

## Pharmaceutical regulatory consultancy in Bangladesh

We are pharmaceutical, cosmeceutical & medical device regulatory consultants in Bangladesh. Our team consists of registered pharmacists, supply chain graduates, biostatisticians and lawyers having more than 13 years of experiences in this field.

### Current clients:

1. Meril Bangladesh Pvt. Ltd.
2. Medtronic Bangladesh Pvt. Ltd.
3. Roche Diagnostics GmbH, Germany
4. Fresenius Medical Care Bangladesh Ltd.
5. MicroPort Medical (Group) Co., Ltd., China
6. Alliage S/A Industrias Medico Odontologica, Brazil
7. Guangdong Baihe Medical Technology Co. Ltd., China

### We are the API registration holder of:

1. Chemeca Drugs Pvt. Limited, AP, India
2. Hetero Labs Ltd., Hyderabad, Telangana, India
3. Glochem Industries Pvt. Limited, Hyderabad, India

Pharma DRA possesses all legal documentation for holding your product registration (i.e. Marketing authorization) as a local agent/importer.

### Services we offer

- ❖ Medical device & medicine registration service.
- ❖ Software (as medical device) registration service.
- ❖ Regulatory intelligence service & documents review.
- ❖ API Source validation (registration) service in DGDA.
- ❖ Product registration holding in favor of manufacturer.
- ❖ Cosmetics registration and regulatory intelligence.
- ❖ Pharmacovigilance service & ADR Monitoring service.
- ❖ Translation service from Bengali to English & vice versa.
- ❖ New project profile preparation, submission & approval.
- ❖ Content writing service for medical & pharmaceuticals.
- ❖ Price certificate application to DGDA for import purpose.
- ❖ Indent & clearance of shipping documents during import.
- ❖ Dossier preparation of finished medicine and medical device.
- ❖ Warehouse/wholesale drug license for import & distribution.

## Products of Pharma DRA

- Bilirubin & Haemoperfusion cartridge.
- Disposable plastic apron for medical use.
- Baby safety travel bed (0-2 months of age).
- Registration software database for renewal/expiry date.

## Our expertise

- ✓ We communicate with local authority 5 days a week.
- ✓ We have successfully got registration of 130 medical devices.
- ✓ We completed 12 APIs source validation registration in DGDA.
- ✓ Two project profiles of manufacturing plant have been submitted.
- ✓ We are the MA Holder of 6 foreign medical device manufacturer.

## Contact us

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