APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Continued Compliance

Regulatory Services

Regulations in the pharmaceutical sector are rapidly changing - thus making regulatory compliance even more imperative. Pharmaceutical companies are trying to keep pace with them and facing challenges due to difficulties in filing and submission for seeking timely drug approvals. These trends have impacted their product marketing and market expansion activities.

Key Regulatory Challenges Faced by Pharmaceutical Companies

- **Correct Interpretation of Regulations**
- **Delays in submission** of dossiers and impact on marketing approvals
- **Limited inhouse regulatory intelligence & Skills**
- **Maintenance of dossiers**
- **Quality of submissions**
- Internal business pressure for **speedy regulatory clearance**
- Ensuring **Timely Regulatory Approvals**

To help the pharmaceutical companies identify the optimal regulatory pathway across the drug development cycle (pre-clinical, clinical, registration, and post-approval stages), and maintain regulatory operations, APCER has a team of qualified and experienced regulatory consultants who provide comprehensive solutions related to new product licenses and market expansion, post-marketing product lifecycle management, compliance with global regulations, and liaising with regulatory agencies.

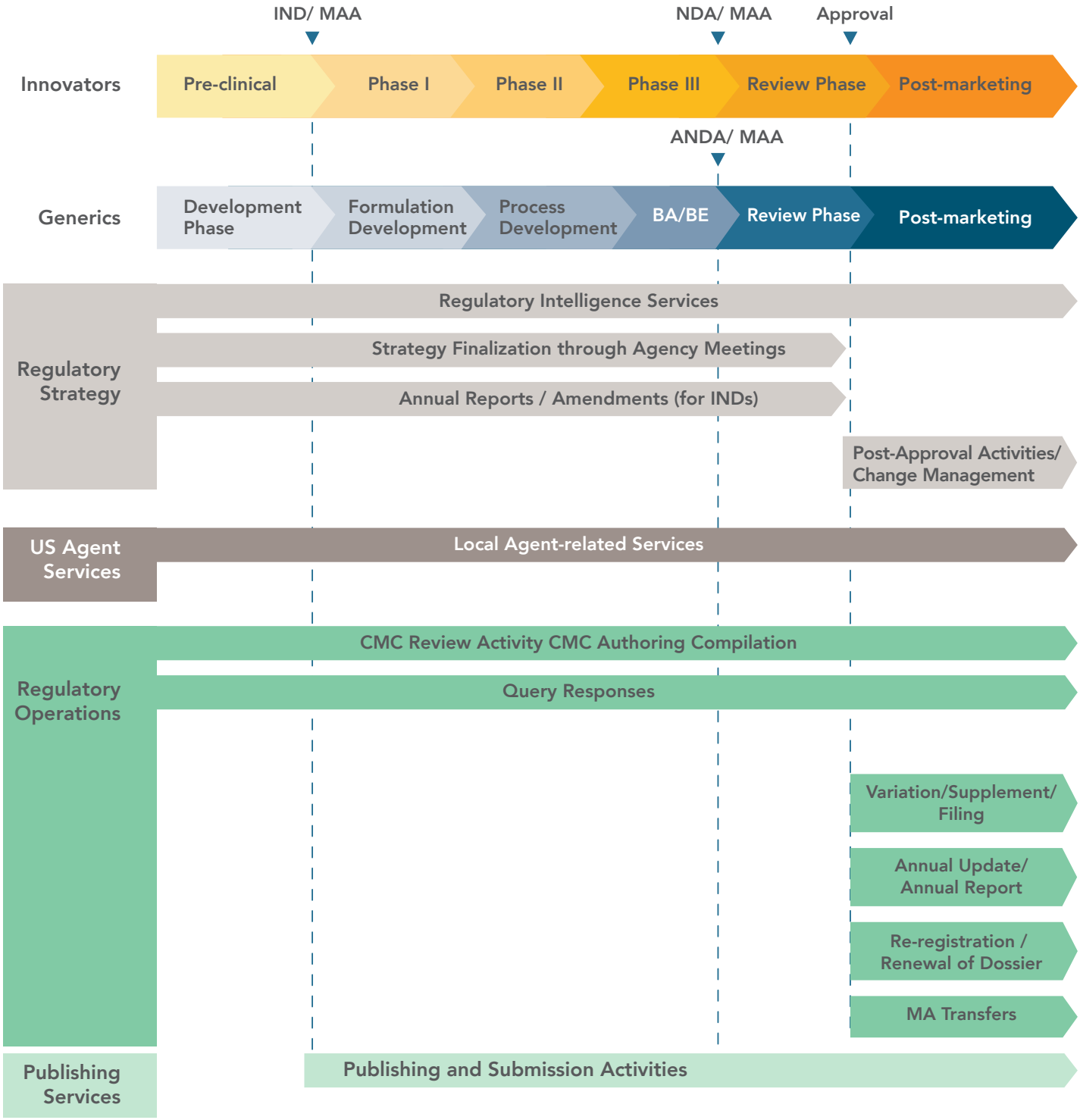
Regulatory Consulting Services

- Identifying and defining the regulatory strategy road map.
- Regulatory intelligence services for Quality/ Chemistry & Manufacturing Controls (CMC), regulatory processes, and Pharmacovigilance.
- Strategy finalization through Agency meetings viz. pre-meeting requests.
- Preparing regulatory strategies for innovator and generic applications for INDs, NDA, ANDAs, and MAAs filing and submissions.
- Gap assessment support related to administrative and CMC modules. Insight on probable queries along with strategies for addressal.
- Change management - Evaluation of change controls and strategizing the change categories, as applicable.
- Post-approval strategies viz. Marketing Authorization (MA) Transfers/Change of Ownerships.
- Due diligence audits to help clients take informed decisions during mergers and acquisitions.
- Strategizing market expansions specifically in North America & Europe.
- US Agent services including translation of documents and coordination with Agency.

Regulatory Operations

- Authoring, review, compilation and submission of Agency Meetings Requests and Briefing Packages
- Pre-approval activities viz. authoring, review, and compilation of administrative and quality sections of innovator and generic dossiers regions such as North America (IND/CTA, NDA/NDS, ANDA/ANDS), the EU, and the UK (New, Generic, Hybrid MAA).
- Authoring, review, and compilation of query responses, as applicable.
- Post-approval services viz. authoring, review, and compilation of change applications, such as amendments, supplements, annual reports, variations along with renewals, and re-registration applications
- Authoring and compiling the MA Transfer and Change of Ownership packages and submission via appropriate routes.
- Electronic publishing and submission of dossiers to different health authorities, including compilation, validation, and submission of electronic sequences in compliance with current validation criteria laid down by respective health authorities as well as publishing and submission of Office of Prescription Drug Promotion (OPDP) materials for the US market.
- Support during quality-driven regulatory audits and associated compliance, for instance Good Manufacturing Practices (GMP) audits, vendor qualification audits, etc.

Value Delivered Throughout the Drug Life Cycle



IND-Investigational New Drug
CMC: Chemistry & Manufacturing Controls
NDA-New Drug Application

ANDA-Abbreviated New Drug Application
MAA: Marketing Authorization Applications

BA/BE- Bioavailability/Bioequivalent

Regulatory Consulting Services.
Regulatory Operations.

The APCER Advantage

Diverse experience across product types - drugs, biologics, medical devices, and combination products

Global coverage for Innovator and Generic companies across North America, UK, Europe

Strong understanding of global/regional regulations and effective communication with Global Regulatory Agencies

Strong scientific and operational excellence

Focus on timely submissions and faster approvals

Qualified and experienced Regulatory personnel

Customized, flexible and scalable solutions

All kind of formulations like solid orals, sterile (injectables, inhalations, ophthalmic), topicals

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com