IPRP
International Pharmaceutical Regulators Programme

Work Plan

Nanomedicines Working Group

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1. Key Milestones and Deliverables

1.1. Current status of key milestones and deliverables

Past completion date	Objective	Key Milestone or Deliverable
Ongoing	Information sharing	Continued distribution of relevant regulatory documents and studies to the WG members through annual teleconferences and an annual face-to-face meeting (GSRS 19)
09 2019	Face-to-face meeting	Face-to-face meeting where regulators can meet and share case studies for complex or emerging products to ensure best practices in their regulation
09 2019	Standards development	Discussion at face-to-face meeting focused on the liposomal reference materials currently under development by the Canadian National Research Council and the development of a framework to facilitate regulatory research collaborative efforts.

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
05 2019	Face-to-face meeting	Face-to-face meeting where regulators can meet and share case studies for complex or emerging products to ensure best practices in their regulation
Ongoing	Information sharing	Continued distribution of relevant regulatory documents and studies to the WG members through

		annual teleconferences and an annual face-to-face meeting (CLINAM 12)
08 2020	Survey of liposome regulations	Publish updated survey to IPRP website (summer 2020) and write reflection paper (Dec 2020)

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**
01/2020	On-going	- Information sharing and mapping (annual regulatory updates) - Public outreach to nanomedicines Innovators' community - Standards development	- Compilation and sharing of regulatory documents for nanomedicines and follow-on nanomedicines through teleconferences, face-to-face meeting and publication to the website/sharepoint - Non-confidential updates on nanomedicine portfolios (general numbers of applications, types of products, etc). - Documentary test method standards and reference material that enable product development
01/2020	On-going	Training	- Sharing/attendance of learning and training opportunities offered by IPRF members or other organizations - Potential extension of training opportunities to nano-enable medical devices - Presentations of case studies to working group members through face-to-face meetings or web-ex seminars
01/2020	On-going	Development of proposal for enabling/enhancing collaborative regulatory research between regulatory agencies	- IPRP management committee approval for proposal– Nov/Dec 2019 - Finalizing questionnaires and databases to catalogue interested research laboratories/researchers and research needs by May 2020 – Discuss at face-to-face meeting

			- Distribution of research needs and laboratories interested/available for collaborative studies – summer 2020
Late 2019	10/2020	Survey of liposome regulations	- Survey questions to be finalized by December - Survey questions distributed to regulatory agencies in Jan 2020 - Preliminary results to be discussed at face-to-face meeting in May 2020
01/2020	10/2020	Organize 2020 face-to-face meeting	Plan and organize face-to-face meeting at CLINAM 2020