Role Description Regulatory Affairs – affiliate lead

Role: Regulatory Affairs (RA) affiliate lead	Version 1
Version Date : 1 September 2017	
Department: <<AP-XX>>Affiliate (Regulatory Affairs Group)	
Reporting line: Solid line: (Sub-)Regional Lead Regulatory Affairs Affiliate Management & Support Local dotted line: Medical Director, Head of Medical, Head of Pharmaceutical/Regulatory Affairs or General Manager	

Purpose of the role:

Manage and lead the affiliate RA department and staff with the overall responsibility for all Marketing Authorizations (MA) in scope of the affiliate.

Ensure timely preparation, submission and follow up of new MA applications to the local NCAs and ensures maintenance of authorized products through timely preparation and/or submission of variations, renewals, PSURs or supplements.

Ensure regulatory compliance with Astellas policies, EU and local laws and guidances.

Liaise within affiliate and with EMEA colleagues on matters relating to MA strategy, life cycle management and compliance.

Collect relevant public available regulatory information and use this information to inform relevant people.

Develop and maintain professional relationships with relevant external contacts such as governmental bodies and pharmaceutical industry association, where appropriate

Major tasks and responsibilities:

General department

Actively investigate and implement ways how the Regulatory Affairs department can contribute to the compliance, growth and profitability of the affiliate.

Implement locally new initiatives, management tools or processes in cooperation with RA-EMEA. Ensure that all affiliate RA staff has access to the necessary tools and systems.

Ensure liaising between RA-EMEA, the affiliate MT and the competent authorities. Be the key contact for the competent authorities.

Ensure that processes, procedures and regulatory files are well documented in an up to date and complete archive.

Contribute to the RA-EMEA and affiliate Quality Management System. Ensure compliance with all applicable SOPs, WPDs and STLs and have CAPAs in place in case of gaps and deviations.

If applicable: Ensure full regulatory support by the local business partners or the local organization and coordinate the required contribution from the local business partners or the local organization to the RA process.

If applicable: manage the department budget.

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Major tasks and responsibilities - continued:

RA staff and training

Ensure that the affiliate has sufficient capacity and capability to conduct all regulatory affairs related matters.

Ensure that affiliate Regulatory Affairs staff is timely and well trained and ensure documentation of such training. Training documentation should include Role/Job descriptions, CVs and training records. Appraise staff and make development plans.

Regulatory intelligence and strategy

Ensure that local regulatory intelligence in all extend is monitored, applied and communicated within RA-EMEA and within the affiliate.

Coordinate the affiliate contribution to the EMEA regulatory strategy wherever possible and needed and communicate the affiliate input to RA-EMEA.

Ensure strategic and operational alignment of RA activities with e.g. Marketing, Sales, Market Access & Pricing and reimbursement and logistics departments to allow the commercial and logistics departments to anticipate and plan product registrations and belonging launches.

Regulatory submissions and approvals

Ensure compliance with the change control process for Marketing Authorizations.

Ensure that the up to date RA-EMEA planning is known and executed.

Ensure development registration strategies for the assigned projects and develop processes for the improvement of registration time lines

Ensure the submission and approval, in time and with high quality, of new marketing authorisations and related regulatory submissions to the concerned, competent authorities.

Ensure that the approved Summary of Product Characteristics (SmPC) or/and the leaflets, are available and updated for internal and external use

Ensure that responsibilities for submission and implementation of Risk Minimization Measures is executed conform internal and external guidance.

If applicable: ensure regulatory reviews and support for tendering processes.

Regulatory compliance

Ensure that approvals of regulatory submission are communicated to the right stakeholders in the right way and with the right timing. Stakeholders include, but are not limited to internal and external databases.

Ensure that artwork (printed packaging component) creations and changes are managed, approved in a consistent and compliant way using the artwork management system. Ensure monitoring of implementation in production.

Provide regulatory representation for GxP Inspection teams and ensure that the regulatory component of these inspections is addressed.

Ensure that regulatory review and approval of (abbreviated) prescribing information and promotional materials are conducted as mandated by Astellas procedures and country legislation.

If applicable: ensure that local mandated task as e.g. responsible regulatory/technical/pharmaceutical person are executed as required by local legislation.

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Key Interactions:

Serve as the point of contact for the RA-EMEA and Regional Affiliate Support Group, the affiliate MT and brand teams and the local Competent Authorities.

Cross functional collaboration and communication both a affiliate and HQ level.

Professional profile:

- MS Degree in Pharmacy or other Life Scienceor equivalent by experience.
- At least 5 years Regulatory Affairs experience, including directly dealing with regulatory agencies
- Knowledge of Regulatory landscape and procedures within the country/region
- Proficiency in local and English language
- Good communication, influential, planning and problem-solving skills, along with the ability to build and manage close relationships with all relevant stakeholders