REAL WORLD CASE STUDY

eCTD submissions in US, EU, ASEAN markets

10 weeks
for go-live

20+
COE resources

100%
Regulatory and timeline compliance

Business Need

- US based TOP 10 pharma company required support in preparation and filing of the eCTD/CTD submissions in US, EU and ASEAN markets
- Client had limited regulatory resources / experience to prepare, publish and file regulatory dossiers
- Product portfolio included 2 groups – drugs and CHC products
- Service portfolio included several individual and grouped variations

Solution

- Dedicated CoE across multiple geographies with US based Program Director and EU based Client Servicing Manager
- 2 onshore and 18 FTEs offshore, including Regulatory Specialists, Associates, QC and Program managers
- Regulatory database management, dossiers creation, compiling per local requirements, publishing and final updates to the RIMS
- Facilitate the approval process by effective coordination with headquarters, local affiliates and manufacturing sites.

Outcomes

- Lead time of only 10 weeks from contract signing to training, on-boarding and go-live
- Reuse of documents for other submissions and updates.
- 28% effort efficiencies delivered within 1 year of engagement
- Consistently good feedback from the Client with discussion on expansion into other service areas

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REAL WORLD CASE STUDY

Clinical Trial Application & Submissions

Business Need

- A Major Global Pharmaceutical company required regulatory submission support in the preparation of Clinical Trial Applications (CTAs) and Submissions in multiple countries within Europe.
- The scope of services included
  - Preparation & planning of CTAs
  - Review & Submission of CTAs
  - Clinical Trial Lifecycle Support and follow-up
  - Regulatory intelligence on the CTA document requirements in various countries

**UK, Belgium, France , Germany, Sweden*

Solution

- Indegene set up a 5 member team of regulatory writers with extensive experience in understanding the complex country-specific and local regulatory requirements.
- Developed a robust Implementation plan to quickly achieve steady state and a strong QC and communication process to track KPIs
- The team carried out the following activities
  - Preparation/review of CTA dossier plans
  - Robust review aligned with competent authorities and sponsor requirements
  - Early identification of deficiencies
  - Effortless navigation of the submission systems used by different countries
  - Provide support during the phase of authority review and query resolution
  - Handling of all substantial and non-substantial amendments
  - Maintain records of all regulatory steps, particular correspondence and applicable documentation

Outcomes

- Robust review and timely communication helped guide the client through the European approval process avoiding too many queries or formal deficiencies from competent authorities
- Accurate interpretation of the regulatory environment and submission scenarios resulted in compliance to regulatory timelines and international standards.

REAL WORLD CASE STUDY

Clinical Trial Disclosure

50+ **Trials**

100% **Compliant - SOP, Quality, and Timelines**

20+ **Client POCs**

3+ **Years Engagement**

Business Need

- CVS clinical research team wanted clinical trial registration and results disclosure support
- Actively track and advise on potential impact of key regulatory reforms
- Help them align with the evolving guidelines and regulations.

Solution

- Regulatory and clinical experts deployed for managing Regulatory compliance.
- Comprehensive disclosure reporting in a centralized, cost-effective manner.
- Tracking, assessments, document management, summarization, release information to registries, registry query, and monthly site/status updates.

Outcomes

- 100% accurately and compliance with minimal sponsor management
- Scalable, flexible, cost-effective model

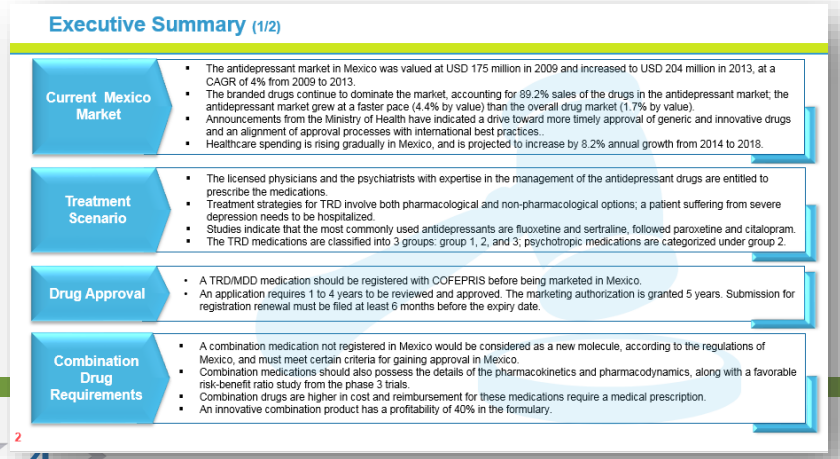
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REAL WORLD CASE STUDY

Regulatory Intelligence: Product Launch Support

Business Need

- Pharma company is developing a combination drug formulation to be launched successfully in brazil and Mexico. Company wants to have a thorough understanding of regulatory market scenario in the countries
- To provide an in-depth analysis of the Brazilian and Mexican markets and their regulatory environment in order to successfully launch of the drug for a neurological disorder.



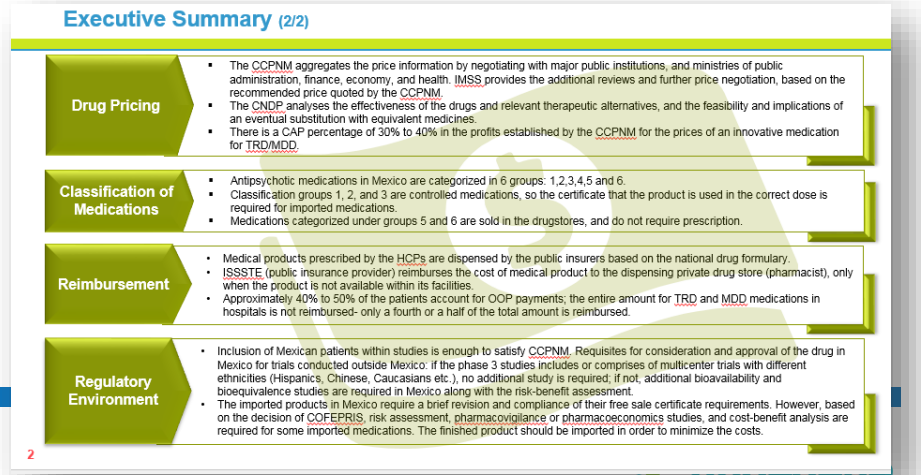
Solution

Indegene executed this project through secondary research (using any data available on the public domain such as country specific regulatory websites, healthcare databases etc.) and Key Opinion Leader (KOL) interviews with emphasis on the following key intelligence topics providing the Overall market scenario

- Factors influencing the launch of new drugs in Brazil and Mexico
- Pricing and reimbursement scenario
- Healthcare coverage and spending (Private versus Government.)
- Regulatory environment including the regulatory pathways

Outcomes

- Two comprehensive reports providing the insights on the regulatory and the market scenario was provided which helped the company to understand the regulatory pathway



REAL-WORLD CASE STUDY

30+
CSRs (Full & Abbreviated)

Business Need

A major biopharmaceutical company required regulatory writing management & support for Clinical Study Reports (CSR) of their studies (including pivotal trials) in US and the EU

100%
Compliance

Solution

- Indegene deployed a dedicated team of experienced senior regulatory writers with extensive therapeutic knowledge (such as cardiovascular, reproductive medicine & gynaecology, immunology, and oncology) & understanding of the drug development process as per ICH standards
- The team worked in close collaboration with the customer to communicate requirements & progress against timelines, and ensure all quality controls are met.
- Our in-house biostatisticians, clinical research experts and medical reviewers worked together with our medical writers to produce high quality clinical reports, with specially formatted tables and charts and detailed custom graphics.
- In addition, a rigorous quality assurance process was implemented to ensure all clinical study reports are accurate, complete, and in compliance with regulatory

3+ Years
Engagement

Outcomes

- The CSRs were submitted to the appropriate regulatory agencies as per the agreed due date in compliance with ICH standards
- Indegene consistently provided high-quality reports by adopting a sustainable, cost-effective,& flexible working model solutions that reduced the need for additional review and re-work and helped our customer to crystallize the essential results that regulators need to know
- The prepared CSRs helped optimize and streamline the preparation of ensuing CTDs, thus saving customer time and money spent by 20%

Client Speak – "Thank you for the exceptional work!!! We all truly appreciate having you involved in what we do and look forward to continuing a close and successful working relationship with you"

REAL-WORLD CASE STUDY

20+
CSRs (Synopsis and Supplemental)

Business Need

A major biopharmaceutical company required the support of Indegene to coordinate and author high quality Clinical Study Reports (CSR) for regulatory submission in the APAC region

100%
Compliance

Solution

- A dedicated team of local and remote medical writers for authoring and QC was deployed who had extensive domain expertise & understanding of the drug development process as per country specific regulatory standards within APAC
- The medical writers worked in collaboration with the biostatisticians, clinical research experts, medical reviewers and regulatory publishers to produce consistently high quality submission-ready clinical reports that met regulatory expectations.
- A rigorous quality assurance process was implemented to ensure all clinical study reports are accurate, complete, and in PDF format with all necessary bookmarks and hyperlinks set to the correct destination PTT tables.

2+ Years
Engagement

Outcomes

- Delivered consistent and measurable high quality reports that met regulatory expectations.
- A winning combination of a dedicated team and flexible support, enabled large volume of documents to be generated on time and within budget. The client continues to remain a long-term partner.

Client Speak – "Indegene has become a true extension of our internal team. The feedback received has been phenomenal! Thank you for the great work!!"