Verification	Product Verification	To ensure that the Design Inputs as documented in the Traceability Matrix have Design Outputs that have been correctly verified and full traceability has been maintained. If there are any exceptions, then a risk assessment will be carried out, documented and appropriate action planned	Product Requirements Traceability Matrix Reliability Reports Design Verification Records Design Verification Summary Report
Design Transfer	Design Transfer and Validation	All deliverables required to transfer the product to manufacture are complete	Process Validation Reports Design Transfer Checklist
Product Release – GLE	Design Transfer and Validation	To ensure that all deliverables required to support the product for commercial release have been	Traceability Matrix Reliability Summary Report

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 11 of 14

Design Review	Phase	Objective	Review Focus
		completed. All validation complete and traceable.	Design Validation Records Technical File
Product Release – IVD and/or Release to RG status	Design Transfer and Validation	To ensure that all deliverables required to support the product for commercial release have been completed. All validation complete and traceable. To ensure that the designs are stable enough to release to RG	Traceability Matrix Reliability Summary Report Design Validation Records Process Validation Records Technical File NPI Release to Production Checklist

9.3. Deliverables and Tailoring

The WIDP includes deliverables associated with instrument product development efforts.

The Design and Development plan will be used to define the deliverables required based upon scope of the product design effort. Each instrument development project is unique and the Project Team may tailor the application of WIDP based on project type and scalability considerations. For instance, some typical deliverables may not be required, other additional deliverables may be required, or some phases may be combined. Some of the potential factors to be considered include commercial, technical, quality, regulatory, and application domain specific risks.

The deliverables and functions responsible for producing them may vary slightly due to project team organization or local development site differences. Detailed diagrams follow showing the typical project deliverables required at each phase of the project lifecycle for Separations products and Mass Spectrometry products.

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 12 of 14

9.4. Separations Instrument Project Deliverables and Product Information

	Concept	Feasibility	Definition	Development	Product Verification	Design Transfer and Validation	Post Release
Product Management	Business Case	Business Case Market Requirements Document User Requirements Document	Commercialization Plan Qualification Product Plan SAP Variant Configurator			Product ECR Released Release Notes Announcement to Field Ordering Guide Specification Sheets Certificate of Structural Integrity	Product Performance Review(s)
Technical Communications			Document Plan			User Documentation	
Project Management		Feasibility Report	Design & Development Plan			Product Release Checklist Product Release Cert.	Post Release Review (Product)-6- and 12-Mo. Post Release Evaluation (Process)
Product Development	Systems Engineering		Product Requirements Document Design Traceability Matrix				
	Mechanical Engineering		Mechanical Engineering Plan	Design Documents and BOM at BE	Design Documents and BOM at PP	Design Documents and BOM at RG	
	Electrical Engineering		Electrical Engineering Plan	Design Documents and BOM at BE	Design Documents and BOM at PP	Design Documents and BOM at RG	
	Software Engineering		Software Engineering Plan		Software and Firmware Release Candidates	Software Media	
	Compliance Engineering		Compliance Engineering Plan		Compliance Engineering Summary Report	Technical File Index Design History File Index Risk Management File Index Declarations of Conformity	
Evaluation			Design Validation Test Plan Design Verification Test Plan	Design Validation Test Cases Design Verification Test Cases Alpha Verification Summary Rpt Eng'g Model Verification Summary Rpt	Design Verification Reports Beta Verification Summary Report	Design Validation Reports PP Verification Summary Report	
New Product Introduction	NPI Project Mgt		Preliminary Manufacturing Plan		Final Manufacturing Plan	Device Master Record Design Transfer Records Product/Process Stability Report	Manufacturing, Supplier, and Material Data
	NPI Engineer or Transfer Manager			Product & Spares Package Design	Product Packaging Report	Process Validation Doc'n Transfer Checklist Summary	
	NPI Product Assurance		Preliminary Product Assurance Plan		Process Risk Assessment Report or PFMEA Final Product Assurance Plan Beta Data Report	Preproduction Data Report	
Reliability Engineering			Reliability Engineering Plan	Reliability Test Cases	Reliability Reports Environmental Test Report	Reliability Summary Report	
Global Services Support				Product Introduction Plan	Product Introduction Plan Deliverables	Qualification Products	Service Support and Training Review
Quality (Includes Technical Product Management)		Previous Product Analysis Report	Risk Management Plan	Risk Assessment		Risk Management Report	Quality Metrics Customer Complaints
Regulatory Affairs			Regulatory Strategy			FDA Clearance Letter	
Finance			Requests for Beta Units	Cost Estimates and NPV	Financial Model Update		

WPDP
Project
Deliverable

WIDP
Project
Deliverable

WPDP
Project
Information

WIDP
Project
Information

BOM Bill of Materials
ECR Engineering Change Request
NPV Net Present Value

BE Beta
PP Pre-Production
RG Release General

Title: Waters Instrument Development Procedure

Document No: 730001286

Version No: 01

Page 13 of 14

9.5. Mass Spectrometry Instrument Project Deliverables and Product Information

	Concept	Feasibility	Definition	Development	Product Verification	Design Transfer and Validation	Post Release
Product Management	Business Case	Business Case Market Requirements Document User Requirements Document	Commercialization Plan Qualification Product Plan SAP Variant Configurator			Product ECR Released Release Notes Announcement to Field Ordering Guide Specification Sheets Certificate of Structural Integrity	Product Performance Review(s)
Technical Communications			Document Plan			User Documentation	
Project Management			Design & Development Plan Risk Management Plan	Risk Assessment Prototype Transfer Checklist		Design History File Index Product Release Cklist Product Release Cert.	Post Release Review (Product)-6- and12-Mo. Post Release Evaluation (Process)
Product Development	Systems Engineering	Feasibility Report	Product Requirements Document Hardware Requirements Document Software Requirements Document Design Traceability Matrix Design Verification Test Plan				
	Mechanical Engineering		Mechanical Design Plan	Design Documents and BOM at BE	Design Documents and BOM at PP	Design Documents and BOM at RG	
	Electronic Engineering		Electronic Design Plan	Design Documents and BOM at BE	Design Documents and BOM at PP	Design Documents and BOM at RG	
	Software Engineering		Software Design Plan		Software and Firmware Release Candidates	Software Media	
	Compliance Engineering		Compliance Plan		Compliance Test Report	Technical File Index Risk Management File Index Declarations of Conformity	
Evaluation			Design Validation Test Plan Design Verification Test Plan	Design Validation Test Cases Design Verification Test Cases Alpha Verification Summary Rpt Eng's Model Verification Summary Rpt	Design Verification Reports Beta Verification Summary Report	Design Validation Reports PP Verification Summary Report	
New Products Operations	New Product Introduction		Preliminary Supplier Assessment Report			Design Transfer Records Transfer Checklist Summ Product/Process Stability Rpt Summ	Manufacturing, Supplier, and Material Data
	Product Assurance Engineering		Product Assurance Plan		Beta Data Report Environmental Test Report	Process Validation Doc'n Product Assurance Plan Deliverables	
	Product Planning		Manufacturing Plan	Cost Estimate and NPV	Process Risk Assessment Report	Device Master Record	
	Production Engineering				Packaging Test Report Product & Spares Package Designs		
	Reliability Engineering		Reliability Engineering Plan	Reliability Test Cases	Reliability Reports	Reliability Summary Report	
Global Services Support				Product Introduction Plan	Product Introduction Plan Deliverables	Qualification Products	Service Support and Training Review
Quality (Includes Technical Product Management)		Previous Product Analysis Report		Supplier Audit Readiness Report		Risk Management Report	Quality Metrics Customer Complaints
Regulatory Affairs			Regulatory Strategy			FDA Clearance Letter	
Finance			Requests for Beta Units		Financial Model Update		

WPDP Project Deliverable

WIDP Project Deliverable

WPDP Project Information

WIDP Project Information

BOM Bill of Materials
ECR Engineering Change Request
NPV Net Present Value

BE Beta
PP Pre-Production
RG Release General

Title: **Waters Instrument Development Procedure**

Document No: 730001286

Version No: 01

Page 14 of 14

10. APPENDICES / ATTACHMENTS

None

DOCUMENT HISTORY

VERSION:	00	ORIGINATOR:	Mike Budnick and Rick Watts	Change ID:	N/A
VERSION:	01	ORIGINATOR:	Mike Budnick and Robin Carruthers	Change ID:	N/A
SUMMARY OF CHANGE: Added Prototype Transfer Checklist and Regulatory Strategy. Moved Product Requirements and associated deliverables to Definition Phase.					