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Head of Regulatory Affairs META

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Company: Galderma

Location: İstanbul

Category: other-general

Description

Lead Regulatory Affairs strategy, its programs and polices and provide strategic direction to regulatory activities on both new and in-line products in accordance with health authorities to define registration strategy and planning.

Role in Middle East, Turkey, Russia and Africa (META) Leadership Team role, and first point of contact for Regulatory for the General Manager of META.

Lead a team of 8 direct reports across UAE, Saudi Arabia, Turkey, Russia, and South Africa.

Job Responsibilities

META LT role and first point of contact for Regulatory for the GM of META.

Lead, shape, drive and execute all Regulatory Affairs priorities for all product classes (medicinal products, medical devices, cosmetics) across META

Lead and manage the entire registration process, ensuring approvals of new products, manufacturing permits, import permits, and amendments to products

Lead regulatory strategy development to enhance speed to market for new product development, and lead execution. Ensure new license applications are submitted within agreed project timelines, and approvals are obtained as planned.

Ensure compliance with, and maintenance of, existing licenses.

Provide strategic directions to the business, accountable for delivering project goals and

aligning functional strategies with business needs.

Team leadership. Build functional capabilities to enable growth. Manage resources capacity/allocation for required activities.

Lead interactions and negotiations with Health Authorities UAE and drive and oversee those in other markets, in connection with Pharmacists in Charge / Scientific Office managers, where applicable.

Shape the regulatory environment, driving an agenda to create an external environment in which our portfolio can thrive. Build a network with external experts.

Partnership with distributors and agents, where applicable

Ideally, has the credentials to take the role of Scientific Office Manager for Galderma Middle East (GME).

Minimum Requirements

Pharmacist Degree (PharmD)/ Bachelor's degree in pharmaceutical science.

Preferred UAE MOH licensed pharmacist (with active certificate)

12 years' experience in Regulatory Affairs, with at least 5 years in a team-leading role across multiple territories.

Hands-on technical experience in Middle East and(oversight) experience in one or more of the other territories (Russia, Southern Africa, Turkey)

Experience in the field of medicinal products and with additional relevant experiences in medical devices and/or cosmetics.

Galderma is the world's largest independent dermatology company, present in approximately 100 countries. Since our inception in 1981, we have been driven by a complete dedication to dermatology. We deliver an innovative, science-based portfolio of sophisticated brands and services across Aesthetics, Consumer Care and Prescription Medicine. Focused on the needs of consumers and patients, we work in partnership with healthcare professionals to ensure superior outcomes. Because we understand that the skin we're in shapes our life stories, we are advancing dermatology for every skin story.

For more information, please visit our website:

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