



Jordan Food and Drug Administration (JFDA)

Good Regulatory Practices (GRP) Policy

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سياسة معتمدة من لجنة اعتماد السياسات الداخلية والأدلة والإجراءات الخاصة بعمل المؤسسة العامة للغذاء والدواء المشكلة وفقا لقرار مجلس إدارة المؤسسة رقم (80) تاريخ 2026/03/28

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Document Control

Version	Author	Date	Comments
01	Prepared by : Dr. Maha Jaghbeer Dr. Suna Habahbeh Reviewed by : Planning committee	15.03.2026	First version of the Policy , approved by the Planning committee
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1. Purpose

This Policy establishes the institutional framework through which JFDA applies Good Regulatory Practices to the development, implementation and review of regulatory instruments and to day-to-day regulatory activities and decisions relating to medical products.

It aims to ensure that regulatory requirements, processes, outputs and decisions are lawful, consistent, independent, impartial, proportionate, flexible, clear, efficient, transparent, timely and based on sound science and reliable data.

The Policy supports protection of public health and patients' interests, appropriate access to safe, effective and quality-assured medical products, public confidence in JFDA, and alignment with applicable national legislation and relevant World Health Organization standards.

1. Protect public health and patients' interests.
2. Strengthen the quality, effectiveness and sustainability of the JFDA regulatory system.
3. Ensure consistency, predictability and legal compliance in regulatory requirements and decisions.
4. Promote independent, impartial, ethical and science-based regulatory decision-making.
5. Apply risk-based, proportionate and flexible regulatory approaches.
6. Improve the efficiency and timeliness of regulatory processes and the responsible use of resources.
7. Improve transparency, accountability and stakeholder confidence.
8. Support innovation and timely access to quality-assured medical products without weakening regulatory oversight.
9. Promote regulatory cooperation, convergence, harmonization, work-sharing and reliance.
10. Strengthen institutional performance, learning, monitoring and continuous improvement.
11. Support alignment with the WHO Global Benchmarking Tool and the applicable WHO Listed Authority framework.

2. Scope

This Policy applies to:

1. All legally binding and non-binding regulatory instruments issued, adopted or implemented by JFDA in relation to medical products, including laws, regulations, instructions, guidelines, guidance documents, technical standards and procedures.
2. All regulatory processes, activities, outputs and decisions, including assessments, inspections, laboratory testing, authorizations, licenses, approvals, enforcement actions, regulatory communications and post-market actions.
3. All JFDA regulatory functions relating to medical products, including clinical trials oversight, marketing authorization, vigilance, market surveillance and control, licensing of establishments, regulatory inspection, laboratory testing and official lot release of vaccines and other biological products.
4. All JFDA directorates, departments, units, committees, staff members and external experts involved in regulatory work.

The Policy applies throughout the lifecycle of regulatory instruments and activities, including identification of need, development, consultation, approval, publication, implementation, monitoring, review, revision and withdrawal.

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3. References and Regulatory Framework

This Policy is issued pursuant to applicable national legislation and with reference to relevant national and international governance and regulatory standards, including:

1. Jordan Food and Drug Administration Law and its amendments.
2. The Drug and Pharmacy Law and its amendments.
3. The Guideline of Governance Practices in the Public Sector, Jordan.
4. WHO Good Regulatory Practices in the Regulation of Medical Products, WHO Technical Report Series No. 1033, Annex 11.

4. Definitions

4.1 Good Regulatory Practices

A set of principles and practices applied to the development, implementation and review of regulatory instruments – Laws, regulations and guidelines - and to regulatory activities and decisions in order to achieve public-health policy objectives in the most effective, efficient, consistent and transparent manner and on the basis of law, sound science and reliable data. Successful application of GRP is the hallmark of a modern, science-based, responsive regulatory system in which regulations are translated into desired outcomes. GRP provide a means of establishing and implementing sound, affordable, efficient regulation of medical products as an important part of health system performance and sustainability.

4.2 Regulatory Framework

The laws, regulations, instructions, guidelines, guidance documents, technical standards and other regulatory instruments through which medical products and related activities are regulated.

4.3 Regulatory System

The combination of institutions, processes, regulatory framework and resources that together provide regulatory oversight of medical products.

4.4 Regulatory Instrument or Document

A legally binding or non-binding requirement or document issued, adopted or implemented by JFDA, including laws, regulations, instructions, guidelines, guidance documents, technical standards and procedures.

4.5 Guideline or Guidance Document

A generally non-binding document that provides technical or procedural recommendations and describes acceptable approaches for complying with regulatory requirements. A guideline shall be treated as binding only where this is provided by applicable legislation or an authorized decision. Alternative approaches may be accepted when adequately justified and when they achieve the intended regulatory objective without compromising public-health protection.

4.6 Stakeholders

Individuals, organizations or institutions affected by or interested in JFDA regulatory activities, including patients, consumers, health-care professionals, regulated entities, industry associations, academic institutions, research centers and governmental or regulatory bodies.

4.7 Regulatory Impact Assessment or Impact Screening

A proportionate process used to examine the expected public-health benefits, legal basis, risks, alternatives, implementation feasibility, resource implications, cumulative regulatory burden and potential effects of a proposed regulatory instrument or significant regulatory change.

4.8 Reliance

The act whereby JFDA takes into account and gives significant weight to assessments, decisions or authoritative information from another regulatory authority or trusted institution while remaining independent, responsible and accountable for its national regulatory decision.

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5. Policy Statement

JFDA is committed to applying Good Regulatory Practices across its medical-product regulatory system and throughout all regulatory functions.

JFDA shall act in the public interest and shall ensure that regulatory instruments, processes and decisions are lawful, consistent, independent, impartial, proportionate, flexible, clear, efficient and transparent, while remaining timely and based on sound science and reliable data.

Regulatory decisions shall be based on:

1. Applicable legislation and the legally assigned mandate and authority.
2. Scientific evidence, accurate data and relevant international standards.
3. Defined regulatory, assessment and decision-making criteria.
4. Risk-based and benefit-risk approaches.
5. Appropriate stakeholder input, without compromising regulatory independence.
6. Ethical principles, integrity, confidentiality and effective management of conflicts of interest.

JFDA shall remain independent, responsible and accountable for all national regulatory decisions, including decisions that use reliance, recognition, work-sharing or other forms of regulatory cooperation.

6. Principles and General Commitments

6.1 Principles of Good Regulatory Practices

The following principles shall guide the development and implementation of regulatory instruments and all day-to-day regulatory activities and decisions.

6.1.1 Legality

1. All regulatory activities and decisions shall have a clear legal basis and remain within JFDA's legally established mandate and authority.
2. Roles, responsibilities, lines of authority and delegation of powers shall be clear, documented and applied in accordance with legislation.
3. The respective roles of institutions forming part of the national regulatory system shall be clear and coordinated.
4. Regulatory decisions and sanctions shall be subject to applicable review, appeal or judicial mechanisms.
5. Legally authorized international regulatory cooperation, reliance and recognition shall not alter JFDA's national responsibility and accountability.
6. Where any regulatory activity is performed by, delegated to or coordinated with another governmental institution or authorized entity, a documented arrangement shall define the legal basis, scope of activity, roles, responsibilities, decision-making authority, reporting lines, communication channels, timelines, record requirements, confidentiality controls, oversight mechanisms and accountability arrangements.
7. JFDA shall retain the regulatory authority, oversight and accountability assigned to it under applicable legislation.

6.1.2 Consistency

1. Regulatory instruments shall be coherent, complementary and consistent with applicable legislation, government policies and public-health objectives.
2. Unnecessary conflict, overlap, duplication and contradiction shall be avoided.
3. Requirements, decisions and enforcement measures shall be applied consistently and predictably; different treatment shall be scientifically, legally or risk-justified.
4. Decisions and their rationale shall be documented to support traceability, institutional memory, internal review and fair treatment.

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5. Formal mechanisms shall be maintained for coordination and information-sharing within JFDA and with other institutions involved in medical-product regulation.

6.1.3 Independence

1. Regulatory activities and decisions shall be protected from improper or undue political, commercial, institutional or other influence.
2. JFDA shall be institutionally and functionally independent from researchers, manufacturers, distributors, wholesalers, procurement entities and other regulated parties whose direct or indirect interests may be affected by JFDA regulatory decisions.
3. JFDA shall not engage in manufacturing, distribution, procurement or research activities that conflict with its regulatory mandate or place it in the position of regulating its own activities. Scientific research conducted by JFDA, including its laboratories, may be undertaken only where it does not create a conflict of interest with regulatory oversight and where the independence of regulatory decisions is maintained.
4. Scientific and technical assessment bodies and bodies responsible for individual regulatory decisions shall not include, be directed by or be subject to influence from persons representing institutions with a direct or indirect interest in the development, manufacture, marketing, distribution or procurement of the medical product concerned.
5. Collaboration and communication with industry, academia, researchers and other stakeholders may be maintained through structured consultation or advisory mechanisms, provided that such participation does not confer authority over scientific assessment or individual regulatory decisions and does not compromise JFDA independence, impartiality or confidentiality.
6. Where regulatory testing is required for market surveillance, official lot release or another regulatory purpose, such testing shall be performed by JFDA or by an appropriately authorized and independent laboratory and shall not be performed on behalf of JFDA by the quality-control laboratory of the manufacturer concerned.
7. Governance arrangements shall distinguish strategic oversight, executive management, scientific or technical assessment and legally authorized final decision-making.
8. Scientific and technical assessments shall be protected from interference by persons or activities that may create conflicting interests.
9. Sustainable resources, transparent decision-making arrangements, segregation of duties and effective conflict-of-interest controls shall support actual and perceived independence.
10. JFDA funding sources, regulatory fees and resource-allocation arrangements shall be managed transparently and shall not create actual, potential or perceived influence over regulatory assessments, inspections, enforcement actions or decisions.
11. Payment of regulatory fees shall not provide preferential treatment or affect the scientific standard, regulatory outcome or order of processing, except where legally authorized expedited pathways apply equally under published criteria.
12. Resources shall be planned and prioritized according to JFDA's mandate, workload, public-health risks and regulatory priorities.
13. JFDA shall remain independent, responsible and accountable when using reliance, recognition or other forms of international regulatory cooperation.

6.1.4 Impartiality

1. All regulated parties shall be treated equitably, fairly and without bias, regardless of ownership, nationality, size or institutional status.
2. Decisions shall be based on evidence, applicable requirements and defined criteria rather than personal interest, preference or unsupported judgement.

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3. Staff, committee members and external experts shall declare and manage actual, potential and perceived conflicts of interest, including recusal where required.
4. Regulatory decision-making shall be functionally separated from procurement, service delivery and other activities that may be subject to regulatory oversight.

6.1.5 Proportionality

1. Regulatory requirements, oversight measures, enforcement actions and decisions shall be proportionate to public-health risk, the seriousness of non-compliance, the benefit-risk profile and JFDA’s capacity to implement and enforce them.
2. Regulatory resources shall be directed towards activities with the greatest public-health significance.
3. The least burdensome effective approach shall be used, and unnecessary requirements, duplication, administrative burden and disproportionate costs shall be avoided.
4. Regulatory instruments shall be implementable, enforceable and proportionate to national capacity and available resources.

6.1.6 Flexibility

1. The regulatory system shall be sufficiently responsive to scientific and technological developments, innovation, public-health emergencies, shortages, unmet medical needs and unforeseen circumstances.
2. Alternative, exceptional or expedited approaches may be used when legally permitted, scientifically justified, risk-based, proportionate, documented and subject to defined controls.
3. Temporary or exceptional measures shall be time-bound where appropriate and periodically reviewed.
4. Regulatory flexibility shall not compromise the quality, safety, efficacy or performance of medical products.

6.1.7 Clarity

1. Regulatory requirements and documents shall be clear, precise, accessible and appropriate to their intended users.
2. Terminology shall be defined and used consistently and, where possible, aligned with internationally harmonized terminology.
3. Requirements, processes, timelines, criteria and the basis for decisions shall be communicated clearly, subject to confidentiality requirements.
4. Regulatory documents shall use approved formats and be subject to appropriate legal, technical, quality and document-control review.

6.1.8 Efficiency

1. Regulatory objectives shall be achieved within the required time and with reasonable use of effort, cost and resources while maintaining public-health protection.
2. Efficiency shall be supported through risk-based approaches, digital systems, reliance, work-sharing, information-sharing, competent personnel and an effective Quality Management System.
3. JFDA shall identify and address unnecessary duplication, delays, bottlenecks and recurrent deficiencies.
4. Performance indicators and periodic reviews shall be used to assess the quality, timeliness, effectiveness and efficiency of regulatory processes.
5. Efficiency measures shall not weaken scientific standards, legal compliance, independence or the quality of regulatory oversight.

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6.1.9 Transparency

1. Regulatory requirements, processes, criteria, fees, target timelines and appropriate decisions shall be made accessible through authorized channels.
2. Stakeholders shall be informed of significant proposed regulatory instruments and shall be given proportionate opportunities to provide input.
3. Regulatory decisions, actions and their rationale shall be documented and published where applicable and legally permitted.
4. Regulatory performance targets, results and periodic reports shall be communicated as appropriate.
5. Transparency shall be balanced with legal obligations relating to confidentiality, personal data, trade secrets and protected commercial information.

6.2 Governance and Enablers for GRP

Successful implementation of GRP requires the following enablers to operate together within JFDA's legal and institutional mandate:

1. Sustained leadership and support at the highest institutional and governmental levels.
2. Effective organization, good governance and clearly defined structures, roles, responsibilities, authorities and reporting lines.
3. Effective internal and external communication, collaboration, coordination and timely information-sharing.
4. A robust and well-functioning Quality Management System, including quality risk management, document control, internal controls, audits and management review.
5. Sufficient and sustainable financial, human, technological and infrastructural resources.
6. Competent personnel supported by transparent assignment of responsibilities, induction, continuing professional development and training.
7. Organizational ethics, integrity, professional values, confidentiality and effective management of conflicts of interest.
8. Science- and data-driven decision-making supported by reliable information, defined criteria and relevant international standards.
9. Performance management, stakeholder feedback, accountability and continuous improvement.
10. Externally provided processes, products and services that may affect regulatory activities or decisions shall be subject to documented selection, qualification, contractual requirements, confidentiality controls, performance monitoring and periodic evaluation.
11. The use of external providers, laboratories, consultants or experts shall not transfer JFDA's regulatory responsibility or accountability.

The enablers shall be planned and managed as an integrated system; the presence of an individual enabler does not by itself demonstrate effective GRP implementation.

6.3 Institutional Implementation of GRP

JFDA shall implement this Policy through an institution-wide, risk-based and proportionate approach integrated into its governance arrangements, strategic and operational planning, Quality Management System and all regulatory functions.

Implementation shall include:

1. Translating this Policy into approved procedures, function-specific SOPs, work instructions, decision criteria, templates and proportionate checklists.

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2. Incorporating GRP requirements into the development and review of regulatory instruments and into daily assessments, inspections, testing, licensing, authorization, vigilance, market-control and enforcement activities.
3. Preparing periodic implementation and improvement plans that define actions, responsible owners, required resources, timelines, indicators and expected evidence.
4. Applying implementation tools proportionately to the public-health risk, legal significance, complexity, scope and expected impact of the activity or regulatory instrument.
5. Providing role-based awareness, induction and continuing training for staff, committee members and external experts, and periodically evaluating the effectiveness of such training against defined competency and performance requirements. Where training is found ineffective, appropriate retraining or other corrective action shall be taken.
6. Maintaining records and objective evidence demonstrating application of GRP principles, implementation of decisions and completion of corrective or improvement actions.
7. Each regulatory function shall maintain representative, traceable and periodically updated examples demonstrating the practical application of GRP principles to regulatory instruments, assessments, inspections, laboratory activities, authorizations, enforcement actions and other regulatory decisions. Such examples shall form part of the periodic GRP implementation report and the institutional evidence repository.
8. JFDA shall identify and document its core and supporting regulatory processes, their process owners, inputs, outputs, interfaces, dependencies, risks, controls and performance measures. Changes affecting process interactions shall be assessed, controlled and monitored through the Quality Management System.
9. This Policy, its objectives, implementation arrangements, significant updates and relevant performance results shall be communicated throughout JFDA through approved internal communication channels. Records of communication, awareness and training shall be maintained.
10. Monitoring implementation through the Quality Management System and reporting results to senior management for review, accountability and direction.

Implementation shall use the existing legally approved governance and organizational structure. Coordination by the Quality Management Unit does not transfer responsibility for implementation from the directorates, departments, units and decision-makers that own the relevant regulatory processes.

Detailed operational steps, forms, approval pathways, records and timelines shall be established in the applicable procedures and function-specific SOPs and shall not be repeated in this Policy.

6.4 Application to Regulatory Instruments and Decisions

6.4.1 Regulatory Instrument Lifecycle

JFDA shall ensure that new or revised regulatory instruments:

1. Respond to a defined public-health need, regulatory problem or policy objective.
2. Have a clear legal basis and are developed by the competent authority.
3. Are consistent with the regulatory framework and do not create unnecessary conflict, duplication or complexity.
4. Are supported by scientific evidence, reliable data, international standards and relevant regulatory experience.
5. Consider risk, expected benefits, feasible alternatives, resource needs, implementation capacity and regulatory burden through proportionate impact screening or assessment.

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6. Are subject to proportionate internal coordination and stakeholder consultation where appropriate.
7. Receive the required legal, technical, quality and administrative review and approval.
8. Are published and communicated through authorized channels with an effective date and transitional arrangements where needed.
9. Are supported by implementation measures, responsible owners, resources, training and monitoring arrangements.
10. Are periodically reviewed, revised or withdrawn when obsolete, ineffective, duplicated, inconsistent or no longer proportionate.

6.4.2 Daily Regulatory Activities and Decisions

Regulatory activities and individual decisions shall:

1. Follow applicable legislation, approved procedures, defined criteria and authorized delegations.
2. Be based on appropriate scientific evidence, accurate data and a documented risk or benefit-risk assessment.
3. Be undertaken by competent personnel with declared and managed conflicts of interest.
4. Be completed within established target timelines or have delays documented, analysed and addressed.
5. Include a clear and traceable record of the assessment, recommendation, decision and rationale.
6. Be subject to applicable supervisory review, quality checks, internal review, appeal or reconsideration mechanisms.
7. Be monitored for consistency, outcomes and unintended effects, with proportionate corrective action where required.

6.5 Transparency and Stakeholder Engagement

Subject to applicable legal and confidentiality requirements, JFDA shall make accessible, as appropriate:

1. Its mandate, organization, responsibilities and official contact points.
2. Applicable laws, regulations, instructions, guidelines, procedures, submission requirements, fees and target timelines.
3. Notices of proposed regulatory instruments, consultation periods and methods for submitting comments.
4. Approved product and establishment information, public-health advisories, safety information, alerts and recalls, where applicable.
5. Regulatory decisions, assessment summaries or public assessment reports and their rationale, where applicable and legally permitted.
6. Regulatory performance targets, results, periodic reports and other information required for public accountability.

Stakeholder engagement shall be proportionate to the nature, risk, complexity and expected impact of the matter. Stakeholder views shall be considered and documented where appropriate, but shall not replace scientific assessment or the legally authorized regulatory decision.

Stakeholder participation shall be structured to preserve JFDA's independence, impartiality and confidentiality and shall be subject to applicable conflict-of-interest requirements.

Regulated parties shall have access to assessment or inspection information that relates to them in accordance with applicable legislation, disclosure rules and confidentiality protections.

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JFDA shall maintain accessible mechanisms for feedback, complaints, requests for information and, where applicable, administrative review or appeal.

Confidential and protected information shall be accessed only by authorized persons on a need-to-know basis and shall be received, used, stored, transmitted, retained and disposed of through approved security and record-management controls.

Actual or suspected unauthorized access, disclosure, loss or misuse of confidential information shall be promptly reported, assessed and managed in accordance with approved procedures.

6.6 International Cooperation and Reliance

JFDA shall promote and participate, where legally authorized and appropriate, in regulatory cooperation, convergence, harmonization, information-sharing, work-sharing, joint activities, reliance, regulatory networks and capacity-building.

JFDA shall maintain a documented mechanism for the systematic identification, assessment, prioritization, adoption, adaptation and implementation of relevant internationally recognized regulatory standards and guidelines.

Target timelines for completing the assessment and, where appropriate, adoption or adaptation of such guidelines shall be established through approved institutional implementation mechanisms, as applicable.

The use of reliance or recognition shall be based on:

1. The relevance, completeness and applicability of the relied-upon information.
2. The competence and trustworthiness of the reference authority or institution.
3. Applicable national legal and regulatory requirements.
4. A proportionate level of independent verification or assessment by JFDA.
5. A documented regulatory justification and traceable decision.

JFDA shall remain independent, responsible and accountable for the national decision and shall protect confidential information received through regulatory cooperation.

7. Roles and Responsibilities

7.1 Director General and Senior Management

1. Approve this Policy in accordance with applicable authority and provide strategic oversight of its implementation.
2. Demonstrate institutional commitment to GRP and ensure alignment with JFDA's mission, strategy and public-health objectives.
3. Ensure clear governance, reporting and accountability arrangements.
4. Support allocation and prioritization of appropriate resources within available means.
5. Review periodic GRP implementation, performance, risk and improvement reports and direct necessary actions.

7.2 Assistant Directors General, and Directors

1. Translate this Policy into operational plans, procedures and controls within their areas of responsibility.
2. Assign competent personnel, define responsibilities and ensure appropriate supervision and segregation of duties.
3. Ensure that regulatory activities and documents under their responsibility comply with this Policy.
4. Monitor performance, risks, timelines and implementation evidence and report significant issues.
5. Implement corrective, preventive and improvement actions and verify their effectiveness.

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7.3 Quality Management Unit

1. Maintain this Policy and coordinate its periodic review.
2. Support integration of GRP requirements within the JFDA Quality Management System.
3. Coordinate institution-wide monitoring, internal review and reporting of GRP implementation.
4. Support development of common implementation tools, indicators and evidence requirements without replacing process ownership.
5. Follow up corrective and improvement actions through applicable quality-system mechanisms.

7.4 Legal Affairs Directorate

1. Review the legal basis, competence and legal consistency of regulatory instruments and significant regulatory arrangements.
2. Identify legal conflicts, gaps, overlap, duplication or inconsistency and provide advice on corrective action.
3. Advise on delegation, confidentiality, disclosure, appeals, enforcement and international cooperation arrangements.

7.5 All Directorates, Departments, Units and Staff

1. Apply GRP principles in regulatory activities and decisions within their assigned responsibilities.
2. Follow applicable legislation, approved procedures, decision criteria and conflict-of-interest requirements.
3. Maintain complete, accurate and traceable records and evidence of implementation.
4. Participate in consultation, impact assessment, performance review, training and improvement activities as applicable.
5. Report significant risks, conflicts, delays, inconsistencies, obsolete requirements and opportunities for improvement.

7.6 Committees and External Experts

1. Apply GRP principles within their approved mandates and terms of reference.
2. Declare and manage conflicts of interest and recuse themselves where required.
3. Base advice and recommendations on evidence, applicable requirements and defined criteria.
4. Maintain confidentiality and document recommendations and their rationale.

Final regulatory responsibility and accountability shall remain with the legally authorized JFDA decision-making body.

8. Monitoring and Evaluation

JFDA shall monitor and evaluate the implementation, effectiveness and impact of Good Regulatory Practices through appropriate indicators, reporting, internal review, audit, management review and other relevant Quality Management System mechanisms. Indicators and monitoring arrangements shall be defined and maintained through approved institutional implementation and monitoring mechanisms.

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9. Review and Update

This Policy shall be reviewed and updated at least once every three years, or whenever needed, in accordance with the approved JFDA Quality Management System (QMS) and applicable document control requirements, to reflect relevant organizational, regulatory, legislative, procedural, technical, or other applicable changes.

10. Related Documents

1. JFDA Quality Manual.
2. Legislative Development Policy.
3. Transparency Policy.
4. Communication and Regulatory Communication Policy.
5. Stakeholder Consultation Procedure.
6. Conflict of Interest Management Policy and Declaration Form.
7. JFDA Code of Conduct and Professional Ethics.
8. Regulatory Impact Assessment or Impact Screening Methodology.
9. Procedure for Regulatory Document Lifecycle Management.
10. Function-specific regulatory SOPs, decision criteria and review procedures.
11. JFDA document- and record-control procedures.
12. Applicable reliance and international cooperation policies or procedures.
13. Applicable risk management, internal audit, management review and corrective-action procedures.
14. External Experts and External Committee Members Management Policy and Procedure.