APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Continued Compliance

Regulatory Services for the European Union

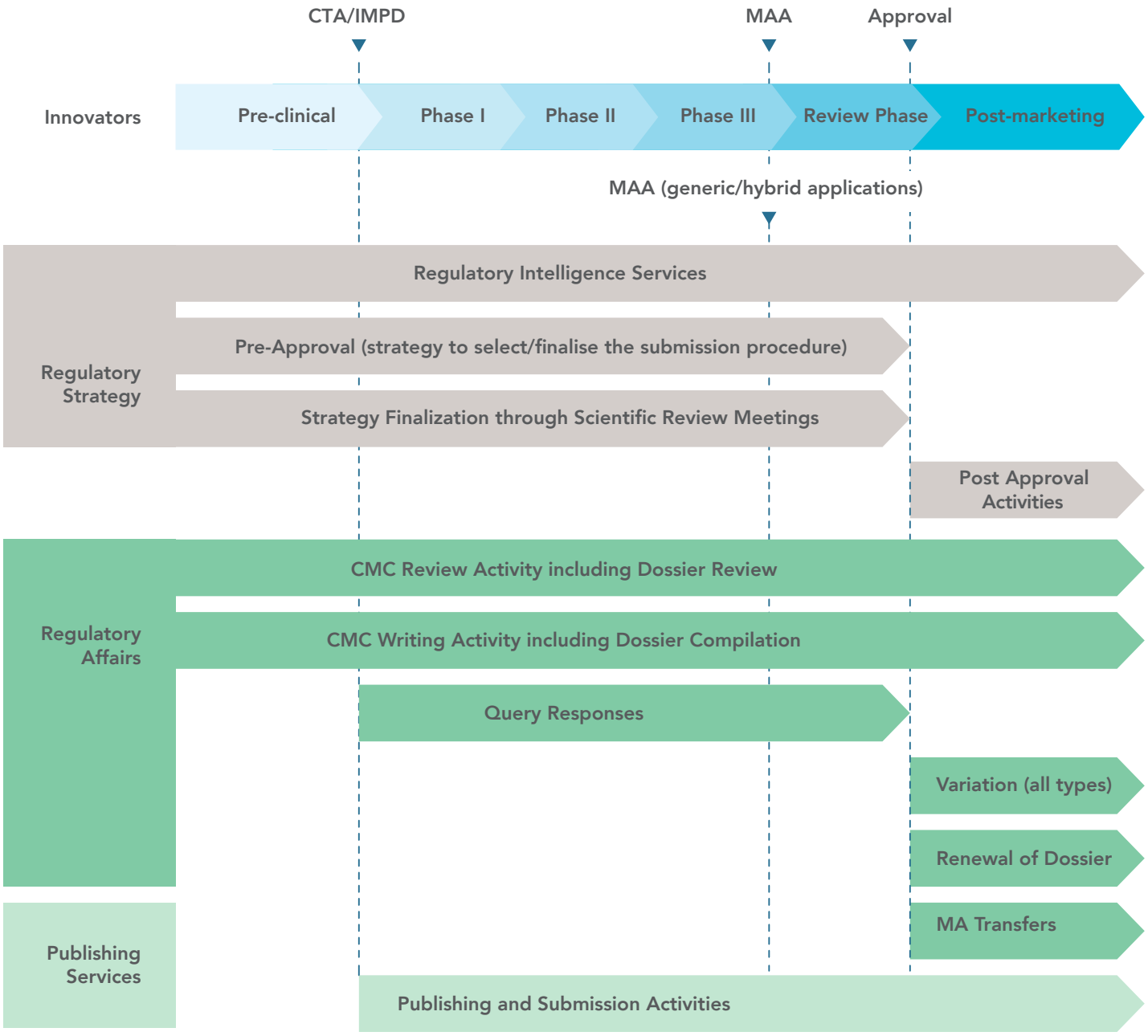
The Regulatory landscape is changing, making it challenging to understand and navigate the application and submission processes. APCER can help interpret guidelines and regulations for different types of products and therapies in the European Union (EU).

Key Regulatory Challenges Faced by Pharmaceutical Companies

- **Interpretation of regulations**
- **Delays in submission** of dossiers and marketing approvals
- **Limited in-house regulatory intelligence & skills**
- **Maintenance of dossiers**
- **High-quality submissions**
- **Internal business pressure** for speedy regulatory clearance

APCER's team of highly qualified, experienced regulatory experts provides end-to-end Regulatory Consulting and Regulatory Execution services throughout a drug's life cycle. APCER helps pharmaceutical companies to streamline submission processes, liaise with regulatory agencies and expedite drug approvals.

Value Delivered Throughout Product Life Cycle



CMC: Chemistry, Manufacturing and Controls;
CTA: Clinical Trial Application; IMPD: Investigational Medicinal Product Dossier;
MA: Marketing Authorisation;
MAA: Marketing Authorisation Applicationt

Regulatory Consulting Services

Regulatory Execution Services

Regulatory Consulting Services

APCER's team of regulatory consultants helps biopharmaceutical companies identify the optimal regulatory pathway across the drug development cycle (pre-clinical, clinical and post-approval stages), consult for product submissions and maintain regulatory operations.

The various steps in the strategic road map include:

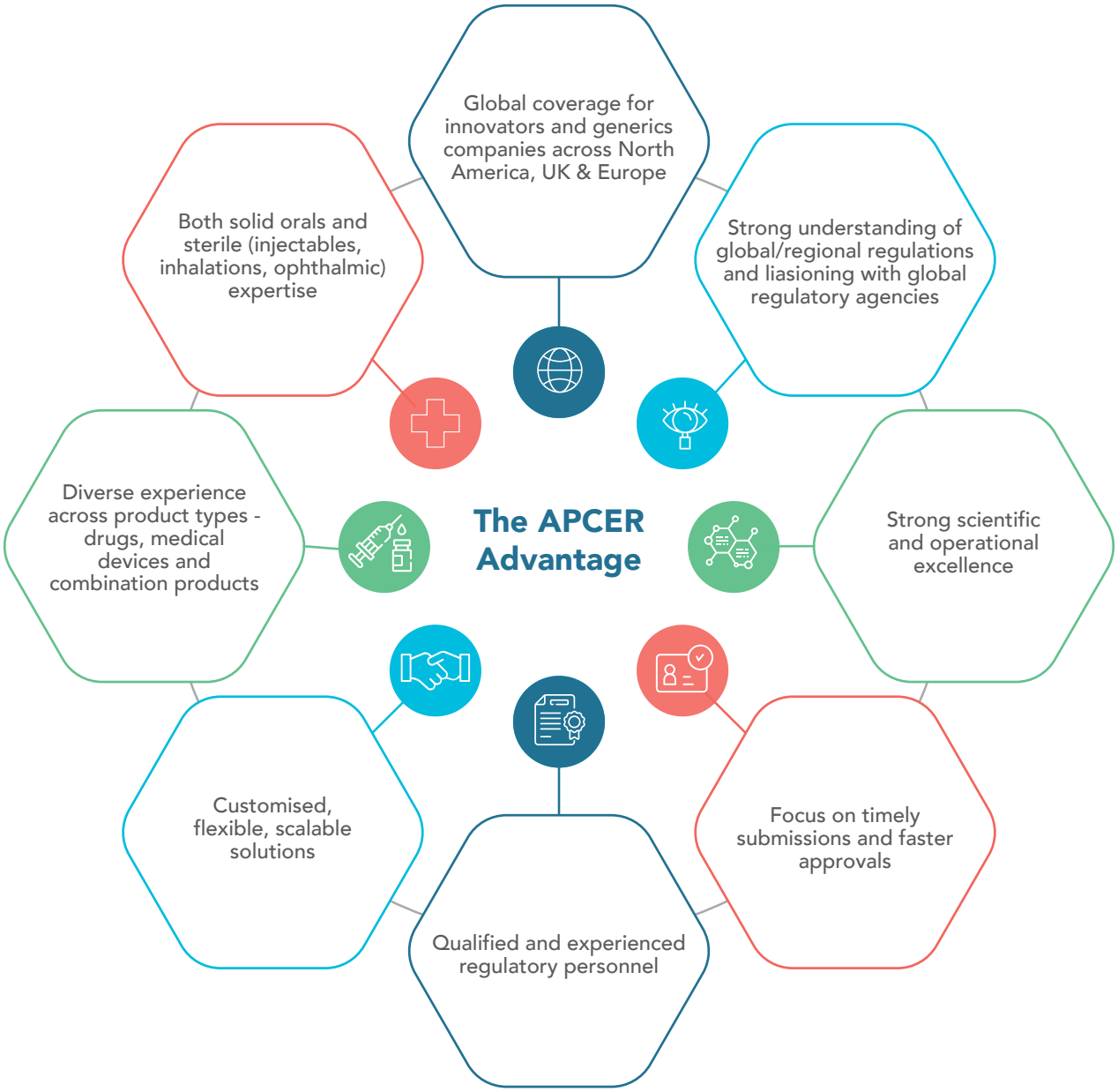
- Identifying and defining the Regulatory strategy route map.
- Regulatory intelligence services covering guidelines on Clinical Trial Applications (CTAs) in the EU countries; Chemistry, Manufacturing and Controls (CMC); and Pharmacovigilance.
- Pre-approval services covering CMC review activity (Modules 2 and 3).
- Strategy finalisation through scientific review meetings for quality-related technical questions.
- Preparing Regulatory strategies for CTA and Marketing Authorisation Application (MAA) filings and submissions.
- Market expansions and approvals in various markets (Europe).
- Support in strategising query responses.
- Gap assessment (Marketing Authorisation [MA] transfers resulting from mergers and acquisitions).
- Due diligence audits to help clients in taking decisions on mergers and acquisitions.
- Providing strategy guidance for post-approval changes.
- Post-approval activities, including MA transfers, evaluation of change control and strategising the category of variations.

Regulatory Execution Services

With the current regulatory framework, APCER's regulatory experts provide comprehensive and flexible solutions to biopharmaceutical companies seeking new product licenses and market expansion, post-marketing product life-cycle management, compliance to global regulations and liaising with regulatory agencies.

The various processes in execution services include:

- Life-cycle maintenance support.
- Pre-approval activities, including CMC services (review and writing activities) of Modules 1, 2 and 3 for Europe (new, hybrid, generic and biological).
- Expertise in dossier preparation, compilation and submission activities for MA applications [8(3), 10(1), 10(3), 10(4) and 10(a–c)].
- Query responses, including preparation and review of responses and submission of package.
- Post-approval activities, namely authoring, compilation, review and submission of quality variations, renewals and MA transfers.
- Electronic publishing and submission: Assisting in submissions via IRIS for marketing status, orphan drug designation and scientific advice.
- Assisting in CTAs via the Clinical Trials Information System (CTIS) portal.



Testimonial

"APCER's end-to-end Regulatory Service capabilities has helped us ensure full compliance to regulatory guidelines and timelines."

Head - Regulatory Affairs
A global pharmaceutical company

"The APCER team has detailed understanding of US regulations and their impact at every stage of the approval process. Their insights helped us progress our regulatory submission process in a timely manner."

Regulatory Head
A large pharmaceutical company

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) 79 6677 8600

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