“Local regulatory maintenance activities South Korea”

PLX-21-22656/PLX-21-24200

1 Scope and territory

In the frame of this work order **CONSULTANT** performs consultancy services / regulatory support for **PharmaLex** in **South Korea.** These include the following tasks (without being restricted to them):

	Activities		KR
1	Regulatory frameworks and strategy for lifecycle management. Including all types of variations, additional indication, renewal and MAH change. In case a change results in an NDA this is in scope.	• Anticipates regulatory obstacles and emerging issues throughout the product lifecycle and develops solutions.	Y
		• Negotiates with regulatory authorities on non-complex issues throughout the product lifecycle.	
		Represent RA in cross function meeting (i.e. S&OP) and provides regulatory information and guidance for proposed change.	
3	Product Claims / Labelling	• Reviews change controls to determine the level of change and consequent submission requirements	Y
		• Provides regulatory information and guidance for proposed product claims/labelling.	
		• Check regulatory compliance of product information /artworks (Text Verification Tool)	
4	Information communication in relation to regulatory strategy and submission	• Primary RA contact and provides regulatory input & technical guidance to internal/external stakeholders, e.g. MA, CTO, GSM, Marketing, Business team, Legal team, Product Supply, PV, QA, RRAM, GRA, GRS, CMC, R2S, BRAVE Compliance & HA.	Y
		• Support to Global (rPTS for selected project; Regulatory Strategy; Local Surveys; New MA)	
		• Escalates and effectively communicates issues to relevant stakeholder and ensures alignment on issues, questions, and goals.	
5	Translation activities	• Update / local PI (Labelling translation)	Y
		• Any other document for submission required to be translated.	
6	Advertising and Promotion	• Review advertising / promotional material against approved label (where applicable)	Y
		• Reviews and approves advertising and promotion to ensure regulatory compliance.	
7	MAH withdrawal	• Non-voluntary MA withdrawal: Participates in implementation of regulatory strategy and processes for handling recalls and communication to stakeholders (e.g., Dear Healthcare Professional letters, patient letters, distributor letters, and health authorities).	Y

	Activities		KR
		• PQSC support with or without withdrawal: Report product safety issues to regulatory authorities as required, to comply with local, regional and global regulations.	
9	PV related document	• Provide RA documentation and strategy support, when PVCH received requested from authority's pharmacovigilance department.	Y
12	Regulatory Intelligence	• Understands the impact of changing regulations on preapproval and post-approval strategies and approaches and advises internal stakeholders on a course of action.	Y
		• To communicate regulatory Intelligence, strategic activities, consultation via the Client APAC RPI process e.g. email communication template, summary template, update CATweb and RAPID.	
13	Cross-functional communication on Scientific Issues	• Perform RA submission as per Client SOP 1224 Local Supplements Document on Heath Authority interaction and perform its related BRAVE entry.	Y
		• Provide RA feedback for activities stated in Client SOP 1224 (RA consultation)	
		• Provide latest regulated information to support the following activities: medical information in case of questions from patients, customer letter issued by commercial.	
		• Provide RA support for documentation for tender, market access, commercial request; with legal in consultation or preserves confidentiality of product information as appropriate.	
14	Critical issue management	• Understands the issue and provides guidance to integrate regulatory considerations to support issue management	Y*
		• Participates in risk-based decisions on special access approvals/compassionate use based upon patient needs and risk assessment. Provide RA support to secure special consignment, import permit, NPP, EAP.	
		• Participates in and provide RA support in S&OP (if necessary or provide information for the meeting, management of out-of-stock situations and Product Quality and Safety Committee (PQSC).	
		• Perform RA submission to HA following local ACF manager or local Crisis team decision as per Margo No. 50 and local SOPs	
		• Assists other departments in the development of SOPs to ensure regulatory compliance.	
		• Helps train stakeholders on current and new regulatory requirements to ensure organization-wide compliance.	
17	RA representative during site inspections		Y
18	Launch	• Provide RA support in new launch such as supporting Product Supply in creation of new SKU from new manufacturing site (Change Application process) and give estimated timeline of target approval to APAC Supply Chain Department and during Demand meeting to ensure continuous supply.	Y
		• Provide RA information such as regulatory pathway, registration timeline to enable for a business case or a launch application submission by commercial colleagues and performs relevant Client system updates e.g. BASIC and BRAVE	
19	Business compliance & Ethic	• Abides by and upholds the laws and regulations of the authorities under which he or she operates and the organization’s internal/external policies and directives.	Y

	Activities		KR
		• Takes all possible steps to prevent and resolve any real, apparent or potential conflicts of interest between work responsibilities and private affairs.	
		• Ensure regulatory aspects of business relationships to ensure compliance and protect Client corporate interests.	
		Performs regulatory operational activities post due diligence and decision is concluded by Client.	
21	Medical device	Performs same activities as above.	Y

*On case by case after decision of Client caretaker/supervisor.

New registration for Medicinal Product (Woman Health):

- Responsible for the overall registration process from defining local registration strategy / dossier preparation / HA interaction from submission, DL management to final approval
- Internal interaction with Client stakeholders including Client global (RA CMC, label and CPC etc.) for submission and Client local team (periodic update to local commercial / RA, or interaction with other functions if required)
- Specifically for submission dossier gap analysis of old dossier and current KR requirements, and activities to create up-to-dated dossier, if required, (including update/creation of CTD M2)
- Entries / updates of Client systems required during the process, if required

Timeframe

Contract Duration: 1 month onboarding + 12 months operational activities (until 31-Jul-2023).

Trainings

Company representative has to ensure that any trainings are completed within given timeframe. If the training cannot be finished before anticipated due date a notification shall be send well in advanced to the project supervisor to align next steps. PharmaLex and Client trainings will be assigned by the respective colleagues in charge of the onboarding process.

Work will be conducted by COMPANY's employees on approx.: 0.8 FTE

Requirements

Countries	Remote Work	Access to HA portal	Remotely payment of HA fees	Replacement during absence
KR	In country required including in country mobile phone (HA	Not mandatory, but practically Korean	Local credit card is	Company has to ensure

Countries	Remote Work	Access to HA portal	Remotely payment of HA fees	Replacement during absence
	communicates frequently using mobile phone including notice of review phase change. E.g. DL issuance)	nationality is needed to have ID and passcode for HA portal	needed or banking transfer	appropriate replacements during any absence

Appendix 1 – Product list

7 medicinal products (Woman Health and General Medicines)