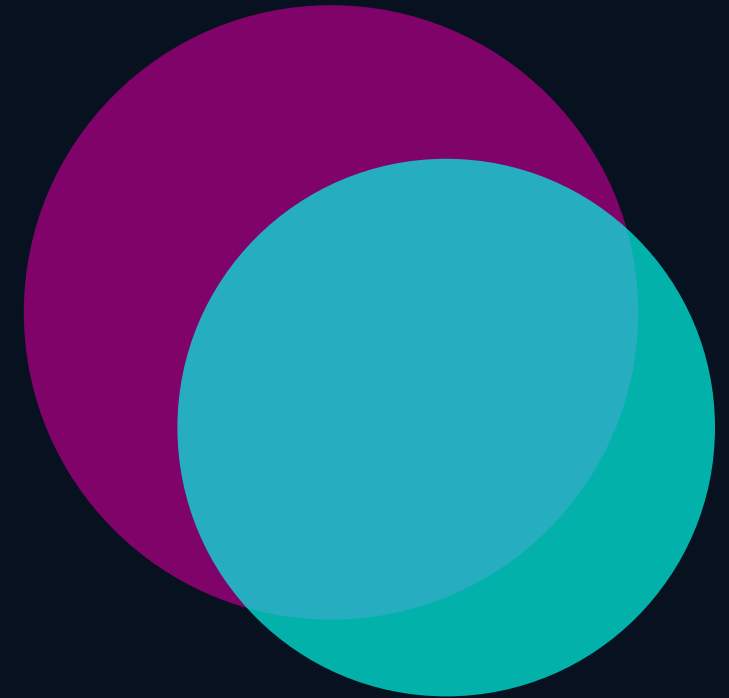


GLOBAL PHARMA REGULATORY BODIES

Practical Comparison Guide • 2026

FDA • EMA • MHRA • PMDA • TGA • Health Canada • CDSCO • NMPA • WHO

Use this guide to compare roles, workflows, and global coordination.



DOWNLOADABLE GUIDE

1. What a Regulatory Authority Actually Controls

Think across the full medicine lifecycle—not only approval.

Development

Scientific advice, trial oversight, evidence expectations

Market Access

Review of quality, safety, efficacy, and benefit–risk

Manufacturing

GMP oversight, inspections, quality defects, recalls

Post-Market

Pharmacovigilance, safety signals, labeling changes

Communication

Product information, safety notices, public guidance

Enforcement

Compliance actions when legal or quality requirements fail

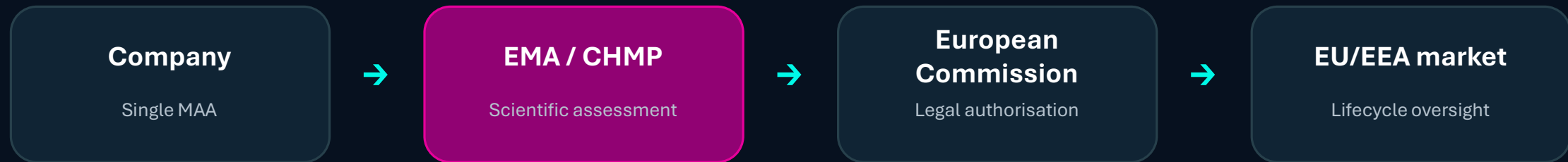
2. The Major Agencies: Who Does What?

A quick map for regulatory affairs, QA, PV, and manufacturing professionals.

Agency	Region	Core role	Practical takeaway
FDA	United States	Federal regulator; CDER oversees most human drugs.	FDA review + compliance
EMA	European Union	Scientific evaluation for centralised EU authorisations.	EU network + EC decision
MHRA	United Kingdom	UK regulator for medicines and medical devices.	UK national pathway
PMDA / MHLW	Japan	PMDA reviews and advises; MHLW holds key legal authority.	Japan pathway
TGA	Australia	Regulates therapeutic goods and maintains the ARTG.	Australian pathway
Health Canada	Canada	Federal health-product regulator for drugs and devices.	Canadian pathway

3. Do Not Treat “EMA Approval” Like a National Agency Decision

The EU system is a network: EMA evaluates; the European Commission grants centralised authorisations.



Why this matters for job interviews and daily work

- Know which body evaluates the dossier.
- Know which body grants the legal authorisation.
- Know when national competent authorities still matter.

4. Compare Agencies by Lifecycle Stage

A reusable framework works better than memorising agency names.

Region	Clinical development	Submission	Assessment	GMP / inspections	Post-market safety
FDA	IND	NDA / BLA	CDER / CBER review	Risk-based inspections	FAERS / safety actions
EU	CTA / CTIS	MAA	EMA/CHMP or national route	EU GMP network	EudraVigilance / PRAC
UK	CTA	MAA	MHRA review	MHRA GMP oversight	Yellow Card / safety actions
Japan	Clinical trial notification	NDA	PMDA review + MHLW role	GMP conformity	Post-marketing safety

Note: routes and product-specific requirements vary. Always confirm the current official guidance before filing.

5. The Five Differences That Change Global Submission Strategy

These differences drive extra work, sequencing, and local planning.

- 1 Legal pathway** Centralised, national, reliance, or hybrid routes
- 2 Local evidence** Local population, bridging, or country-specific expectations
- 3 Submission mechanics** Portal, eCTD structure, forms, language, metadata
- 4 Review interaction** Scientific advice, questions, deficiency cycles, meetings
- 5 Lifecycle obligations** Variations, RMPs, PV reporting, renewals, inspections

6. Global Harmonisation: Three Names to Know

Harmonisation reduces duplication, but it does not erase local legal responsibility.

ICH

Develops harmonised technical guidelines for pharmaceutical registration across quality, safety, efficacy, and multidisciplinary topics.

ICMRA

Strategic coalition of medicines regulators supporting cooperation, information sharing, and joint responses to global regulatory challenges.

WHO WLA

WHO framework identifies high-performing regulatory authorities and supports regulatory reliance.

Practical rule: harmonise the core dossier, then map each market's legal, procedural, and lifecycle differences.

7. A Regulatory Professional's Market-Entry Workflow

Use this before building a country submission plan.

01 Define product

Drug, biologic, generic, advanced therapy, device?

02 Select markets

Commercial priority + patient need + feasibility

03 Map authority

Agency, legal route, applicable committees

04 Gap assess

Dossier, CMC, clinical, PV, local requirements

05 Plan interaction

Advice meetings, questions, inspections

06 Manage lifecycle

Variations, safety reporting, commitments

8. Interview Questions You Should Be Able to Answer

Use the comparison framework to turn memorised facts into practical answers.

1. How does FDA drug approval differ from the EU centralised procedure?

2. What is EMA's role versus the European Commission's role?

3. How would you plan one dossier for several major markets?

4. What changes after approval from a regulatory perspective?

5. Why do ICH and regulatory reliance matter for global development?

Tip: answer using “authority → legal route → evidence → review → post-market.”

9. Quick Global Regulatory Readiness Checklist

Before you rely on a global strategy, validate the local details.



Authority and jurisdiction confirmed



Local data expectations assessed



Product classification confirmed



Scientific advice needs identified



Applicable submission route mapped



GMP / inspection impact assessed



Current agency guidance checked



PV and risk-management duties mapped



eCTD / portal requirements confirmed



Lifecycle change process defined

Always verify the latest official authority guidance before making a submission decision.