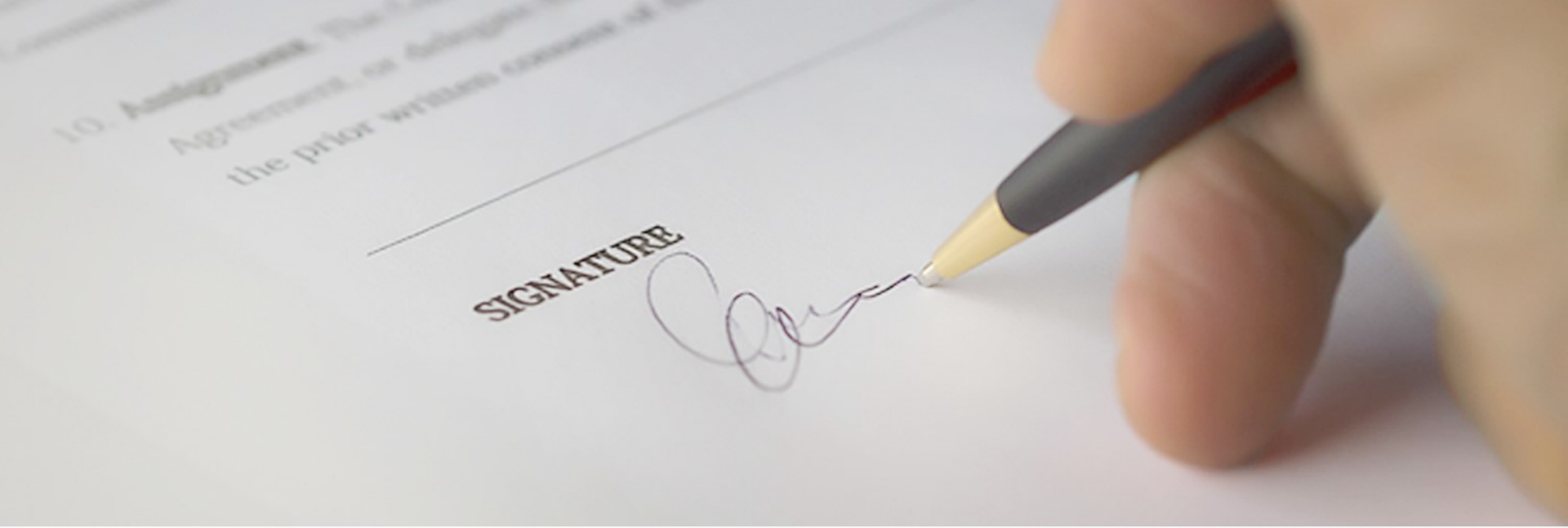
Aariya Regulatory Services

Corporate Presentation

Agenda Style



About Aariya

A Global Regulatory Services Company

About Aariya

Vision

To become a noble regulatory consultancy, delivering high quality regulatory support to clients for introduction of wide range of generic and branded products in the key market.

Mission

We thrive to provide focused, quality and flexible services to the utmost satisfaction of our clients building long-term relationship.

Core Values

Success and strength of any company rests on its strong beliefs and values. We believe in Customer service excellence, Uncompromising quality, Ethics and integrity, Rapid Continuous improvement, and Promotion of team work.

Focus Markets

U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY

Health Canada

pmda

Australian Government Department of Health Therapeutic Goods Administration

MEDSAFE NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY

SAHPRA South African Health Products Regulatory Authority

asean

ANVISA

COFEPRIS

NATIONAL MEDICAL PRODUCTS ADMINISTRATION

WHO

CDSCO

fssai FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA Inspiring Trust, Assuring Safe & Nutritious Food

Aariya Facts

12+ Global Clients

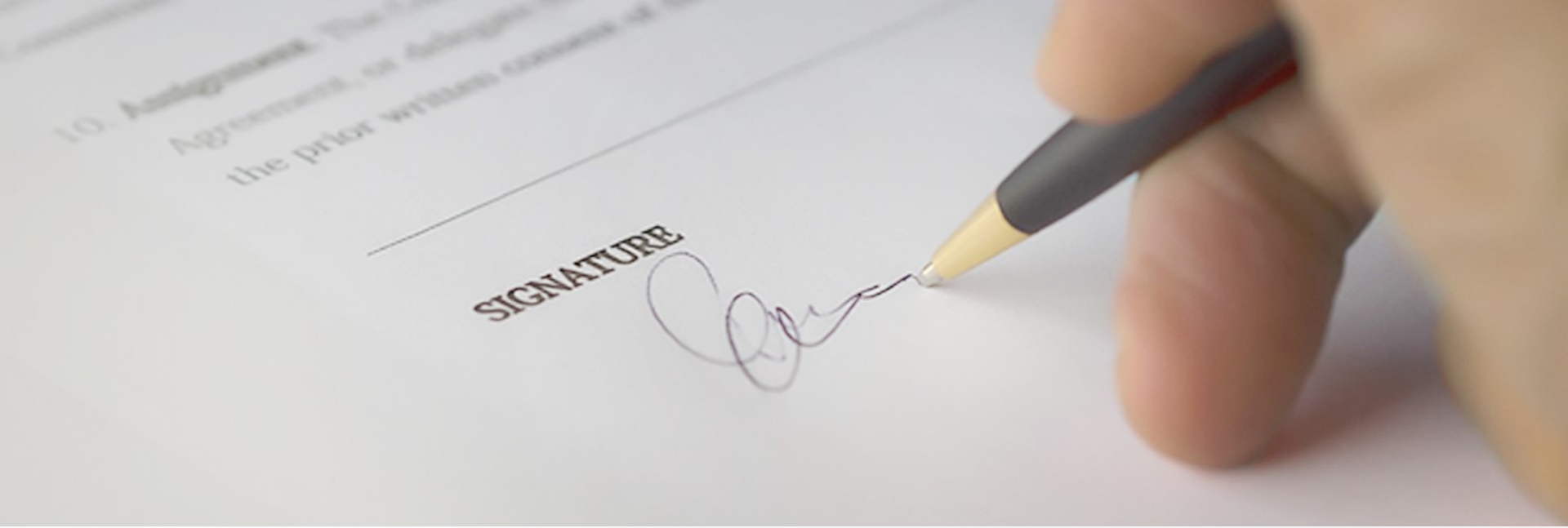
60+ Projects

100% Project Success & Customer Satisfaction

2+ Years of Relationship

15+ Regulatory Strategy & Operations Experts

50+ Regulatory Affiliates in 20+ Countries



Our Services

End-to-End Regulatory Services

Our Services

End-to-End Regulatory Services

Drugs . Biologics . Vaccines . Medical Devices . Cosmetics . Food . Nutraceuticals

REGULATORY OPERATIONS – CMC

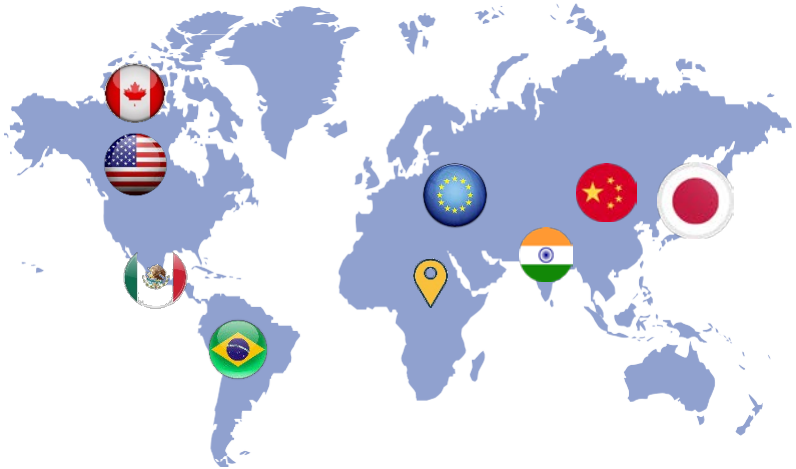
ELECTRONIC PUBLISHING & SUBMISSION MANAGEMENT

REGULATORY LABELING

MEDICAL WRITING & PHARMACOVIGILANCE

GRAPHICS & ARTWORK MANAGEMENT

LEGAL REPRESENTATION/ LOCAL AGENT



Our Differentiators

- ✓ We are a team of highly experienced individuals with an experience of **over 15 years** in Regulatory Affairs
- ✓ We maintain a **robust process** for handling each project and ensure in time completion of projects
- ✓ We believe in **"customers first"** and focus on quality

Regulatory Consulting Services

Strategy through Operation

Regulatory Strategy

- Regulatory Roadmap and Advisory
- Strategic Input during Product Development
- Engagement with Health Authorities (HAs)
- Strategizing Global Filings

Regulatory Intelligence

- Portfolio Management
- Regulatory Stewardship
- Harmonized Master Dossier Templates

Regulatory Operations – CMC

- New Product Registrations – Drugs, Biologics, Vaccines, Medical Devices, Cosmetics, Food and Nutraceuticals
- New Market Authorizations – APIs, Excipients and Premix(es)
- Orphan Drug Application
- Local Testing for Drugs and Medical Devices
- CCC Marking for Medical Devices
- Response to HA Queries
- Post-Approval Lifecycle Management – Supplements, Annual Reports/ Notifications, Renewals and Re-registrations

Regulatory Operations – CMC

Conceptualization to Dossier Preparation

Regulatory Strategy

- ❑ Identification of reference product as per global commercialization plan
- ❑ Strategic input through-out product development phase, be it:
  - Setting of QTPP
  - Identification of CQAs/ CMAs and Risk Assessment
  - Formulation and Process Optimization using DoE
  - Designing of Specifications (*for* SM, API, RM, PM, Intermediates and FP)
  - Pilot bio-studies
  - Technology Transfer
  - Scale-up establishing Design space
  - Exhibit batches
- ❑ Engage with Regulatory Agencies via. Meeting Requests, Controlled Correspondences and Protocol Assistance
- ❑ Strategize global filings by ensuring adequate data generation in line with most recent regulatory expectations.
- ❑ Defining the appropriate regulatory pathway when regional complexities are present (e.g. EU – National Procedure, De-Centralized Procedure, Mutually Recognized Procedure)

New Product Registrations

- ❑ Regulatory content authoring, review and compilation of:
  - INDs, 505(b)(2) NDAs, BLAs and ANDAs for USFDA
  - ANDSs for Health Canada
  - MAAs for Europe via Centralized Procedure or National Procedure or Mutual Recognition Procedure or Decentralized Procedure
  - Article 10(4) Application via Centralized procedure for Biosimilars with EEA
  - MAAs for Australia and New Zealand
  - Dossiers for all emerging countries:
    - South Africa
    - Russia and Commonwealth of Independent Nations (CIS)
    - Latin America (LATAM)
    - Middle East and North Africa (MENA)
    - Asia-Pacific (APAC)
    - Association of Southeast Asian Nations (ASEAN)
    - World Health Organization (WHO)
  - Drugs, Cosmetics, Device and Food registration in India
- ❑ Due diligence for extending products approved in one region to other markets

Regulatory Operations – CMC

Filing through Approval to Lifecycle Management

New Market Authorizations – API/ Excipient/ Premix

- Regulatory writing, review and compilation of:
  - Drug Master Files (DMFs)
  - Active Substance Master Files (ASMFs)
  - Certificates of Suitability (CEPs)

Health Authority (HA) Queries - Responses

- Handling of HA queries to secure fast-track approvals through:
  - Prompt resolution of filing deficiencies to rescind RTR decisions
  - Swift addressal of ECDs, IRs, DR letters, SDNs, CMC/ BE Clarifax(es), CMS/ RMS comments, etc. received from HAs
  - Requesting scientific advice from HAs for action on CRLs and NONs

Post-Approval Lifecycle Management

- Evaluation of change, assessment of submission category and identification of required supporting documents
- Compilation and submission of post-approval submissions:
  - Line extension
  - Commitment to Conditional Approval
  - Supplements (PAS, CBE-30, CBE-0) and Variations (Type I & II)
  - Annual Reports and Annual Notifications
  - Renewals and Re-registrations
  - PV Compliance

Regulatory Labeling

Concept to Implementation

Labeling Services - USA

- Preparation of Prescribing Information (PI), Patient Information Leaflet (PIL), Medication Guide (MG), Instructions for Use (IFU)
- Preparation of side-by side Labeling and Label comparisons
- Preparation of Labeling Quality-based-Review (QbR) document
- FDA Deficiency Response Management
- Continuous Monitoring/ Tracking of the Reference Listed Drug (RLD) Labeling.
- Updating Generic Product Labeling as per Safety or Non-safety changes approved for the Reference Listed Drug (RLD) Labeling
- Preparation of Labeling History document for tracking the changes in labeling throughout the life cycle.
- Preparation of Labeling Changes Summary for Annual Reports

Labeling Services - EU

- Preparation of Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labeling text (LT)
- Preparation of Annexure 1, 2, 3 & 4 in accordance with Quality Review of Documents (QRD)
- Coordination of EU Linguistic review activity
- Visual Quality Control (QC) of different translated labeling documents in line with English text.

Labeling Services - Canada

- Preparation of Product Monograph (PM), and Patient Medication Information (Part III)
- Preparation of Annotated and Non-Annotated Product Monographs
- Continuous Monitoring/ Tracking of Canadian Reference Product (CRP) Monograph
- Preparation of Notifiable Changes (NC) submissions in case of Safety changes as per CRP updates for Generic Drug Products in accordance with the “Guidance Document: Post-Notice of Compliance (NOC) Changes: Safety and Efficacy" document to reflect the Plain Language Labeling Regulations.

Regulatory Labeling

Concept to Implementation

Lalebling Services - OTC

- Preparation of Drug Facts labeling in accordance with 21 CFR 201 labeling requirement
- Preparation and maintenance of Master Label Copy (MLC) for approved OTC products
- Review and maintenance of OTC templates
- OTC monograph Labeling
- Review and approval of multiple customer artworks

Structured Product Labeling (SPL)

- SPL for Original/ Existing Submissions for NDA, ANDA, BLA products
- SPL for Drug Listing
- SPL for Establishment Registration
- SPL for Self-Identification
- SPL for Labeler Code request
- SPL for REMS
- SPL for No Change Certificate
- SPL for Active Pharmaceuticals Ingredients (API)

REMS

- Preparation of REMS for Generic companies in line with innovators REMS.
- Supporting Generic companies to develop Single-Shared REMS in coordination with innovator companies and FDA.
- Continuous monitoring of FDA's REMS website for the REMS revisions/ Modifications.

Graphics & Artwork Management

Creative but Compliant

Graphics Designing

- Artwork Creation – Bottle labels/ cartons, Blister foils/ cartons, Tube labels, Sachets, etc.
- Artwork Creation – Prescribing information (PI), Package insert (PI), Package Outsets (PLR/ Non-PLR), Patient Information Leaflets (PIL), Medication Guide (MG), Instructions for Use (IFU).
- Artwork Creation for OTC products (Drug Facts) – labels, cartons, blisters, stand-alone label, extended labels, clamshells as per 21 CFR 201.
- Creation of actual size Pill illustrations
- Creation of multi-language artworks including “Braille”
- Logo Creation
- Designing of Brochures, Flyers, Danglers, etc.

Commercial Artwork Management

- Supply of customer-specific process (native) files for commercial printing
- Proof-reading of artworks and other labeling components
- Change Control Management

Publishing & Submission Management

eCTD Made Easy

Electronic Publishing

- ❑ Worldwide support for both eCTD and Non-eCTD electronic Submission (NeeS) formats
- ❑ Streamlined process, through:
  - Document level publishing
  - eCTD population and compilation
  - Technical Validation – Verification and Correction
  - Quality Check (QC)

Submission Management

- Legacy paper management and Conversion to NeeS to eCTD
- Conversion of DMFs to eCTD
- eCTD Lifecycle Management
- ESG services using authorized submission portal

Medical Writing & Pharmacovigilance

Medical Strategic Platform

Regulatory Medical Writing

- Clinical and Non-clinical sections of the Common Technical Document (CTD), including Overviews and Summaries
- Clinical Study Reports (full, abbreviated, interim, and synoptic)
- Protocol Development (including synopses and amendments)
- Investigator's Brochures (IBs)
- Prescribing Information (PI), Patient Information Leaflets/ Medication Guide, Summary of Product Characteristics (SmPCs)
- Company Core Data Sheets (CCDS)
- Briefing documents for Agency meetings

Drug Safety and Pharmacovigilance

- Aggregate Reports/Periodic Safety Update Reports
- Risk Management Plans (RMP)
- Case Processing and Reporting
- Patient Safety Narratives
- Signal Detection
- Literature Monitoring Services

Clinical Trial Disclosure

- Anonymization Report and Redacted Reports as per EMA Policy 0070
- Protocol and Results Disclosure to Clinicaltrials.gov, EudraCT, and Local Registries
- Lay Person Summary (LPS)

Scientific Information and Communications

- Manuscripts
- Co-authorship to journal submissions
- Conference Materials (Abstracts, Posters and Slide decks)
- Publication Planning (Literature reviews and Journal submission)
- Product Website Content (for both scientific and patient audiences)
- Educational Material (for patients, healthcare professionals and industry personnel)
- Medical Marketing Reviews and Reports
- Web Synopses

Thank You!

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