IPRP
International Pharmaceutical Regulators Programme

Work Plan

Quality Working Group (QWG)

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1. Key Milestones and Deliverables

1.1. Current status of key milestones and deliverables

The QWG has completed the following projects, within the International Generic Drug Regulators Programme (IGDRP) and IPRP:

Past completion date	**Objective**	**Key Milestone or Deliverable**
2016	Tools for ASMF/DMF assessment	Gap analysis survey ASM/DMF frameworks and procedures: Results of the survey published in J Pharm Pharm Sci. 2016 Apr-Jun; 19(2):290-300

2015-2016	Tools for ASMF/DMF assessment	Lexicon of Quality Terms, common ASMF/DMF Submission Form, criteria for the submission of separate ASMF/DMF – published on the IPRP website
2016-2017	Tools for ASMF/DMF assessment	Common ASMF/DMF Quality Assessment Report template – published on the IPRP website
2016-2017	Tools for ASMF/DMF assessment	Guidance for Quality Assessors - Drug Substance – published on the IPRP website
2017	Tools for ASMF/DMF assessment	Repository of Technical Issues of Interest (ROTII) for Drug Substances
2018	Tools for ASMF/DMF assessment	Commence pilot ASMF/DMF database. Review of commonality of ASMF/DMFs submitted to member agencies
2018	Tools for ASMF/DMF assessment	ASMF/DMF database: created a spreadsheet in secure IT environment (hosted by the EDQM) with relevant data fields, developed a list of APIs of interest, engaged Industry about the concept, and requested ASMF/DMF holders consent to enter the data
2019	Tools for drug products assessment	Repository of Technical Issues of Interest (ROTII) – expanded scope to include Drug Product issues
Nov 2019	Tools for ASMF/DMF and drug products assessment	Survey of uptake and implementation of IPRP tools completed by all WG members
May 2020	Tools for drug products assessment	Guidance for Quality Assessors - Drug Product assessment – published on the IPRP website

1.2. Future anticipated key milestones

Expected future completion date	**Objective**	**Key Milestone or Deliverable**

Regular item	Tools for ASMF/DMF and drug products assessment	Deliverable 1: ROTII (DS & DP)
2021	Tools for ASMF/DMF assessment	Deliverable 2: Survey on administrative procedures and terminologies for Quality variations/post-approval changes
2021	Tools for ASMF/DMF and drug products assessment	Deliverable 3: Repository of key Quality Guidance documents and procedures
2021	Tools for drug products assessment	Deliverable 6: Quality Assessment Report template for drug product assessment
2021	Tools for drug products assessment	Deliverable 10: Opportunities for convergence in Drug Product assessment (as part of ROTII)
2021	Tools for ASMF/DMF assessment	Deliverable 5: ASMF/DMF assessment tools – Quality Information Summary template
2021	Mechanisms for information sharing on ASMF/DMF assessment	Deliverable 9: Project is currently at an exploratory stage. The objective is to investigate options for increased reports sharing, including identification of which ASMF/DMF has been submitted to which agency and industry participation.

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2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Deliverable	Project lead	Tasks and Activities details
	Regular item	Deliverable 1: ROTII for Drug Substance and Drug products (Prj 10)	ANVISA	Regular updates with questions and answers brought by members
October 2018	December 2020	ASMF/DMF database (Prj 16)	EDQM	End of pilot phase for the use of the ASMFs/DMF database by members - Start reviewing outcome of the pilot
	May 2021		EDQM	Prepare report from pilot phase review for endorsement by the IPRP MC
June 2018	Oct 2020	Deliverable 2: Survey on administrative procedures and terminology for Quality variations/post-approval changes (Prj 17)	All	- Update spreadsheet with recent changes and information from new QWG members
	March 2021		EU	- Update and finalise summary report - Consider options for publication
	May 2021		IPRP MC	Seek endorsement of the document by the IPRP MC and decision on publication
October 2018	Dec 2020	Deliverable 3: Repository of key Quality Guidance documents and procedures (Prj 18a)	INVIMA All	- Adapt spreadsheet structure to host links to agencies quality webpages - Get contribution from QWG members to add the links
	2021			- Expand spreadsheet to links to quality guidance documents and procedures - Get contribution from QWG members to add the links
October 2018	Oct 2020	Deliverable 6:	HC	Adapt template after finalisation of Guidance - Drug Product document and circulate for review
	Feb 2021		HC	Review of comments and agreement on content of the QAR template

	May 2021	Quality Assessment Report template for drug product assessment (Prj 20a)	HC	Endorsement by IPRP MC
October 2020	2021	Deliverable 10: Convergence for Drug Product assessment	TGA	Discussions in areas where opportunities for convergence in Drug Product assessment have been identified (as part of ROTII)
Nov 2018	2021	Deliverable 5: ASMF/DMF Quality Information Summary template (Prj 19)	All	Discussion and elaboration of a common template, available for use by members to facilitate identification of similar ASMF/DMF documentation and reports sharing
	2021		EU	Finalise template based on WG members comments and discussions in F2F meeting
	2021	Deliverable 9: Enabling greater inter-agency ASMF/DMF reports sharing and industry support for such activities (Prj 23)	All	Exploratory discussion on how inter-agency report sharing can been increased and how industry can be encouraged to support such initiatives. Recommendations to the IPRP MC