AAHVI PHARMA PVT.LTD. is a pharma consultancy company has expertise for managing liaison assignments in all sections of the Drug Departments, working for varied R&D Sites, Manufacturers (API & Formulations), Sales (Wholesale and Retail) & Importers.

AAHVI generally look at the drug regulatory compliance from the angle of customs laws to avoid future complications.

AAHVI provide comprehensive regulatory agency liaison services to pharmaceutical (API and Formulations) companies to help navigate the complex regulatory landscape and ensure compliance with applicable regulations.

AAHVI also provide complete preparation of Dossiers. We are regularly retained to prepare dossiers for obtaining R&D Site Approval, Manufacturing Licenses, Sales Licenses, GMP, GLP etc. from respective State Drug Controller (DCA), Regional (Zonal) CDSCO and DCGI (HO) Delhi.

We *AAHVI PHARMA PVT.LTD*, acting as a bridge between the company and relevant government bodies national level, facilitating communication and ensuring compliance.

Our Capabilities

- Filing necessary applications and handling all government interactions pertaining to the regulation and certification process for a R&D Centres, Manufacturing plants, Distribution and sales of API & Formulations,
- Provide support as needed for routine Health Authority (HA) submissions including New Protocol Submissions, Protocol Amendment, Renewal, Production Transfer (PT) Submissions, New Product Planning (NPP) (non EU countries) etc. and as applicable act as main liaison with RA Operations to ensure accurate and timely submissions to HAs.
- Serve as the primary point of contact between your company and regulatory agencies to communicate and work with agency representatives to account for regulatory compliance.
- Provide guidance to internal stakeholders, such as product development teams, on regulatory requirements and expectations.
- Helps your organization stay up-to-date with all relevant regulatory requirements, including changes in regulations, guidelines, and industry standards, and advises the company on any necessary changes to maintain compliance.

Services for Regulatory and Statutory Compliances (Approvals/Licenses/ Permissions)

- Product registrations & compliance management for R&D Centres as per NDCT Rules 2019.
- Licensing & approvals from state drug authorities (DCA) Telangana, Zonal office CDSCO – Hyderabad and DCGI – New Delhi as per Drugs and Cosmetics act 1940 and rules 1945.
- Assistance in factory, labour, and legal compliance.
- R&D Recognition from DSIR (Department of Scientific and Industrial Research) Registration and Renewal.

R&D Sites: *Preparation and Approvals of EIGHT SCHEDULE of NDCT Rules 2019.*

- Preparation of Protocols and Reports of Technology Transfer of products from R&D site to various manufacturing facilities).
- **Form 29/30** (license for manufacturing drugs for examination, testing, and analysis)
- **Form CT-01/02** (Grant of Registration of Ethics Committee Relating to Clinical Trial or BA And BE Study.
- **Form CT-04/06** (Permission to Conduct Clinical Trial of New Drug or Investigational New Drug)
- **Form CT-07** (Permission to Conduct Bioavailability or Bioequivalence Study of New Drug or Investigational New Drug
- **Form CT-10/11** (Test License NOC for approved API and Unapproved Formulations)
- **Form CT-12/14** (Test License NOC for Unapproved API and Unapproved Formulations)
- **Form -12** (Import of approved API/Formulations for test and analysis)
- **Form CT-15** (License to manufacturing of unapproved API)
- **Form CT-16/17** (Import of Unapproved API/Formulations for test and analysis)
- **Form CT-18/19/20** (Grant of Permission to Import (API and Formulation) New Drug for Sale or for Distribution)
- **Form CT-21/22/23** (Permission to Manufacture New API and Formulation for Sale or for Distribution)

Licensing & Approvals from state drug authorities (DCA):

Manufacturing: *-*

- Registration of **ODLS/ONDLS/SUGAM/NSWS/IPDMS** portal.
- Formulation/Bulk Drugs in Form 24/25 (API and Orals) (Grant, License Retention and Amendment).
- Formulation/Bulk Drugs in Form 27/28 (API and Schedule C,C1 (Injections) (Grant, License Retention and Amendment.
- Repacking License in Form 25B (Grant, License Retention and Amendment)
- Loan Licenses in Form 24A/25A and Form 27A/28A (Grant, License Retention and Amendment).
- Formulation in Form 27D-Large Volume Parenteral (Grant, License Retention and Amendment).
- Approval/Deletion of additional products (API and Formulations)
- Change of Premises of Manufacturing facility.
- Change of Firm name.
- Change of Constitution.
- Change of Directors
- Change of Technical Staff
- Change of Composition.
- Change of Specification.
- Specific Export Quantity (NOC) of API and Formulation for manufacturing.
- Dual Use NOC for drug (bulk and finished form) and cosmetics,
- Grant/Renewal/Additional products of Cosmetics preparations.
- GMP Certification for Manufacturing facility
- GLP Certification for Quality Control Laboratory
- WHO GMP Certification of Products (API and Formulations)
- CoPP (Certificate of Pharmaceutical Products)
- Free sale Certificate of Export Products
- Non-Convection Certificate
- MMC (Mfg.&Mrktg.) Certificates.
- Performance Certificate.
- Production Capacity Certificate
- NEUTRAL CODE Certificate

Sales (Grant, Renewal & Amendment)

- Documents Preparation for retail sale license in Form 20 and Form 21
- Documents Preparation for wholesale license in Form 20B and Form 21B
- Documents Preparation for Schedule X wholesale and retail license in Form 20G
- Documents Preparation for NDPS 1 License.

- Change of Premises, Constitution, Firm name, Directors, Pharmacist and Competent person in all sales licenses.
- Submissions at Regulatory Govt. Offices in State FDA, CDSCO- Central, Zonal and Sub Zonal Offices
- Submission of Govt. fee for various Licenses, NOCs and Permissions.
- Submission, Meetings and Collection of Test Reports from Govt. Labs (NABL, CDTL/CDL etc.,)
- Participation in SEC meetings at DCGI-New Delhi for NDA/ANDA in India.
- Technical and Regulatory Support for queries by Drugs authorities & officers.

How AAHVI Can Aid

Our team of experienced regulatory professionals has the expertise to help you navigate the regulatory landscape and ensure compliance with applicable regulations. We work closely with you to understand your specific needs and develop customized solutions that meet your unique requirements.

AAHVI can also aid you in customized requirements:

- NLEM (National List of Essential Medicines) periodical submissions to authorities.
- Compliance of NPPA as per the DPCO 2013.
- MRP updating and Periodical submission of Form –II, Form –III and Form-V in IPDMS 2.0
- Issues resolving related to MRP violations and compliance with DPCO 2013 for Scheduled and Non-Scheduled products.
- Technical and Regulatory Support to Dealing with legal associates related to NSQ (Not of Standard Quality).
- Approval of ARTWORKS required for Formulation preparations as per the Rule 96 (manner of Labelling) of Drugs and Cosmetics act 1940 and Rules 1945 and other notifications issued by DCGI – New Delhi.
- Manufacturing Site Audits (GAP Analysis).
- Product adduce procedure via local courts and sending the samples to CDTL-Kolkata for retesting of NSQ Samples.
- Dealing with CDTL–Kolkata related to testing of samples collected by Drug authorities in Form 17.
- Grant and renewal of FSSAI (Food Safety and Standards Authority of India) certification.
- Approval of Commercial lab in Form 37.
- Approval of Blood banks.
- **TRADEMARK/BRAND NAME** Registrations for Pharma products.
- Animal toxicity studies as per Schedule “Y” of D&C act 1940.

AAHVI eCTD Preparation & Submission Services
eCTD Preparation for Applications & Submissions

We have the expertise to assemble all the required documentation for preparing eCTDs related to the following:

- Investigational New Drug (INDs)
- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Drug Master Files (DMF)

AAHVI Product Registration & Import License

Pharma companies are required to complete Product registrations and obtain import license to launch a pharmaceutical product in a new market. This regulatory process ensures that the product meets the regulatory standards of the country in question and is safe and effective for use by patients. Agencies require sponsors to submit detailed information about the product, including its composition, manufacturing process, and clinical data, to the regulatory authority for review. Once the product has been approved, it is listed on a national registry, and the manufacturer is granted permission to market and sell the product within the country.

Import license is a formal permission granted by a regulatory authority that allows a company to bring a pharmaceutical product into a country from another country. The import license is typically obtained in parallel with the product registration process, and the requirements for obtaining an import license can vary among different countries.

Both product registration and import license are important steps in the process of bringing a pharmaceutical product to market, as they The process of obtaining product registration and an import license can be complex and time-consuming, and companies may need to engage the services of regulatory consultants to ensure a successful outcome.

AAHVI Impending Services:

eCTD Preparation & Submissions

The preparation and submission of regulatory information in the standard electronic Common Technical Document (eCTD) format is a critical step in the regulatory approval process for new drugs and medical devices, and it requires a significant investment of time, resources, and expertise.

The process involves gathering of enormous amount of information from clinical trials that accounts for the safety, efficacy, and overall risk-benefit quality of the medicinal product. Most global regulatory agencies such as US FDA (USA), EMA (EU), Health Canada (Canada), TGA (Australia), Japan's MHLW, and few other health authorities

have mandated eCTD for regulatory submissions making it a globally accepted submission format.

Pharmacovigilance Services

- Strategic and operational benefit/risk safety services.
- Management of case reports and adverse event reporting, Individual Case Safety Report (ICSRs) Processing.
- Post-Marketing Surveillance Non-Solicited/Spontaneous Reports.

Medical Writing Services/ Clinical & Regulatory Writing Services

- Clinical Study Reports
- Company Core Safety Information (CCSI), Company Core Data Sheet (CCDS),
- Summary of Product Characteristics (SmPC),
- Creation of detailed NDA, ANDA and IND applications (Module 1,2,3,4 and 5)

***MEDICAL DISTRIBUTION*:**

AAHVI Deals with the distribution of medicines to Retail Medical shops, Institutions, Hospitals, Clinics in various places of twin cities.

AAHVI Distributes, all ranges of formulation medicines like Tablets, capsules, Syrups, Suspensions, Drops, Injections (Ampoules, Vials & PFS) of the below category;

Analgesics, Antibiotics, Antibacterial, Antimicrobial, Antihistamines, Antipyretics, Anticoagulants, Antidepressants, Anticonvulsants, Antidiarrheal, Antihypertensive, Antidiabetics**,** Insulins, Antifungal, Antiviral, Anti-Anxiety, Anthelminthic, Antineoplastic (Anti-Cancer), Neurology, Urology, Antacids, Beta-Blockers, Bronchodilators, Cold Cures, Corticosteroids, Cough Suppressants, Decongestants, Diuretics, Expectorant, Hypoglycaemic, Immunosuppressive, Laxatives, Muscle Relaxants, Orthopaedic, Gynaecology, Paediatric, Pre-Probiotics, NSAID drugs,

Inhalants, Critical Care Injectable (ICU), Anaesthetics, Tranquilize, Vitamins, Minerals, Antioxidants etc.,

Ophthalmic Preparations,

Dental Medicines,

Digestive Medicines,

ENT Medicines,

LVPs (Large Volume Parenteral), like RL, NS, DNS, Mannitol, Metronidazole etc.,

Topical preparations like Ointments, Lotions, Creams, of Analgesics, Antibiotics, Antibacterial, Antimicrobial, Antiseptics etc., categories.

Nutraceuticals & Food Products.,

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