IPRP
International Pharmaceutical Regulators Programme

Work Plan

Quality Working Group (QWG)

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Co-Chair: Hélène Bruguera, EDQM

Co-Chair: Gary Condran, Health Canada, Canada

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

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)
Nov 2020	Tools for ASMF/DMF assessment	Deliverable 2: Survey on administrative procedures and terminologies for Quality variations/post-approval changes
Nov 2020	Tools for ASMF/DMF and drug products assessment	Deliverable 3: Repository of key Quality Guidance documents and procedures
Sep 2020	Tools for drug products assessment	Deliverable 6: Quality Assessment Report template for drug product assessment
May 2020	Tools for drug products assessment	Deliverable 7: Guidance for Quality Assessors for drug product assessment
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	Who	Tasks and Activities details
2017	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	Apr 2020	ASMF/DMF database (Prj 16)	EDQM	Pilot phase for the use of the ASMFs/DMF database by members: getting agreements from companies, recording entries, identifying matches and exchanging information among members
	Nov 2019		All	Monitory off database, sharing of database metrics.
	Oct 2020		EDQM	Review of project to be performed at the end of the pilot
June 2018	Oct 2019	Deliverable 2: Survey on administrative procedures and terminology for Quality variations/post-approval changes (Prj 17)	HC + EU All	- Prepare updated spreadsheet with items related to administrative procedures and terminology for Quality variations - QWG members to fill in the spreadsheet
	Jun 2020		HC + EU All	- Prepare an updated draft summary report of the survey, taking into account the new entries and suggestions from members - Consider possible options for publication
	Sep 2020		HC + EU All	- Finalise summary report - Agree on final report
	Nov 2020		IPRP MC	Seek endorsement of the document by the IPRP MC and decision on publication

October 2018	May 2020	Deliverable 3: Repository of key Quality Guidance documents and procedures (Prj 18a)	INVIMA	Prepare spreadsheet structure with areas of interest, intended to compile links to key Quality Guidance documents & procedures of member agencies for ASMF/DMF and for drug products
	Nov 2020		All	- Get contribution from QWG members to add the links
October 2018	End Dec 2018	Deliverable 6: Quality Assessment Report template for drug product assessment (Prj 20a)	HC	Scoping and preparation of a template report, based on work carried out by ACSS Generics Working Group
	Nov 2019 F2F meeting		All	WG discussion of draft document and finalisation
	Jun 2020		HC	Adapt template after finalisation of Guidance - Drug Product document and circulate for final review
	Sep 2020		HC	Endorsement by IPRP MC
October 2018	End Dec 2018	Deliverable 7: Guidance for Quality Assessors – Drug Product (Prj 20b)	TGA	Scoping and preparation of draft guidance, based on work carried out by ACSS Generics Working Group
	Nov 2019 F2F meeting		All	WG discussion of draft document
	May 2020		TGA	Finalisation of document and endorsement by IPRP MC
Nov 2018	1 Dec 2018	Deliverable 5: ASMF/DMF Quality Information Summary template (Prj 19)	EU	Compilation of existing tools and practices from member agencies
	Nov 2019 F2F meeting		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