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 stringent. Pharma companies are trying to keep pace with them due to difficulties in filing, submission and seeking timely drug approvals. These trends have impacted their product marketing and market expansion activities.

Key Regulatory Challenges Faced by Pharmaceutical Companies

- **Interpretation of regulations**
- **Delays in submission** of dossiers and marketing approvals
- **Limited inhouse regulatory intelligence & Skills**
- **Maintenance of dossiers**
- **High quality submissions**
- Internal business pressure for **speedy regulatory clearance**
- **Complexity in compliance to post Brexit regulations**
- **Timely approvals** of drugs

APCER's team of qualified and experienced regulatory consultants help the pharma companies identify the optimal regulatory pathway across the drug development cycle (pre-clinical, clinical and post-approval stages), consult in product submissions and maintain regulatory operations. In addition, our subject matter experts (SMEs) provide comprehensive solutions related to new product licenses and market expansion, post-marketing product lifecycle management, compliance to global regulations and liaising with regulatory agencies.

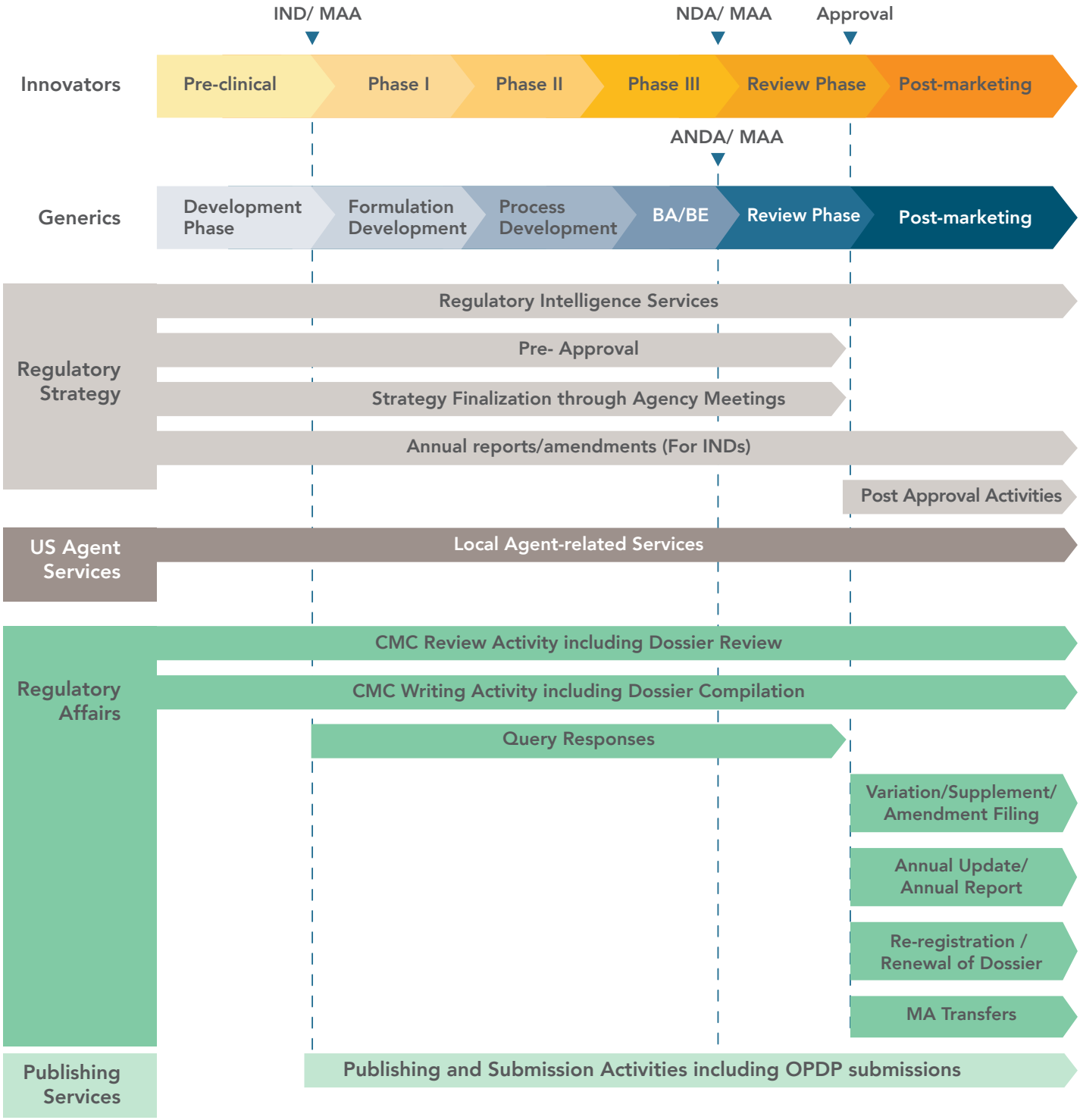
Regulatory Consulting Services

- Identifying and defining the Regulatory strategy route map.
- Regulatory intelligence services covering guidelines related to CMC, Pharmacovigilance and Medical Information.
- Pre-approval services covering CMC review activity (Module 1, 2 and 3), Strategic query responses and Dossier review as per RTR (Refuse to Respond).
- Strategy finalization through agency meetings including Pre-Meeting request compilation, Meeting briefing package and preparing documents ready for submission.
- Post-approval activities including MA Transfers, Evaluation of change control and strategizing the category.
- Local Agent-related services including translation of documents and coordination with Agency as a US agent.
- Preparing Regulatory strategies for IND and NDA filing and submissions.
- Market expansions and approvals in various markets (North America & Europe).
- Enabling electronic Common Technical Document (eCTD) submission of dossiers.
- Support strategizing Query Responses.
- Gap assessment (MA transfers resulting from mergers and acquisitions).
- Due Diligence audits to help clients for taking decisions on mergers and acquisitions.
- Providing strategy guidance for post approval changes.

Regulatory Execution Services

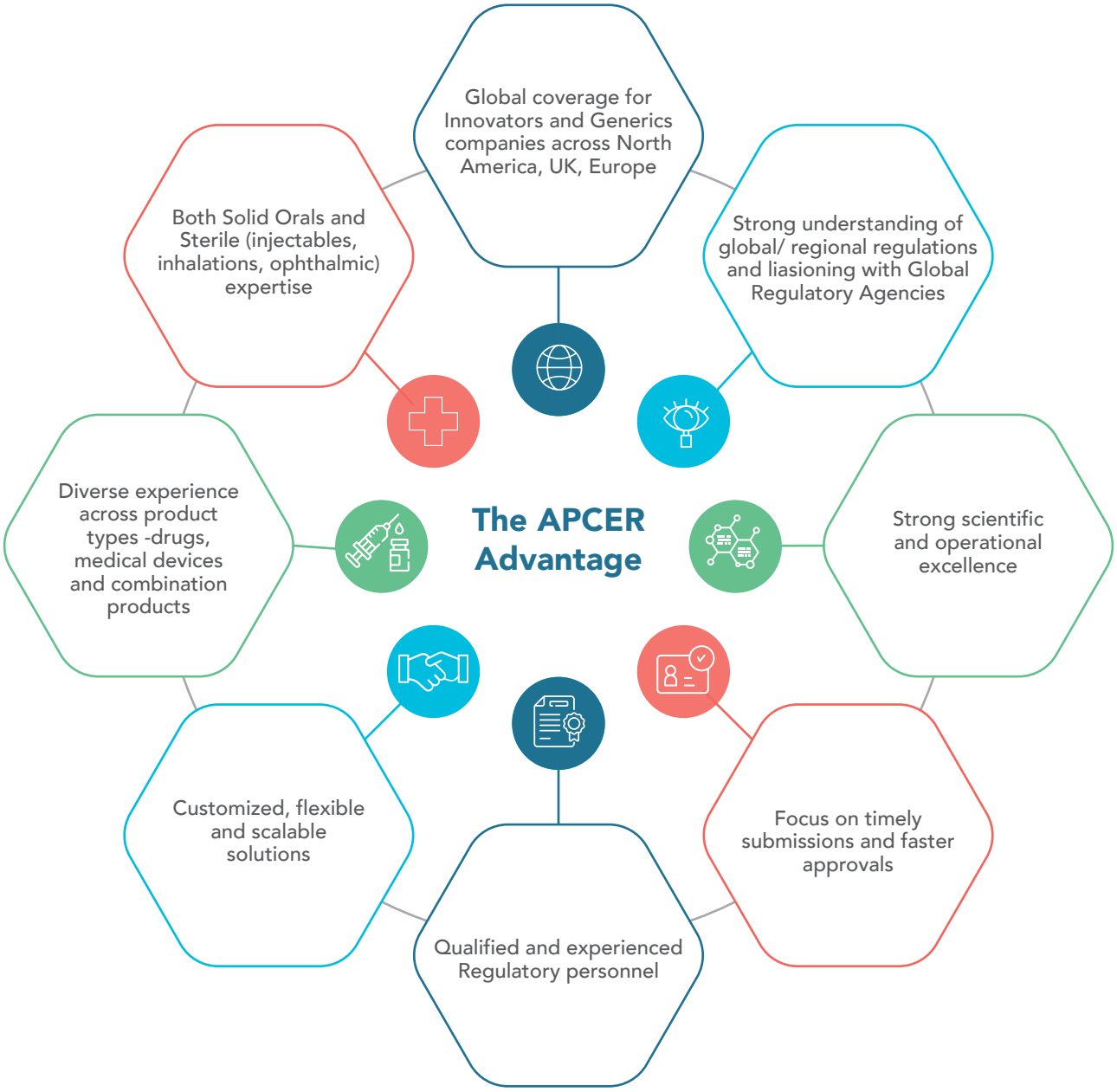
- Lifecycle maintenance support.
- Pre-approval activities including Chemistry, Manufacturing, and Controls (CMC) services (Review and Writing activities) of Module 1, 2, 3 for countries like USA (IND, NDA, ANDA, BLA), Europe (New, Hybrid, Generic, Biological), Canada and other countries.
- Query responses including strategy for responding queries, preparation of responses and submission of package.
- Expertise in dossier preparation, compilation and submission activities (505b1/NDA/NewMAA, 505b2/NDA/ Hybrid MAA or 505j/ANDA/ Generic).
- Health authority Query Responses.
- Post-approval activities (Variations/ supplements, Annual Reports, Renewals/ reregistrations, art work labelling changes or MA transfers etc).
- US agent and Local agent related services.
- Publishing and submission activities including validating and submitting PDF-ready documents with OCR (Optical character recognition), hyperlinks, bookmarks and OPDP (Office of Prescription Drug Promotion) submissions.
- Quality driven regulatory audits and compliance.

Value Delivered Throughout The Life Cycle



IND-Investigational New Drug
NDA-New Drug Application
ANDA-Abbreviated New Drug Application
MAA-Marketing Authorization Agency
BA/BE- Bioavailability/Bioequivalent

Regulatory Consulting Services.
Regulatory Execution Services.



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 27001:2013, 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

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