

Implementation of Good Regulatory Practices: Foundational Principles and Applications in FDA Rulemaking

FDA Office of Global Policy and Strategy (OGPS),
Office of Trade and Global Partnerships (OTGP)

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Good Regulatory Practices (GRPs)

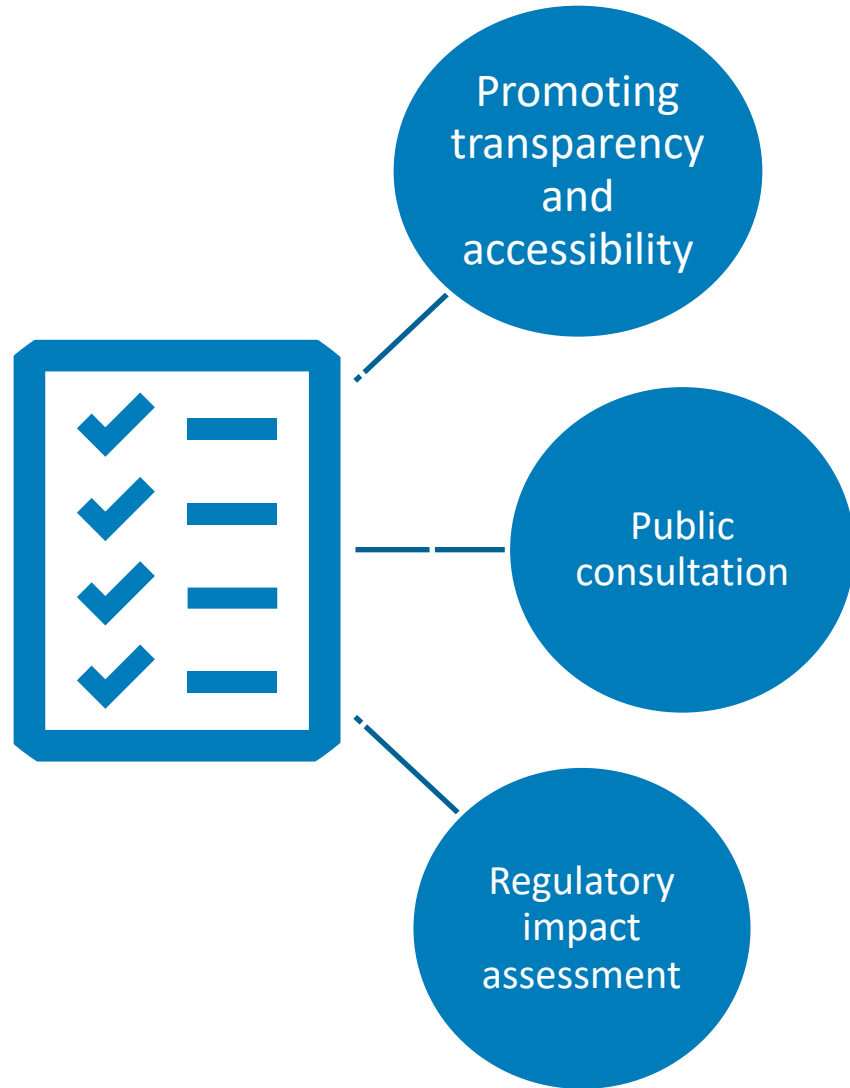
Internationally-recognized processes and procedures that improve the quality and cost-effectiveness of domestic regulations

GRPs guide regulatory authorities in:

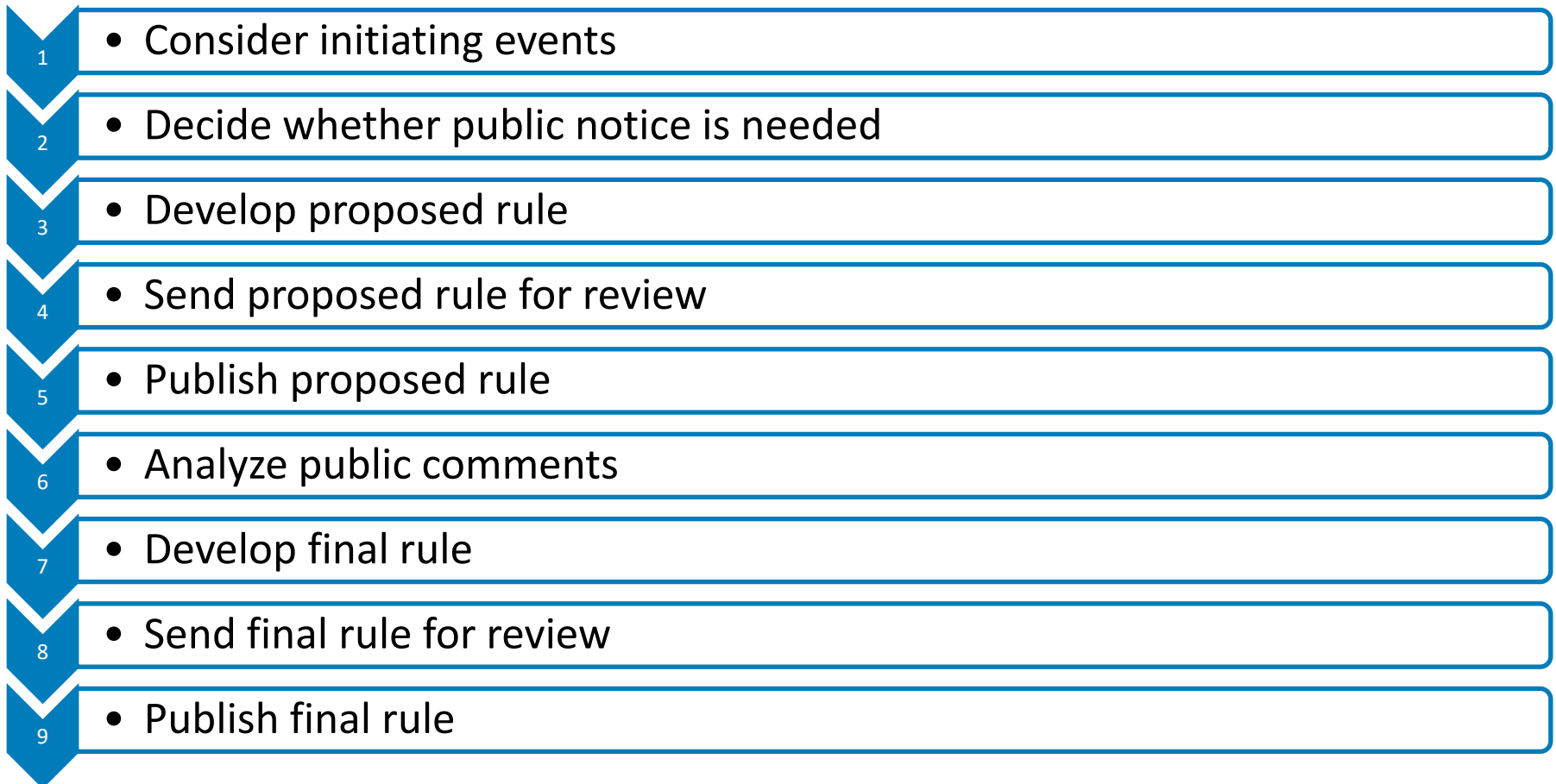
- Setting appropriate regulatory requirements
- Formulating decisions that are clear, transparent, consistent, timely, and based on sound science

GRPs at FDA

Three general principles for the use of GRPs in the rulemaking process include the following:

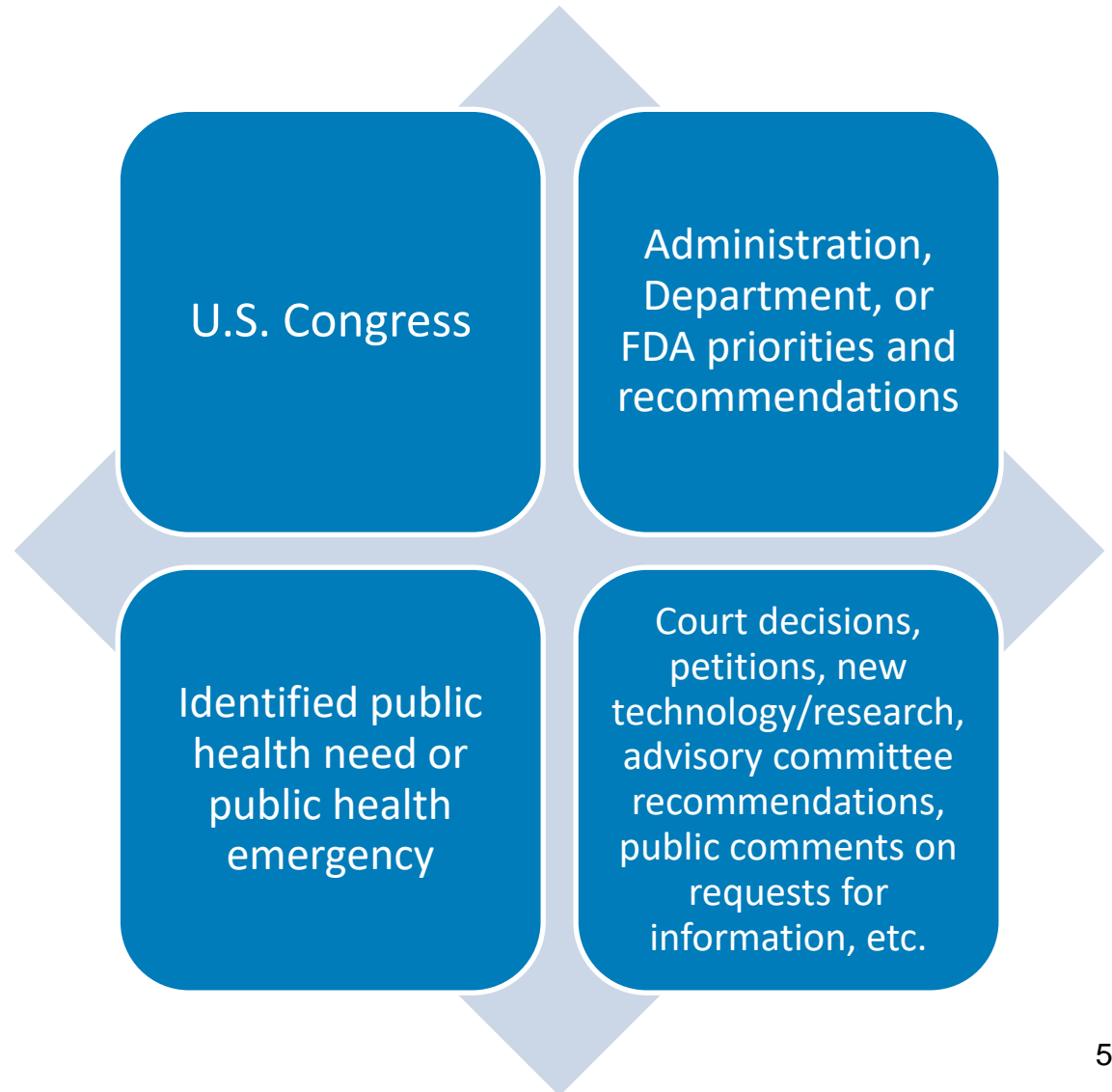


Rulemaking Process

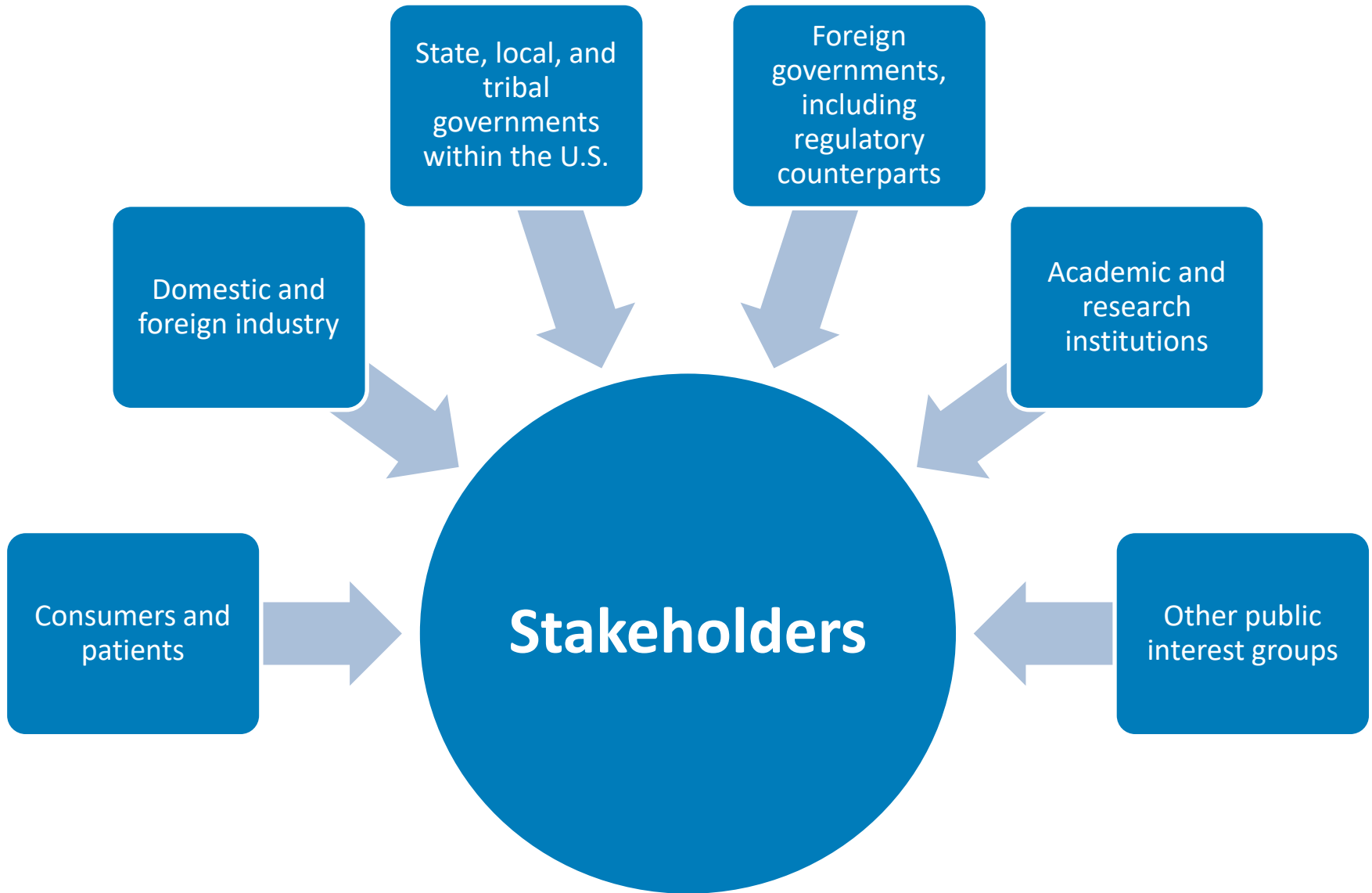


Identifying Regulatory Priorities

New rules can arise from multiple sources, including:



Who are stakeholders?



Why seek input?

Regulators benefit from public participation in important ways.

- Supporting transparency, accountability, confidence, and trust in the rulemaking process
- Producing a better regulation by allowing those affected to provide input to improve clarity of regulatory requirements and avoid unintended consequences
- Providing regulators with data and information to inform rulemaking
- Promoting an understanding of how regulatory actions can have impacts beyond a country's borders

Developing a Draft Regulation

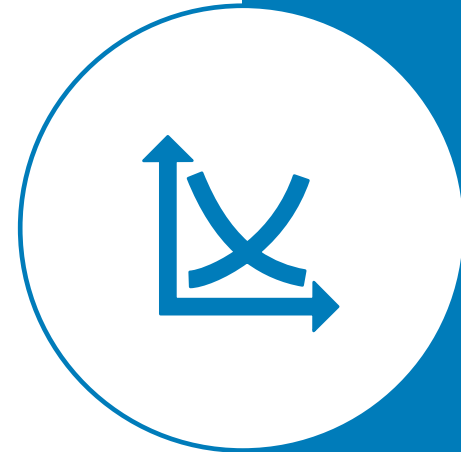
FDA promotes transparency and facilitates public participation in a variety of ways, as applicable:

- Holding listening sessions and public meetings or public workshop
- Opening a docket on [regulations.gov](https://www.regulations.gov) for comments on specific topics
- Seeking information, data, or alternatives via an Advanced Notice of Proposed Rulemaking (ANPRM)
- Maintaining an updated agenda of the Agency's upcoming rulemakings ([FDA-TRACK](#))
- Consulting with advisory committees
- Considering scientific and voluntary [consensus standards](#)
- Abiding by the principles of [plain language](#)



Benefits of Conducting RIA

- To understand the impacts of draft regulations, FDA conducts regulatory impact analyses (RIAs) when applicable.
- The RIA:
 - Provides an objective, unbiased assessment that is an essential component of policy development
 - Considers both qualitative and quantitative impacts
 - Can inform policy decisions



Why conduct RIAs?

There are important benefits to regulators from well-conducted RIAs, including:



Indicating whether regulation is necessary and justified to achieve a social goal



Identifying the regulatory option that provides the largest net benefits to society



Providing comprehensive consideration of impacts and avoiding unintended consequences

The [OECD has developed best practice principles for RIAs](#), and different countries make different determinations about the use of RIAs in the development of regulations.

Why conduct RIAs?

Executive Order (EO) 12866 on Regulatory Planning and Review:

- Regulatory philosophy and principles related to when agencies should promulgate regulations and what agencies should consider in developing regulations.
- An agency must identify the nature and assess the significance of the problem it intends to address as well as possible alternative solutions to address the problem; and, where possible, select approaches that maximize net benefits to society.

Reviewing a Draft Regulation



Draft regulations are subject to an intensive review process.



The Office of Management and Budget (OMB) coordinates interagency review of significant and economically significant rules.



[Reginfo.gov](https://www.fda.gov/regulatory-information/search-fda-guidance-documents) provides information on regulatory actions currently under 12866 review.



Stakeholders may request [12866 meetings](#) with OIRA to discuss a rule under review.

Notice and Comment (Public Consultation)

After OMB review, FDA will:

- Publish the draft regulation in the Federal Register
- Open a docket at [regulations.gov](https://www.regulations.gov)

FDA may also:

- Alert the appropriate U.S. point of contact to notify the corresponding WTO committee
- Extend comment period (case-by-case basis)
- Hold listening sessions, public meetings, or public workshops to support commenting process

Analyzing Public Comments

FDA reviews every comment filed during the comment period by the following:

- Gathering comments by unique identifier and commenter
- Consolidating form, duplicate, and out-of-scope comments
- Identifying issues and categorizing comments by topic
- Preparing high-level summaries of comments (including specific data or recommendations)
- Discussing and preparing detailed responses
- After considering substantive comments, drafting the final rule and clearly referencing any changes within comment response





Issuing a Final Rule

- FDA responds to comments received during the comment period that are within the scope of the rulemaking.
- OMB reviews significant final regulations and coordinates interagency comments and feedback.
- After internal and external feedback is evaluated and addressed, FDA publishes the final rule in the Federal Register and its effective date.
- FDA will periodically review the effectiveness of the rule.

GRPs at FDA

These best practices are foundational to developing regulations that protect and promote public health.

