How to Use the Form:

1. All BLACK text shall remain in the document. **BLUE** text serves as instructions, description, or examples and is to be deleted, modified and replaced. All **GREY** text is to be evaluated for relevance within the SOP, if the **GREY** text is relevant the text shall be turned BLACK, if the **GREY** text is not relevant it shall be deleted.

2. All text shall be BLACK when completed.

3. Delete this page after creating the document.

Project Development Plan for <Project ID/Offering and Version>

PROJECT DEVELOPMENT PLAN APPROVALS

The following people acknowledge that:

The appropriate verification and validation activities are to be conducted for the <Project ID/Offering and Version>

Approval Signatures:

Role	Signature (Printed Name)	Date (dd-MMM-yyyy)
<Offering Manager or Delivery Manager>	<Reviewer's Printed Name>	
Development Manager	<Reviewer's Printed Name>	
Quality and Regulatory Lead	<Reviewer's Printed Name>	
Architecture	<Reviewer's Printed Name>	
Independent Reviewer	<Reviewer's Printed Name>	

Project Development Plan - <Project ID/Offering Name and Version>

Date: <dd-MMM-yyyy>	
Version: <Insert version of Plan>	
Initiator(s): <Insert the name(s) of person(s) who are completing the form>	Role: <Insert the Initiator(s) Role(s)>

1 Purpose

2 Scope

1.1. In Scope

1.2. Out of Scope

3 Definitions, Abbreviations, Acronyms

Terms listed here are found within the content of this document.

General terms are defined in black and required for all SOPs and Work Instructions. The table should be sorted by Term, alphabetically.

Term	Definition	Abbrev./ Acronym
Code of Federal Regulations	Is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States	CFR
Good x (Clinical, Manufacturing, Laboratory) Practices	Good “anything” Practices per Watson Health QMS specific to food, drug, biologics or devices	GxP Also (GCP, GMP, GLP)
Offering or Solution	IBM Watson Health software, hardware, or services designed to deal with a problem or need, which is comprised of technology and/or support, and is packaged, sold, delivered and/or offered commercially.	---

Project	A pre-defined objective (or set of objectives) with scope, activities, deliverables, and timeline assigned to a project team	---
Quality Management System	A collection of business processes focused on achieving quality policy and quality objectives to meet customer and regulatory requirements (includes organizational structure, policies, procedures, and resources).	QMS
Record	A document retained as evidence of action that needs formal management under a QMS.	---
Standard Operating Procedure	Established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations	SOP
Watson Health	IBM Healthcare unit	WH

4 References

4.1 Prerequisites

List of procedures or documents that must be read or trained on prior to using this procedure.

4.1.1 First prerequisite, etc.

4.2 Dependencies

List of procedures or documents associated with this procedure that may need update if this document is changed, refer to the Document Log for dependencies

4.2.1 First dependency, etc.

4.3 Regulations / Guidance / Standards

List regulations, guidance documents, or standards that apply to the procedure (if listed in background, corresponds here); if global requirements apply, address generally

4.3.1 First Regulations/Guidance/Standards, etc.

1. Project Overview

<Insert Goals and Objectives of the project (i.e., what is to be developed)>

2. Project Roadmap

<Insert or attach high-level roadmap showing planned releases with the associated functionality(ies) for each release>

3. Major Tasks and Deliverables

<Identify major tasks to be undertaken, deliverables for the tasks and corresponding individuals or teams responsible for completing the tasks>

Role	Key Deliverable										
R – Responsible (creating deliverable) A – Accountable (ensures deliverable is done) C – Contributor I – Informed	Project Development Plan	Review of Project Development Plan	Design Input Specification	Review of Design Input Specification (high-level)	Review of Design Input Specification (detailed)	Build	Verification and Validation Plan	Verification and Validation Protocol	Verification and Validation Summary Report	Review of Verification and Validation Summary	<Add as needed>
Project Manager	R			A	A			A			
Tester				A			R,C	R,C	R,C	A	
Quality and Regulatory Representative					A			A			
Quality and Regulatory Lead		A		A						A	
Offering Manager	C	A	R,C	A						A	
Functional Manager of Architect	C	A		A						A	
Development Team	C		R,C			R	R,C	R,C	R,C		
Independent Reviewer (Name)		A		A						A	
Functional Manager of Development	C	A		A						A	
<add as needed (e.g., technical lead)>											

<Or use the approach below>

Planning (include timing at the high-level (eg., Q2 2017))

Project Planning

- Tasks – Creation of this document and a planning design review
- Deliverable – Project Development Plan (this document).
- Teams - Development, Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader

- Tasks –planning design review
- Deliverable – Design Review record
- Teams - Development, Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader

Design Inputs: (ie., Requirements)

- Tasks – Design input document will be developed and updated
- Deliverables – Design input specifications
- Teams – Development, Testing, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader
- Tasks – Requirements Review
- Deliverable – Design Review record
- Teams - Development, Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader

Design Outputs

Tasks – Design, code, unit tests and integration tests

Deliverables – build of executables

Design Verification and Validation

Tasks – Validation Plan will be developed for each phase.

Deliverables 1 – Validation Plan

Teams – Testing, Project Leader, Quality and Regulatory

Tasks – create the Verification Validation Test Protocol

Deliverables 2–Verification Validation Test Protocol

Teams – Testing, Project Leader, Quality and Regulatory

Tasks – Test Execution/Defect Management

Deliverables – Completed test cases

Teams – QA, Project Leader, Quality and Regulatory

Tasks – create the Validation Summary Report

Deliverables 3– Validation Summary Report

Teams – Development, QA Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader

- Tasks – Testing Review
- Deliverable – Design Review record

- Teams - Development, QA Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Commercial Operations, Project Leader

Design Transfer and Deployment to Pre-Production (see Installation SOP (WH_QMS_SOP_0019 for information)

Tasks – a verification test(s) confirm the functionality of the Offering prior to release into a production environment

Team – Installers

Deliverable – Offering Release Record, Release of the Offering

Design Changes

Tasks – Manage design changes

Deliverables – Change Request Form

- Teams - Development, QA Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Project Leader

Risk Management

Tasks – Create the Risk Management file

Deliverables – Risk Management Plan, Risk Assessments

- Teams - Development, QA Testing Lead, Architecture, Offering Management, Quality and Regulatory, Independent Reviewer, Analytics, Project Leader

Document Control (Maintenance and Management of Design History File)

Tasks- manage all project records

Deliverables – compilation of all the DHF records

Teams – Quality and Regulatory

5 Definition of timing of the Release and approvals to move to the next phase of the Release.

<Insert or reference timeline for releases and approval gates>

6 Identification of Offering Classification

<Insert classification >

7 Identification of Major Interdependencies of Key Activities

<List and describe any interdependencies of key activities>

8 Software Development Approach

<Identify the software development life cycle procedure that will be followed including any specific *tailoring* of the process. Include all supporting procedural documentation that will be used in the development of the software including vendor-supplied documentation (e.g., user/reference manuals).

9 Integration Planning

<Indicate the high level plan for integration of the components of the Offering>

10 Verification and Validation Planning

<Indicate the high-level Verification and Validation Plan>

11 Plan for Software of Unknown Provenance (SOUP)

<Indicate the plan for SOUPs>

12 Software Configuration and Change Management

<Indicate the plan for addressing the software configuration and change management processes in the development (including the SOUP (Software of Unknown Provenance) configuration items and software used to support development)>

13 Software Used to Support Development

<List the software used to support development of the Offering>

14 Software Resolution Plan

<Indicate the plan for software resolution and handling problems detected in the software products, deliverables and activities at each stage of the development>

15 Risk Management Plan

<Indicate high level risk management plan>

16 Traceability Plan

<Indicate the plan for addressing traceability between system requirements, software requirements, design information, software system tests, and risk control measures implemented in the software.>

17 Document Control and Records Management

<Indicate plan for document control and records management>

18 Description of Planned Deviations (if applicable)

<Description of planned deviations>

19 Design Review Committee Members Selection

- Planning Review Committee

  <Insert Review Committee Member Name (Role) and indicate lead with a *>

  <Name (Offering Manager/Delivery Manager), Name (Quality and Regulatory Lead), Name (Development Manager), Name (Senior Architect), Name (Independent Reviewer)>

- Requirements Review Committee

  <Insert Review Committee Member Name (Role) and indicate lead with a *>

  <Name (Offering Manager/Delivery Manager), Name (Development Manager), Name (Tester), Name (Architect), Name (Quality and Regulatory Lead), Name (Independent Reviewer)

- Testing Review Committee

  <Insert Review Committee Member Name (Role) and indicate lead with a *>

  <Name (Offering Manager/Delivery Manager), Name (Development Manager), Name (Tester), Name (Quality and Regulatory Lead), Name (Independent Reviewer)>

Template Version History

Version	Change	Revised By	Date (dd-MMM-yyyy)
1.0	Original	N/A	
2.0	Describe	Author Name	