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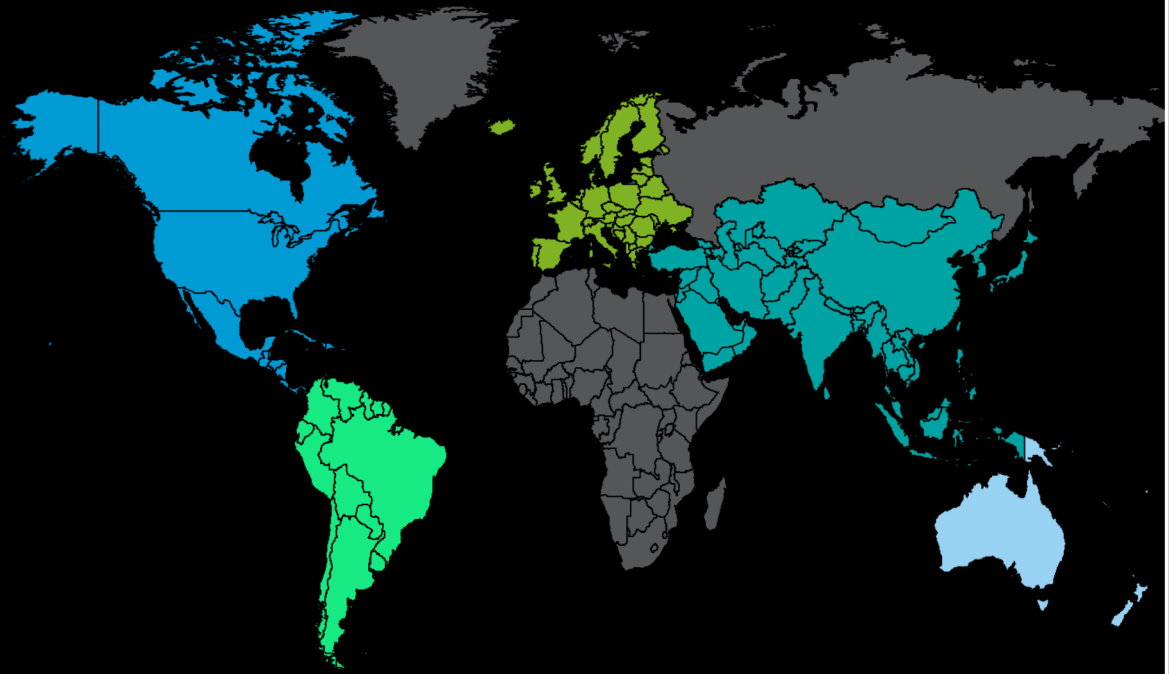
Global regulatory overview

1st October 2018

International pharmaceutical regulations

The current regulations that have global impact



International

International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
| ICH: Guidelines
| ICH: Quality Guidelines
| ICH: Efficacy Guidelines | ICH: MedDRA
| ICH: Safety Guidelines
| ICH: Multidisciplinary Guidelines
| ISPE: Good Manufacturing Practices (GMP) | ISPE: International GMP Guidelines
| ISPE: International GMP Regulations and Preambles
| ISO Standards
| Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme (PIC/S): Guidelines | WHO: Good Manufacturing Practices (GMP) Questions & Answers | WHO: Handbook for Good Clinical Research (GCR) Practice (2002)
| WHO: Medicines Policy | WHO: Medicines Regulatory Support | WHO: Production | WHO: Regulatory Package

Regional and local regulations

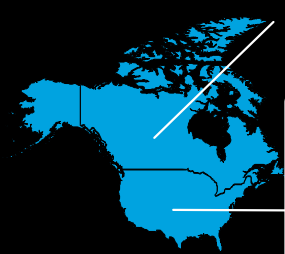
Fragmented landscape of additional regional and country-specific regulations

EU Wide Regulations:

EMA: Article 58 Applications: Regulatory & Procedural Guidance | EMA: Clinical Data Publication | EMA: Regulatory Information | EMA: Good Clinical Practice (GCP) Compliance | EMA: Good Manufacturing Practice and Good Distribution Practice Compliance | EMA: Good Manufacturing Practice Questions and Answers | EMA: Good Pharmacovigilance Practices | EMA: Guide to Information on Human Medicines Evaluated by EMA (2016) | EMA: Guidance for Implementation of Eligibility Requirements (2016) | EMA: Guidebook for Tenderers (2016) | EMA: Pharmacovigilance System Manual (2016) | EMA: Public Consultations | EMA: Risk Management Plan (RMP) Guidance | EMA: Scientific Guidelines | EU: EurdraLex Volume 4, Annex 15: Qualification and Validation (2015) | European Commission: Good Distribution Practice of Medicinal Products for Human Use | European Commission: Good Manufacturing Practice (GMP) Guidelines | European Commission: Procedures for Marketing Authorization - Mutual Recognition | HMA CMDh: Procedural Guidance | TOPRA: Guide to the EU Variation Procedure from a Quality Viewpoint (2015)

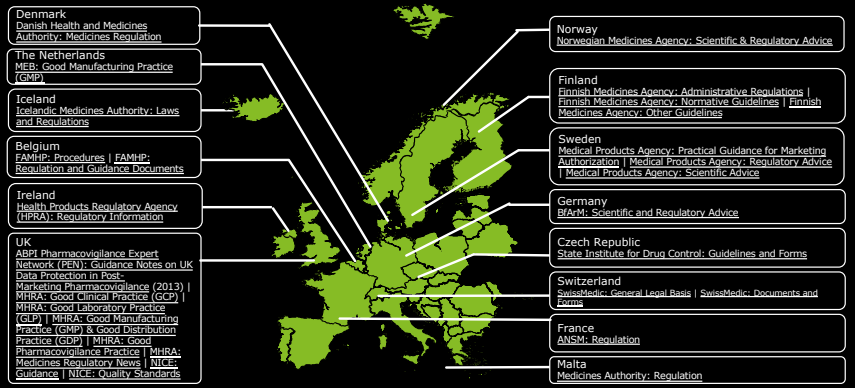
Canada

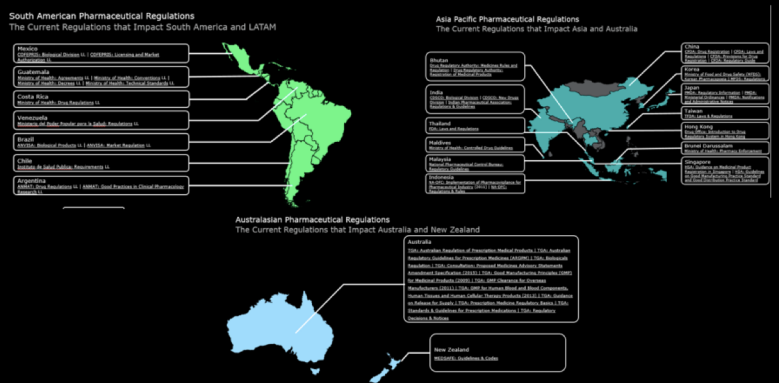
Health Canada: Acts & Regulations | Health Canada: Data Protection under the Food and Drug Regulations (2011) | Health Canada: Good Manufacturing Practices (GMP) | Health Canada: Good Pharmacovigilance Practices (GVP) Guidelines | Health Canada: Guidance Documents | Health Canada: Policies | Health Canada: Reconsideration of Decisions Issued for Human Drug Submissions (2015) | Health Canada: Revised Guidance Document: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) (draft) (2015)



U.S.A

ABIS Priority News Brief: FDA Guidances | FDA: CDER Manual of Policies & Procedures (MAPP) | FDA: Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing and Controls Information (draft) (2016) | FDA: Contract Manufacturing Arrangements for Drugs: Quality Agreements (2016) | FDA: Data Integrity & Compliance with CGMP (draft) (2016) | FDA: Pharmaceutical Quality/CMC | FDA: Compounded Drug Products that are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act (draft) (2016) | FDA: Compounded Drug Products that are Essentially Copies of Approved Drug Products under Section 503B of the Federal Food, Drug, and Cosmetic Act (draft) (2016) | FDA: Current Good Manufacturing Practices (CGMPs) | FDA: E2C(R2) Periodic Benefit-Risk Evaluation Report Guidance (2016) | FDA: E2C(R2) Periodic Benefit-Risk Evaluation Report - Questions & Answers (2016) | FDA: Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies | FDA: Good Laboratory Practices (GLP) Questions & Answers (2007) | FDA: Good Manufacturing Practice (GMP) Guideline/Inspection Checklist | FDA: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment | FDA: Guidances (Drugs) | FDA: Guidances (Biologics) | FDA: Guidance, Compliance & Regulatory Information | FDA: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (draft) (2014) | FDA: Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (draft) (2014) | FDA: Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators (draft) (2015) | FDA: MAPP: CDER Liaisons to Official Compendia and Standards Development Organizations - Selection Process, Roles, and Responsibilities (2016) | FDA: Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act (2016) | FDA: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act (2016) | FDA: Providing Regulatory Submissions in Electronic Format: Submission of Manufacturing Establishment Information (draft) (2016) | FDA: Quality Attribute Considerations for Chewable Tablets (draft) (2016) | FDA: Regulatory Information | FDA: Regulatory Procedures Manual | FDA: Request for Quality Metrics Guidance for Industry (draft) (2015) | FDA: Rules & Regulations | FDA: Safety Considerations for Product Design to Minimize Medication Errors (2016) | FDA: Safety Testing of Drug Metabolites (2016) | FDA: Special Protocol Assessment (draft) (2016) | FDA: Standards | Regulations.gov: Advanced Search

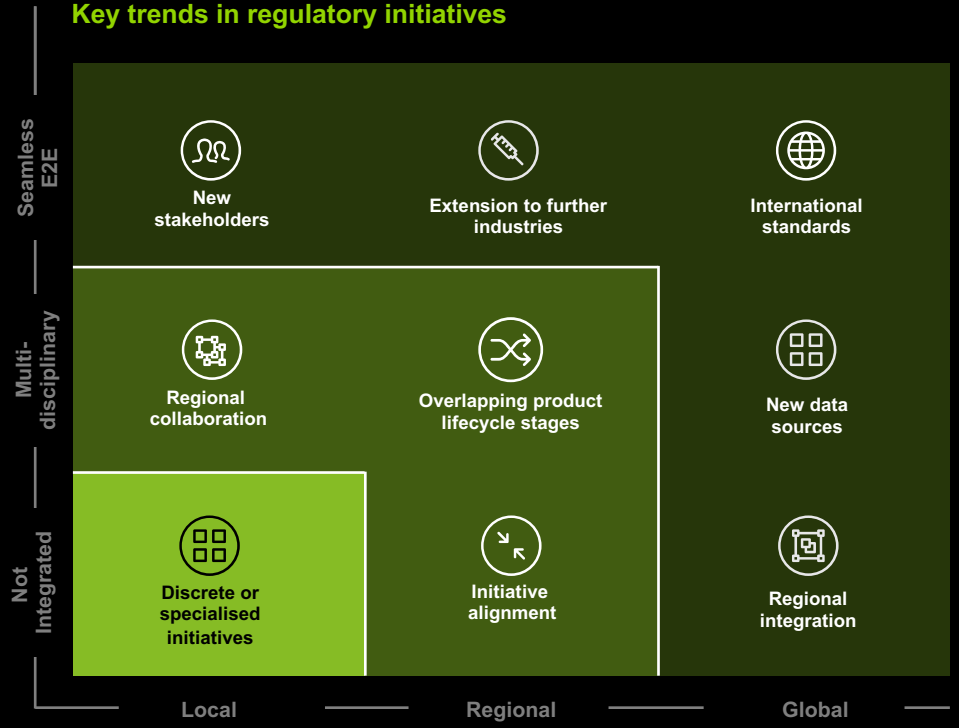




Evolution in the regulatory landscape

Pharmaceutical companies are facing new drivers and disrupters

Key trends in regulatory initiatives



Drivers & disrupters

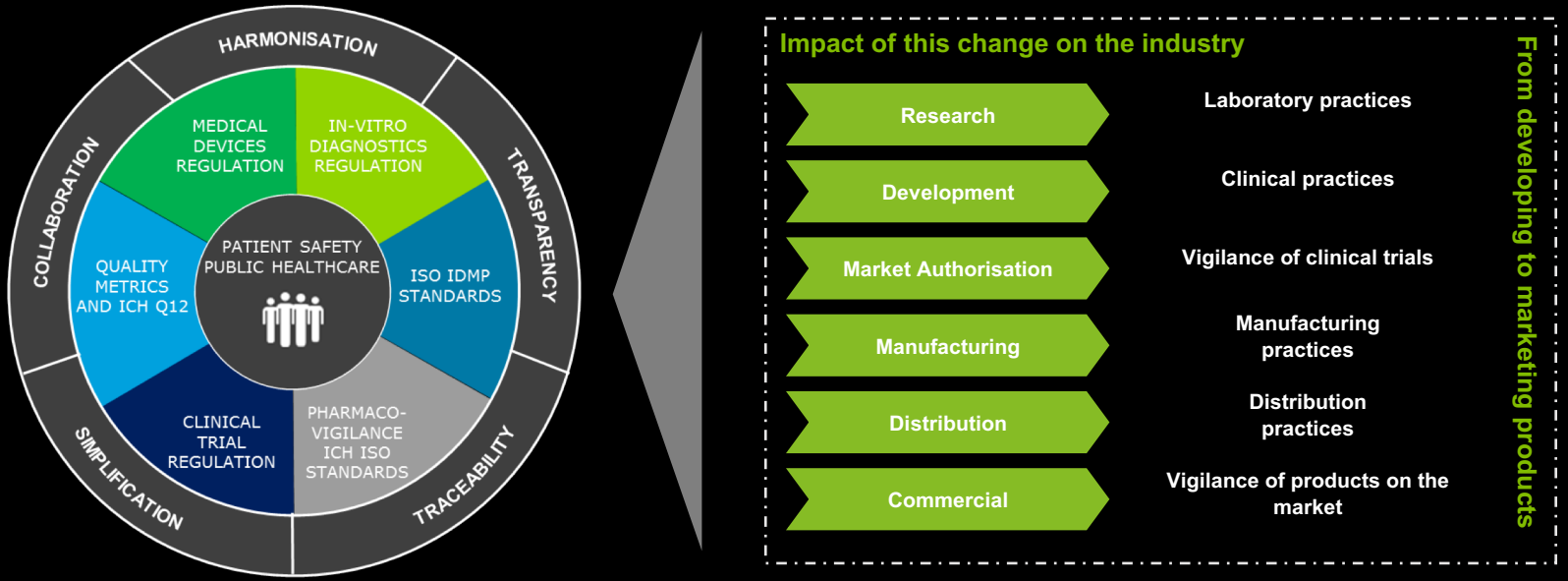
- Stronger customer voice
- Access to information
- New technology

Main impacts

- End-to-end vision on technology and safety needed
- More comprehensive data landscape required
- More seamlessly integrated processes
- New capabilities needed

A decade of unprecedented regulatory change

Anticipating trends to enable clients to reach full compliance



- European Commission are making regulatory changes across the pharmaceutical, medical devices, and in-vitro diagnostics industries
- All companies in these industries marketing products in the EU will need to comply
- Significant impact on regulatory obligations and operating models of these organizations

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