REGISTRATION OF COSMETICS AND QUASI DRUGS IN JAPAN

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DEFINITION OF COSMETICS & QUASI-DRUGS IN JAPAN

In Japan, cosmetics are regulated under Pharmaceutical and Medical Devices Law (PMDL, formerly Pharmaceutical Affairs Law) and they are classified into two categories: General cosmetics and Quasi-drugs.

General cosmetics are defined as "*articles with mild action on the human body, which are intended to be applied to the human body through rubbing, sprinkling or other methods, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition*."

Quasi drugs are defined as articles for the purpose of preventing nausea and other discomfort, preventing heat rash, soreness, etc., encouraging hair growth or removing hair or exterminating and preventing mice, flies, mosquitoes, fleas, etc.

The following is the list of products included in each category:

Cosmetics	Quasi-drugs
• Perfume and eau de cologne • Makeup cosmetics • Skin care cosmetics • Hair care products • Special purpose cosmetics • Cosmetic soaps	• Deodorants • Hair growth treatment • Depilatories • Hair dyes • Permanent waving agent • Bath products • Dentifrice • Medicated cosmetics: Anti-dandruff or anti-itching products; Freckle-removing products; Oily skin products. Shaving products; Anti-sunburn or "snowburn" products; Anti-acne products; Anti-bactericide products; Products to prevent chapping and roughness of the skin

The regulatory requirements for Quasi-drugs are more stringent than those for cosmetics. Quasi-drugs require pre-registration with PMDA before being commercialized in Japan, however, cosmetics require only a notification to PMDA and local authorities. For all products the labelling and product's information should be in Japanese.

REGISTRATION AND NOTIFICATION PROCESS OF QUASI-DRUGS AND COSMETICS IN JAPAN

The different steps for quasi-drugs' registration and cosmetics' notification are described below. In general, most of the steps are similar, except **Step 6**, **Step 7** and **Step 8** that are specific to quasi-drugs.

Step 1 :Appoint a Marketing Authorization Holder (MAH) in Japan

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Step 2: Review Product's Labeling and Assess their Compliance to Japanese Regulations

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Step 3: Review Product's List of Ingredients and Assess their Compliance to Japanese Standards

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Step 4: Conduct Local Testing at Authorized MHLW Laboratory

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Step 5: Prepare and Submit Notification for Cosmetics to PMDA

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Step 6: Prepare and Submit Registration Dossier for Quasi-Drugs to PMDA

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Step 7: Apply for GMP Inspection (applicable to Quasi Drugs only)

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Step 8: Receive the Products Registration Certificate from PMDA

Once the formula has been checked and products have been tested, the importer of cosmetics can fille three forms to competent authorities: a Manufacture and Sales of Cosmetics Notification, a Cosmetics Import Notification for Manufacture and Sales and the manufacturers or importer's brand name. Those forms should be kept with a record of the testing and inspection results verifying that the product does not contain any prohibited ingredients.

The cosmetic marketing notification is submitted to same prefecture as that which has granted the cosmetics marketing license and Cosmetics (foreign manufacturer, importer) notification is submitted to Pharmaceuticals and Medical Devices Agency, Japan (PMDA, Tokyo). I**n the case of GRP, the Governor of Tokyo**. The two notifications must either be accompanied by a list of full ingredients from the importer's supplier or manufacturer or, if this list cannot be obtained, a record of the testing and inspection results confirming the product does not contain any prohibited ingredient combinations instead.

CONTENT OF THE COSMETICS NOTIFICATION IN JAPAN

The cosmetics notification is submitted to PMDA, and it should include the following:

- Notification form
- List of all ingredients,
- A record of the testing and inspection results confirming the product does not contain any prohibited ingredient combinations instead

CONTENT OF THE QUASI-DRUGS REGISTRATION DOSSIER IN JAPAN

The quasi-drugs' registration dossier is submitted to PMDA, and it includes the following information:

- Application form
- List of Ingredients, amount and function
- Description of the manufacturing process
- Usage and dosage
- Function and efficacy
- Storage methods and shelf life
- Specification and testing methods

PMDA FEES

PMDA Classification	PMDA Fee (Yen)
Cosmetics	337,300
Quasi-drugs	355,900

About the Author

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As founder, President and CEO of Global Regulatory Partners Inc. (GRP), Dr. Suzan Davis provides the overall leadership, business strategy and day to day management at GRP. Her unique and extensive profile includes her experiences with various pharma, biotech and medical device companies. Her impressive international experience encompasses work in the United States, Europe, Latin America and Asia.

Dr. Davis has a doctorate in pharmacy and has more than 30 years of experience in strategic planning, regulatory affairs strategy, regulatory submissions, clinical trial operations and management, adverse event reporting and management, quality audits, licensing, CMC, technical transfer and business development within life sciences industry. Dr. Davis assumed many leadership, senior management and consulting roles in large and small biotech, pharma and medical device companies such as GSK, Pfizer, Genzyme, EMD Sereno, Millennium/Takeda, Forum Pharmaceuticals, Olympus, Smith and Nephew in United States and international markets as well.

References

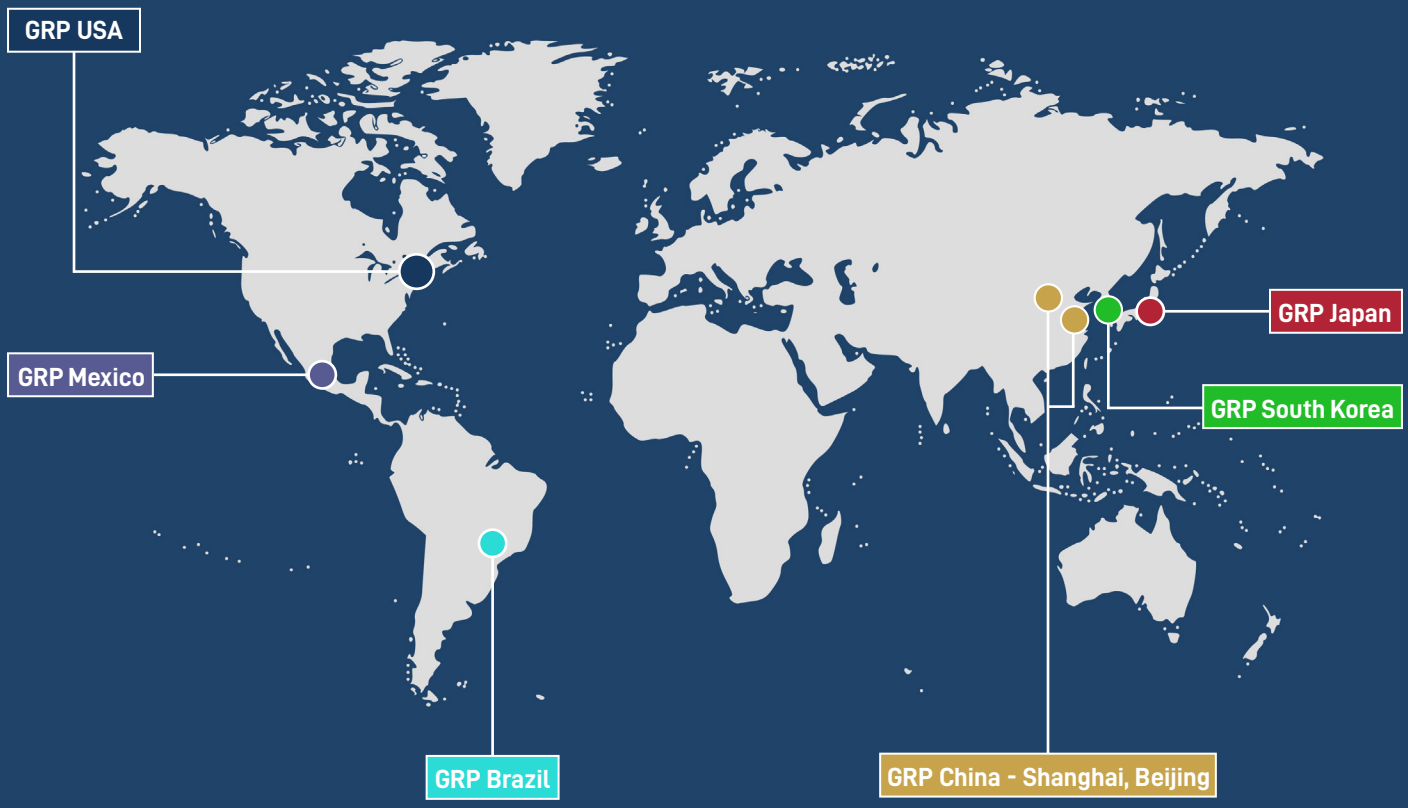
- Act for Ensuring Quality, Effectiveness, and Safety of Pharmaceutical and Medical Devices (Shortly Pharmaceutical and Medical Devices Law)
- Implementation Order of Pharmaceutical and Medical Devices Law
- Enforcement Rules of Pharmaceutical and Medical Devices Law
- Good Quality Practice
- Good Vigilance Practice
- GMP Ministerial Ordinance
- Submission Documents for Application of GMP Compliance Inspection
- Requirements for Applying for Marketing Approval of Quasi Drugs
- Standards for Accreditation of Foreign Quasi-drug Manufacturers
- Standards for Cosmetics
- Japanese Standards of Quasi-drug Ingredients 2006
- Ordinance on Tar Color Used in Pharmaceuticals
- Standards for Ingredients of Biological Origin

ABOUT GLOBAL REGULATORY PARTNERS, INC

Global Regulatory Partners Inc, (GRP) office in Japan provides clinical development, regulatory affairs, quality and pharmacovigilance services to foreign cosmetic, medical devices, and pharmaceutical companies in Japan. GRP Japan has a team of professionals who has expertise, and many years of experience is providing the following services in Japan:

- Market access to foreign cosmetics companies to Japanese market.
- Gap analysis between available information from US and/or EU and Japanese requirements.
- Local representation in Japan.
- Regulatory strategy for the registration of different cosmetics in Japan comprises of formulation review, label review and claims review
- Product Classification
- Product Testing
- Ingredient Analysis (as per Japan Cosmetic Industry Association (JCIA))
- Label Compliance Claims Review
- Regulatory Intelligence
- Japan Cosmetic Packaging Review
- Strategic Regulatory Consulting
- Labeling translation
- Preparation of cosmetics notification to PMDA and
- Preparation of registration dossier for Quasi-Drugs and submission to PMDA
- Cosmetics and Quasi-Drugs importation to Japan.

GRP LOCAL BRANCHES



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