

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 – Similarities and Differences for ASMF/DMF Frameworks and Procedures (Published in <i>J. Pharmacy & Pharmaceutical Sciences</i> ; 2016; Apr-Jun; 19(2):290-300)
2015-2016	Tools for ASMF/DMF assessment	Lexicon of Quality Terms, Common ASMF/DMF Submission Form, and Criteria for when a Separate ASMF/DMF should be submitted. (Published on the IPRP website)
2017	Tools for ASMF/DMF assessment	Quality Assessment Report (QAR) template – ASMFs/DMFs (Published on the IPRP website)
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 (Ongoing project)
2018	Tools for ASMF/DMF assessment	Commence pilot ASMF/DMF database. Review of commonality of ASMF/DMFs submitted to member agencies

Past completion date	Objective	Key Milestone or Deliverable
2018	Tools for ASMF/DMF assessment	ASMF/DMF database: Created a spreadsheet in a 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 product assessment	Repository of Technical Issues of Interest (ROTII) – expanded the scope of the ROTII to include Drug Product issues. (Ongoing project)
2019	Tools for drug substance and drug product assessment	Survey of uptake and implementation of IPRP tools (completed by all QWG members and observers)
2020	Tools for drug product assessment	Guidance for Quality Assessors - Drug Product (published on the IPRP website)
2021	Tools for drug substance and drug product assessment	Quality Assessment Report (QAR) template – Full Dossier (Published on the IPRP website)
2021	Tools for drug substance and drug product assessment	Survey on Administrative Procedures and Terminologies for Quality Variations/Post-Approval Changes (Published on the IPRP website)
2024	Mechanisms for information sharing on ASMF/DMF assessment	Close the pilot on ASMF/DMF database and provide a report on experience and lessons learned (Published on the IPRP website)

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
Regular (ongoing) item	Tools for drug substance and drug product assessment	Deliverables 1 & 10: Repository of Technical Issues of Interest (ROTII) (Drug Substance & Drug Product) Evaluation and identification of opportunities for convergence in Drug Substance and Drug Product assessment
(i) mid 2024 (ii) March 2025	Tools for drug substance and drug product assessment / Linkages with ICMRA's PQ KMS initiative*	(i) Survey of IPRP members and observers and analysis of the implementation of the IPRP Quality Assessment Tools <ul style="list-style-type: none"> • Guidance for Quality Assessors – Drug Substance • Guidance for Quality Assessors – Drug Product

Expected future completion date	Objective	Key Milestone or Deliverable
		<ul style="list-style-type: none"> • Quality Assessment Report (QAR) template for ASMFs/DMFs • Quality Assessment Report (QAR) template – Full Dossier (ii) Final report and recommendations for targeted revisions of existing IPRP Quality Assessment tools for potential updates and improvements
(i) March 2024 (ii) End 2024 (iii) mid 2025	Tools for drug substance and drug product assessment / Linkages with ICMRA’s PQ KMS initiative*	Analysis of similarities and differences for Quality post-approval changes (PACs)/variations (i) Survey of IPRP members and observers on procedures and experiences relating to PACs/variations (ii) Review of literature from industry on experiences relating to PACs/variations (iii) Report and recommendations on potential opportunities for convergence for PACs/variations
(i) Mid 2024 (ii) March 2025	Tools for drug substance and drug product assessment / Linkages with ICMRA’s PQ KMS initiative*	Survey of IPRP members and observers and analysis of the implementation of ICH Q12 (i) Survey of IPRP members and observers (ii) Report on analysis of the implementation of ICH Q12
On hold	Tools for drug substance assessment	Deliverable 5: ASMF/DMF Quality Information Summary (QIS) template
On hold	Tools for drug substance and drug product assessment	Deliverable 3: Repository of key Quality Guidance documents and procedures

* PQ KMS = Pharmaceutical Quality Knowledge Management System (PQ KMS)

(https://www.icmra.info/drupal/strategicinitiatives/pqkms/joint_reflection_paper)

2. TIMELINE FOR SPECIFIC TASKS

See detailed the tables in Section 1.2 and in the Annex.

ANNEX - FUTURE MILESTONES, TASKS AND TIMELINES

Beginning date	End date	Deliverable	Project lead	Tasks and Activities details
Regular (ongoing) item	Regular (ongoing) item	ROTII for Drug Substances and Drug Products (Project 10)	ANVISA, Brazil and INVIMA, Colombia	Regular updates with questions and answers brought by members. Evaluation and discussion on areas where opportunities for convergence in Drug Substance and Drug Product assessment can be identified (as part of ROTII)
March 2025	(i) mid 2024 (ii) March 2025	Survey of IPRP members and observers and analysis of the implementation of the IPRP Quality Assessment Tools	Health Canada, Canada	(i) Conduct a survey and analysis of the implementation of the various IPRP Quality Assessment Tools* by IPRP members and observers * Notably, <ul style="list-style-type: none"> • Guidance for Quality Assessors – Drug Substance • Guidance for Quality Assessors – Drug Product • Quality Assessment Report (QAR) template for ASMFs/DMFs • Quality Assessment Report (QAR) template - Full Dossier (ii) Final report and recommendations for targeted revisions of existing IPRP Quality Assessment tools for potential updates and improvements
Mid 2025	(i) March 2024 (ii) End 2024 (iii) mid 2025	Analysis of similarities and differences for Quality post-approval changes (PACs)/variations	FDA, United States; ANVISA, Brazil; EDQM; INVIMA, Colombia; SAHPRA, South Africa	Building on the IPRP QWG's published <i>Survey on Administrative Procedures and Terminologies for Quality Variations/Post-Approval Changes</i> , conduct a survey and analysis of challenges and identify potential opportunities to facilitate the timely management and implementation of PACs/variations for global markets (i) Survey of IPRP members and observers on procedures and experiences relating to PACs/variations (ii) Review of literature from industry on experiences relating to PACs/variations (iii) Report and recommendations on potential opportunities for convergence for PACs/variations

March 2025	(i) Mid 2024 (ii) March 2025	Survey of IPRP members and observers and analysis of the implementation of ICH Q12	INVIMA, Colombia; Swissmedic, Switzerland; EMA	Conduct a survey of the status of the implementation of ICH Q12 by IPRP members and observers and identify potential challenges of adoption of the Q12 concepts principles (i) Survey of IPRP members and observers (ii) Report on analysis of the implementation of ICH Q12
Pending	On hold	Deliverable 5: ASMF/DMF Quality Information Summary (QIS) template (Project 19)	Tbd	Discussion and elaboration of a common QIS template, available for use by members to facilitate identification of similar ASMF/DMF documentation and report sharing
Pending	On hold	Deliverable 3: Repository of key Quality Guidance documents and procedures (Project 18a)	INVIMA, Colombia	Review spreadsheet structure to host links to agencies quality webpages. Get contribution from QWG members to add the links