Medical Product Regulations Mentor

Bhutan

This assignment has been negotiated in good faith with the Partner Organisation, and the information contained was correct at the time of acceptance of the request. However, while we take responsibility for matters under our direct control, all assignments and arrangements are subject to change. This assignment may be amended or withdrawn to reflect changes in circumstances.

ASSIGNMENT DETAILS

Assignment title	Medical Product Regulations Mentor			
Partner Organisation	Medical Product Division, Bhutan Food and Drug Authority ,			
Location	*Thimphu*			
Website of Partner Organisation	www.bfda.gov.bt			
Total Duration of assignment	6 months		**Start date**	26th October, 2026
Type of assignment	In-person		**Australian Organisation**	N/A
Assignment Phases *(For Hybrid Assignments Only)*		*Volunteer Mode*	*Duration*	*Time Commitment*
	Phase 1	In-country	**6 months**	Full-time (In-Country)
	Phase 2			N/A
	Phase 3			N/A
	Phase 4			N/A

PARTNER ORGANISATION OVERVIEW

The Medical Product Division, under the Bhutan Food and Drug Authority (BFDA), was formerly known as the Drug Regulatory Authority. Following the civil service reform process in Bhutan, the Drug Regulatory Authority merged with the Food and Narcotics Control Authorities to form the BFDA. The agency's vision is to achieve excellence in protecting and advancing the health and safety of the nation. The mission of Medical Product Division is to safeguard the health of humans and animals by ensuring the quality, safety, and effectiveness of medical products.

The Medical Product Division operates through three technical sections i.e. Drug Evaluation Section, Licensing and Vigilance Section and Medical Device Section. The division is responsible for regulating medical products, including medical devices, throughout their life cycle. The regulation includes pre-market control through premise and personnel authorisation and assessment of product dossiers for registration of medical products. The post-market control entails testing, inspection and monitoring, management of defective, substandard and falsified medical products.

Through these measures, the Medical Product Division ensures that medical products available in the market meet established standards for safety, quality, and efficacy, contributing to public health protection.

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ASSIGNMENT DETAILS

Assignment overview

To ensure the safety, quality, and performance of medical devices, the erstwhile Drug Regulatory Authority (DRA) was mandated by the Bhutan Medicines Board in 2019 to regulate medical devices, starting with the regulation of TTI test kits. The formal regulation of medical devices commenced in 2022, marked by the Authority notifying a list of medical devices to be regulated. Given the diversity and varying complexity of medical devices, a phase-wise approach was adopted. Initial efforts focused on pre-market control mechanisms, including the evaluation of technical dossiers and the authorization of personnel and premises involved in the sale and distribution of medical devices.

While pre-market regulation remains critical, the establishment of robust post-market surveillance is equally essential to ensure the safety and performance of medical devices throughout their lifecycle. The Medical Product Division (MPD) is still in the early stages of regulating medical devices and faces significant challenges due to a lack of specialised technical expertise. Currently, the division faces challenges due to insufficient in-depth knowledge of medical device technologies which are necessary for evaluating complex technical dossiers and conducting thorough assessments. Another critical issue is an inadequate skills for Market Surveillance and limited capacity to monitor and manage adverse event reporting; conduct post-market inspections and investigate safety concerns.

In this context, the engagement of an Australian volunteer with expertise in medical device regulation could play a pivotal role. Such support would enable the Medical Product Division to build capacity, strengthen both pre- and post-market regulatory systems, and ensure alignment with international best practices. This collaboration would be invaluable in establishing a robust regulatory system capable of addressing the unique challenges associated with medical device regulation in Bhutan.

Assignment objectives

Framework refinement: Support in the enhancement and implementation of a robust regulatory framework for medical products, aligning with international best practices and tailored to Bhutan's unique needs and regulatory landscape.

Build Capacity and Expertise within the MPD: Support in identifying key areas where the Medical Product Division requires support and build local capacity, focusing on developing a comprehensive understanding of medical products regulations.

Establish a Sustainable Post-market Surveillance System: Support in developing and implementing a post-market surveillance system that can continuously monitor the safety and effectiveness of medical devices in the market, addressing emerging risks and ensuring long-term protection for public health.

To include all people directly affected by the volunteer assignment in the Partner Organisation and community, using strategies that promote: gender equality; inclusion of youth; inclusion of people with a disability; child protection and safeguarding; inclusion of marginalised groups.

Duties and responsibilities of the volunteer

Conduct Situational Analysis for Regulation of medical products in Bhutan:
Support and assess the current regulatory landscape and identify gaps in legislations and guidelines to create a comprehensive situational report.

Refine and Strengthen the Regulatory Framework:
Support in developing proposals and implementing tailored improvements to the regulatory framework, in alignment with international best practices and addressing Bhutan's unique needs.

Conduct Training and Capacity Building for Medical Product Division Staff:
Support in delivering focused training sessions to enhance division staff knowledge and skills in dossier evaluation; risk-based inspections including quality system inspection of manufacturing firm; and enhancement of post-market surveillance (product

Institute Post-market Surveillance System:
Support in designing/instituting a robust system for continuous monitoring of medical products, including adverse event reporting,

inspections, and risk assessments.

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Selection criteria
Minimum bachelor's degree qualification in a relevant field such as biomedical engineering or pharmacy.
Sufficient and demonstrated hands-on experience in medical products regulation, including pre-market evaluation, post-market surveillance, and regulatory compliance.
Strong understanding of both international regulations (e.g., IMDRF, WHO, ICH) and national laws governing medical devices, with the ability to navigate and apply these laws effectively.
Ability to communicate clearly and effectively
Preferably laboratory experience and work experience with the Therapeutic Goods Authority of Australia

Desirable skills, language and experience
Excellent verbal and written communication skills in English
A minimum hands-on experience in medical device regulation, including pre-market evaluation, post-market surveillance, and regulatory compliance.
Excellent ability to deliver training programs with strong analytical and problem-solving skills.

Line Manager	Jigme Tenzin, Chief Regulatory Officer, Medical Product Division
Staff Supervision	No
Working relationships	*1. Jigme Dorji, Sr. Regulatory Officer (RO), 2. Gyelwa Kuenzom, Sr. RO, Licensing and Vigilance Section Licensing and Vigilance Section, 3. Sonam Chophel, Sr. RO, Drug Evaluation Section, 4. Sangay Choden, RO, Drug Evaluation Section,*
Hours and days of work	Monday to Friday, 9:00am-5:00pm, public holidays
Leave	All volunteers are entitled to 1 week of leave for every 3 months worked. They are also entitled to the same public holiday leave as local colleagues.
Professional indemnity insurance (Required for all volunteers who are acting as a medical, allied health or legal professional whilst on assignment.)	***No - This assignment is not deemed to require professional indemnity insurance*** The volunteer should consult the partner organisation about the need for professional indemnity insurance for the role prior to departure. Where required and/or considered essential to hold this insurance, please discuss this with the Volunteer Services Manager in Melbourne prior to departure.

LIVING AS A VOLUNTEER

The Australian Volunteers Program supports volunteers from preparing to go on assignment through to returning home. For a full breakdown of support provided, please visit: https://www.australianvolunteers.com/volunteering/lifestyle-and-support/

Living allowance	**AUD 749 (In-country)** The allowance levels are based on the cost of living in the host country location and are listed in $AUD. Allowances will be reviewed periodically and may increase or decrease.
Accommodation allowance	AUD 660 (In-country)

Language support	Language support is provided during the in-country orientation period. Most often, additional resources for further development later in the assignment will be available if required.
Country profile	Learn more about the host country location by reading the country profile. We encourage candidates to research the specific location of this assignment as it will be discussed and addressed with a recruitment officer during the interview process. https://www.australianvolunteers.com/countries/bhutan

Australian Volunteers Program

Political or faith-based activities	The Australian Volunteers Program supports partner organisations to achieve their development objectives. It does not engage in or support any evangelical activities and is not linked to any political party. We partner with local faith-based organisations on the basis that the volunteer placement does not engage in evangelising; and participation in activities run by the volunteer is not conditional on conversion or adherence to a particular religious denomination. We also partner with advocacy organisations on the basis that volunteer activities are not in support of a political party or candidate.

HOW TO APPLY

All applications must be submitted online through the Australian Volunteers Program website. If you have not already done so, you will need to register on our website prior to applying. For more information about how to apply, please visit:
https://www.australianvolunteers.com/volunteering/how-it-works

We actively support and encourage people of all backgrounds and abilities to volunteer internationally, and aim to make the program as accessible and inclusive as possible. The program has a dedicated Indigenous Programs Coordinator to support Aboriginal and/or Torres Strait Islander volunteers, who can be contacted at indigenouspathways@australianvolunteers.com. Access and inclusion plans are available for volunteers with disabilities, to ensure their assignments and living and working arrangements are made more accessible.

Personal circumstances

Due to security, cultural, legal or visa restrictions associated with this location, we ask that applicants disclose:

- If they want their same-sex partner to accompany them on assignment.
- If they want their partner, to whom they are not legally married, to accompany them on assignment.
- If they want their child(ren) to accompany them on assignment.
- If they have a criminal conviction where a criminal conviction may be relevant to the inherent requirements of the assignment.