**Survey on Regulatory Requirements and Research Needs for Liposome Products**

**(For Non-regulatory Stakeholders)**

Thank you for your participation in our survey. Before you begin, please read the following:

In 2016, a survey was conducted among the International Pharmaceutical Regulators Forum (IPRF) Nanomedicine Working Group (NWG) members to map and exchange regulatory requirements for medicines that contain liposomal products ([Link for survey results](https://admin.iprp.global/sites/default/files/2018-09/IPRF_NWG_LiposomalResults_HC_Survey_Summary_Final.pdf)).

In Jan 2018, the IPRF and the International Generic Drug Regulators Programme (IGDRP) were consolidated to establish the International Pharmaceutical Regulators Programme (IPRP). The membership of the IPRP NWG has since expanded and currently there are 12 members and observers represented in the group ([Link for IPRP NWG Members and Observers](https://admin.iprp.global/sites/default/files/2019-12/NWG_List-MembersObservers_2019_1021.pdf)). The focus of IPRP NWG include non-confidential information sharing, regulatory harmonization or convergence focused on nanomedicines/nanomaterials in drug products, borderline and combination products, and follow-on nanomedicines.

IPRP NWG wishes to extend the survey in order to gain an overview on the regulatory progress that the expanded regulatory members have made with liposomal products over the past 4 years. IPRP NWG prepared two surveys: one for regulatory agencies and the other for non-regulatory stakeholders, to identify the needs of both research and standard development for liposome products. A comparative analysis of the regulatory landscape for liposomal products will also enhance the potential for harmonization of regulatory requirements. As a non-regulatory stakeholder, you are asked to answer two questions regarding regulatory research and standard needs to support liposome product development.

If you have any question regarding this survey, please contact the liposome survey team (Appendix 1) for clarification.

Please submit your survey responses **before Sep 1st, 2020**. Thank you in advance for your cooperation.

**Appendix I: 2020 Liposome Survey Team**

|  |  |
| --- | --- |
| **2020 Liposome Survey Team** | **Email** |
| **Therapeutic Goods Administration (TGA)**Anne Field | anne.field@health.gov.au |
| **European Medicines Agency (EMA)**Dolores Hernan | Dolores.Hernan@ema.europa.eu |
| **U.S. Food and Drug Administration (U.S. FDA)**Wenlei Jiang (Survey Team lead) | wenlei.jiang@fda.hhs.gov |
| **Swissmedic**Roman Leist | Roman.Leist@swissmedic.ch |
| **Federal Institute for Drugs and Medical Devices (**BfArM**)**Rene Thuermer | Rene.Thuermer@bfarm.de |

**Survey on Regulatory Requirements and Research Needs for Liposome Products**

**(For Non-regulatory Stakeholders)**

**Your organization name:**

**Contact person:**

**Contact email:**

**Contact phone:**

|  |  |
| --- | --- |
| 1. What regulatory research needs have your organization identified for liposomes and lipid complex drug products? This will help regulatory agencies to prioritize regulatory research in this area to ensure the body of knowledge, tools and standards needed to assess the quality, safety and efficacy of the products are generated.

Compared to conventional liposomes encapsulating small molecules, are there any specific requirements for such system used in delivery related to:* gene therapy
* oligonucleotide
* RNA/DNA
* Peptides/Proteins
 |  |
| 1. Which reference materials and documentary standards do you think the standards organizations (e.g. pharmacopoeia) should develop to facilitate development of liposome and lipid complex products? (Provide top 3)
 |  |