

The 2025 Regulatory Retrospective: Hotspots, Themes, and What's Next



REDICA
Systems

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Redica Regulatory Intelligence

We've built a precision, AI-driven regulatory monitoring system, combining automation, human expertise, and an infrastructure designed to adapt to regulator evolutions.

We act as the first line of detection for critical regulatory changes & provide timely actionable intelligence.

Staying ahead of global regulatory changes is hard. That's why Redica does the heavy lifting:

Continuously Monitor Global Regulatory Change

Track full document lifecycles or regulatory queries across agencies, regions, and standards.

Detect Relevant Changes Early

Identify new or revised requirements as they happen, including subtle updates that are often missed.

Understand Trends and Impact

Connect regulatory changes to inspection trends, enforcement history, and (soon) SOPs.

Align Teams with Shared Intelligence

Manage early impact assessments across RA, QA, and compliance stakeholders.

Transition to Proactive Compliance

Reduce manual effort, accelerate response time, and stay ahead of regulatory expectations with traceable rationale.



Comprehensive Regulatory Intelligence Coverage

Countries & Sources



Worldwide Coverage

350+ unique sources from 100+ countries with more sources added regularly.

50+ Trade Associations

- EFPIA
- BioPhorum
- IFPMA
- MedTech Europe

40+ Harmonization Orgs

- ICH
- WHO
- PIC/S
- IMDRF

Primary Industries



- Human Drugs
- Biologics
- Animal Health
- Medical Devices
- In Vitro Diagnostics

Scope



- GMP
- GMP for IMP
- GDP
- GVP
- GCP
- GPeP
- GLP
- GTP
- GPP
- Labels
- Design & Dev
- PMS
- RA - Filing
- RA - CMC
- RA - Clinical
- RA - Preclinical
- RA - General
- Pharmacopoeia
- Health, Safety, Environment (HSE)

How we identify Hotspots and Themes

1. We compare publishing velocities of regulatory signals against a baseline for the same cohort.



Combinations of Redica's Source, Type, and Theme labels indicate that major regulators are publishing significantly more or less.

If publishing velocity changes by >10% for major regulators with a steady publication history, we look deeper into the reasons for that change.

Greater % change threshold required from traditionally less vocal regulators due to an objectively lower baseline volume.

2. We add qualitative measures of industry relevancy.



Each definition is governed by a structured, AI-friendly framework, combining our Redica metadata with semantic meanings across both regulations and enforcement data.

Because we have integrated AI with our data through our Redica MCP server, experts spend less time reviewing a more accurate AI-curated data set.

Redica metadata and our relevance framework

Relevance	Redica Metadata
Enforceability	Laws, Regulations, etc. · Final, In Force (binding)
Major Regulatory Shift	Draft → Final transition · Timeframe (e.g., long-awaited Final) · Emerging Themes (AI, Nanotechnology)
Market Access Risk / Economic Impact	Semantic meaning + company information · Likelihood an issue blocks approval, certification, distribution, or continued sale.
Enforcement Momentum	Semantic meaning + enforcement data · Visibility in inspections and actions.
Operational Impact	Semantic meaning + SOPs + impact workflow: Extent of change required in operations.
First of Its Kind	Document Type + Novel themes, e.g. MHRA - first Guidance on Point of Care Manufacturing
What's Upcoming	Regulatory / Guidance Agendas · Strategy · Work Plans · Business Plans · White / Discussion / Reflection / Concept Papers · AI-extracted Themes
Advocacy Opportunities	Draft, Open for comments
Regulatory Context	Version history · Amendments · Associated Documents · Notifications of changes

2025 Publishing Velocities

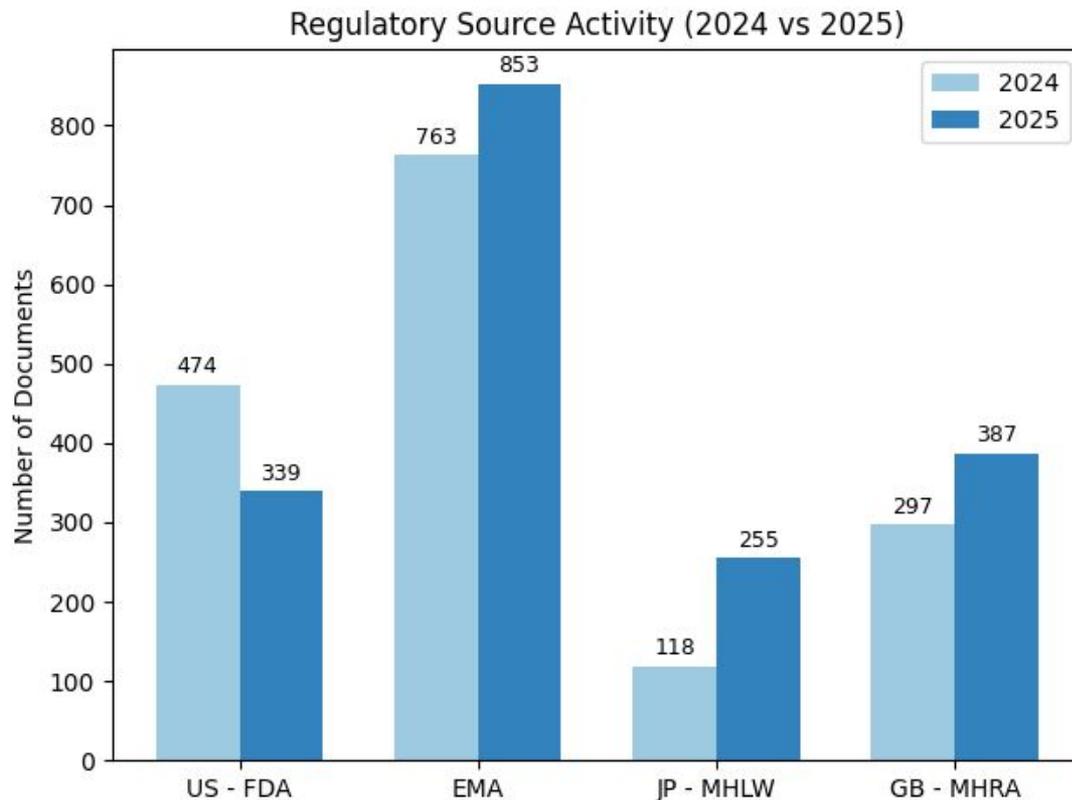


Regulatory Intelligence Landscape

Worldwide regulators published 8,753 signals in 2025, a 6% increase (8,231 signals) compared to 2024. The following regulators were most vocal in 2025:



Noticeable evolution in publication



US FDA

Budget constraints impacting output



European Medicines Agency (EMA)

- Digital & data-driven transformation (PMS, eCTD v4.0)
- Supply chain resilience
- Novel modalities' Guidelines
- 3Rs approach (Animal Welfare)



JP (MHLW)

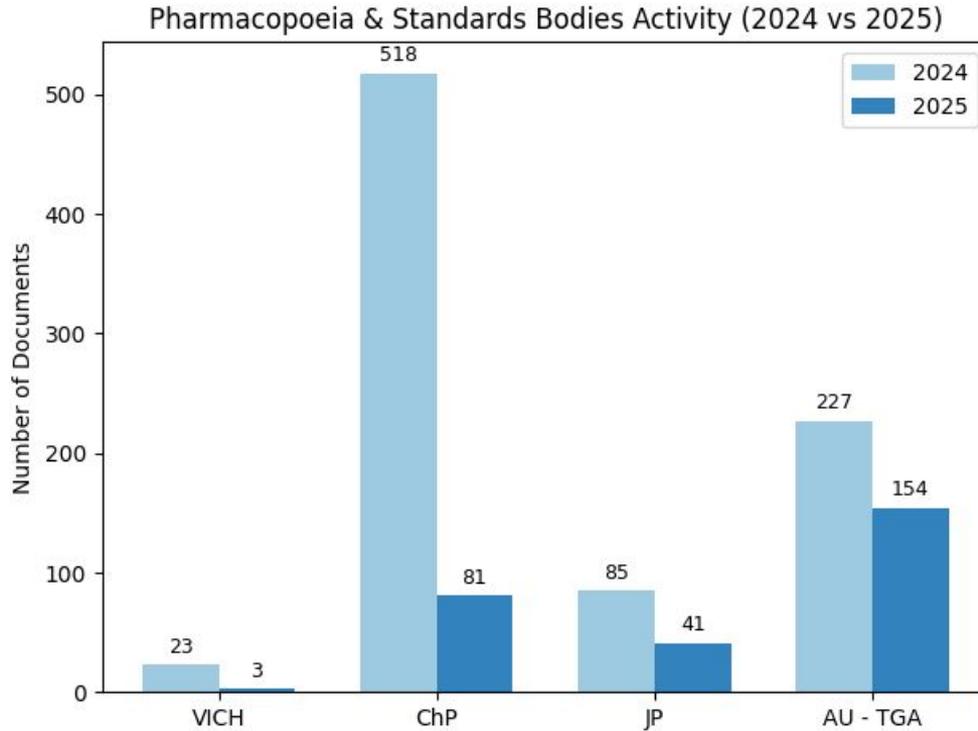
2025 PMD Act amendment



United Kingdom (MHRA)

IRP operationalization & post-Brexit regulatory framework

Noticeable decreases in publication



VICH

End of 5-year Phase 5 cycle



Chinese Pharmacopoeia

2024 front-loaded ahead of 2025 pharmacopoeia edition



Japanese Pharmacopoeia

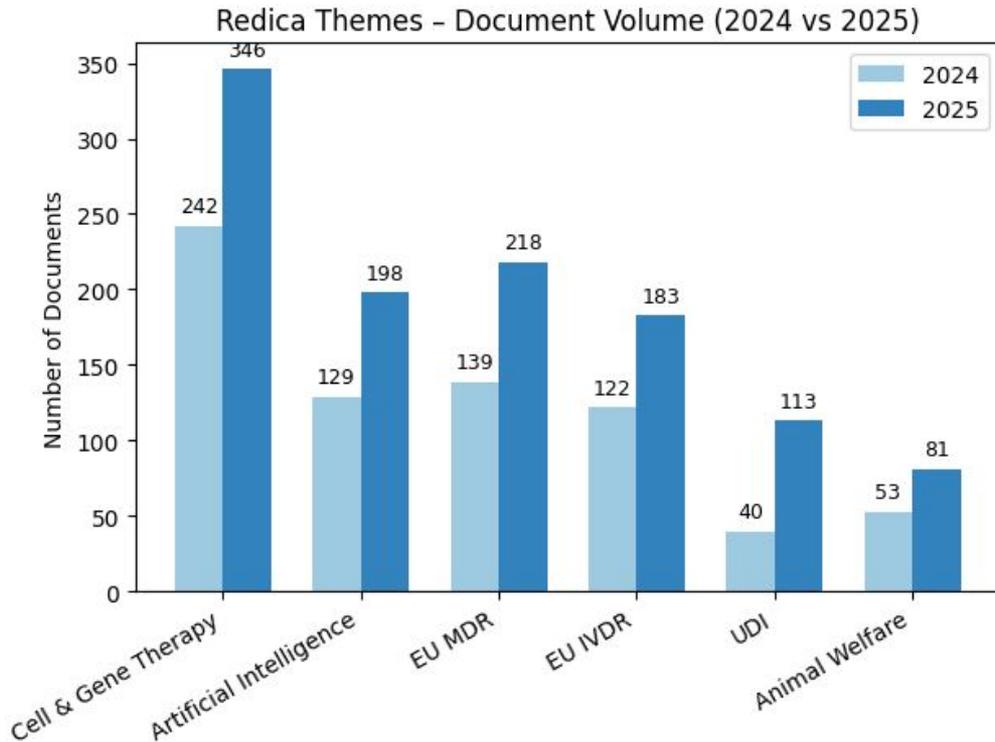
JP19 finalization, next edition preparation



Australia - TGA

From rapid policy development to technical implementation

Noticeable Hot Spots evolution



Cell & Gene Therapy

Remains a top regulatory focus; 2026 will mark expansion and maturation of CGT frameworks.



Artificial Intelligence

Rapid acceleration across digital technologies, industries, and GxPs. E.g., HTAs, GLP smarter models to reduce animal testing.



MDR / IVDR / UDI

Firmly in the implementation phase; sustained regulatory output and operational “jamming” expected.



Animal Welfare (3Rs)

Stronger regulatory emphasis on Reduce, Refine, Replace. Supported by AI-driven models and pharmacopoeial shifts (e.g. alternatives to LAL testing).

2025 Major Regulation Framework Overhauls



ICH: Further development across disciplines (E,Q,M)

- **GCP is evolving:**

E6(R3) is now live and already adopted by most Members, including beyond traditional major markets. e.g., Argentina.

E6(R3) shifts GCP from “check-the-box compliance” to a risk-based, quality-driven, globally aligned clinical trial model.

- **Quality now includes chemical risk, impurity scrutiny is intensifying:**

Q updates embed **toxicological, HSE, and impurity risk considerations** into core GMP/CMC guidance, driven by lessons from the Nitrosamine crisis.

Final Concept Paper Q3C(R10): Impurities: Guideline for Residual Solvents (January 2025);

Q3E Guideline for Extractables and Leachables - Step 2

Chemical and Impurity risk management is no longer optional — it is becoming a **baseline Quality Management System expectation**.

- **Real-World Data goes global:**

M14 has reached adoption (Step 4), providing harmonised principles for non-interventional studies using Real-World Data for safety assessment.

Greater regulatory alignment, reduced duplication, stronger global submissions, and increased credibility of **Real-World Evidence** across regions.

China: Strengthening of core regulations and innovation



- In December 2024, a **Decision of the State Council** further amended **four core regulations** of the Republic of China. This decision **entered into force on 20 January 2025**.
 - a. Regulations for the Implementation of the Drug Administration Law of the People's Republic of China
 - b. Regulations on the Administration of Radiopharmaceuticals
 - c. Regulations on the Administration of Narcotic Drugs and Psychotropic Substances
 - d. Regulations on the Supervision and Administration of Medical Devices

China will continue to build and iterate.

- Throughout 2025, China has maintained an **aggressive cadence to finalize major guidelines around drug development**, e.g., **Technical Guidelines for Clinical Development of Anti-tumor Drugs Targeting Pan-tumor Diseases**
 - ✓ Oncology Focus: heavy emphasis on **cancer therapies**, especially **innovative approaches** (pan-tumor, single-arm trials)
 - ✓ Advanced Medical Technology: Particle therapy, precision medicine showing **China's investment in cutting-edge treatments**

Japan: Reform of the Pharmaceutical and Medical Devices Act



In May 2025, Japan introduced **amendments to its *Pharmaceutical and Medical Devices Act*** that reshape what it means to be a Marketing Authorisation Holder (MAH).

Act Partially Amending the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc.

Act Partially Amending the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc. (May 22, 2025)

For industry, this increases **regulatory consistency across major MDSAP markets**, reduces ambiguity around MAH roles, and supports a more robust, auditable compliance model. In the near term, companies may need to adjust governance and contractual structures, but longer term it strengthens trust, predictability, and the global credibility of MDSAP-based oversight.

As an industry expert rightly pointed out, *“Japan isn’t an outlier, it’s part of a pattern. With US shifting, we have 2 major MDSAP participants shifting, and MDSAP will need to absorb it.”*

US: The QMSR Journey - The FDA aligns with ISO 13485



- In **Jan 2024**, FDA updated **21 CFR Part 820**, aligning it with **ISO 13485:2016**, marking a shift toward global QMS harmonization. The revised rule is now called the **Quality Management System Regulation (QMSR)**. FDA also updated **21 CFR Part 4** to clarify expectations for combination products.
- In **Oct 2025**, a **draft guidance** was issued to support premarket submissions under QMSR.
- In **December 2025**, the **FDA further amended certain medical device regulations** to revise references and language in existing Code of Federal Regulations (CFR) provisions to materialize the QMSR Final Rule, **effective February 2, 2026**.

The QMSR transition allows companies to rely on a single, globally recognized QMS, lowering compliance costs, minimizing duplicate audits, and simplifying quality system maintenance.

US: In-Vitro Diagnostics - Laboratory Developed Tests (LDTs) are dead



FDA's 2024 Final Rule on LDTs is now dead.

In a landmark decision, the United States District Court for the Eastern District of Texas has vacated and set aside the FDA's Final Rule on Laboratory Developed Tests (LDTs), ruling that the agency exceeded its authority.

In September 2025, the FDA formalised this decision in a revised [LDT rule](#), replacing the initial Rule and amending [21 CFR Part 809](#) through the formal APA process.

As a result, on 19 September 2025, the FDA also withdrew [the Guidance "Laboratory Developed Tests: Small Entity Compliance Guide - Guidance for Laboratory Manufacturers and Food and Drug Administration Staff - June 2024"](#).

By reverting and clarifying the framework under amended [21 CFR Part 809](#), the revised 2025 rule provides greater legal certainty while maintaining space for innovation, rapid test development, and continued patient access—particularly for specialized and emerging diagnostics.

What to expect in 2026



US: FDA Guidance Agendas 2026



The FDA has begun publishing their annual Guidance Agendas for FY 2026:

Biologics:

CBER Guidance Agenda for Year 2026 plans an extensive guidance workload for 2026, with a **strong strategic focus on advanced biologics: expansion and maturation of Cell & Gene Therapy regulation** is the dominant theme. Other themes include:

- Xenotransplantation moving toward clinical readiness
- Reinforced blood and blood component safety
- Comprehensive Risk Mitigation for HCT/Ps,
- Vaccines & allergenics clinical evidence and CMC rigor, and
- Digitalization, inspections, and advanced testing methods.

Human Drugs: None yet!

Human Drugs: None yet!

Med Tech:

CDRH Guidance Agenda for Year 2026 announced **eight guidance documents to be released**. It also named 12 guidance documents that the agency says it intends to publish “as resources permit.” Topics include **Artificial Intelligence, Real-World Evidence**, 510(k) submissions, patient preference information, **Quality Management Systems**, and devices that aim to assist with weight loss, surgery, and mental health.

EU: First-of-their-kind Acts



Critical Medicines Act

- Drug shortage mitigation of critical medicines has been a topic of scrutiny and attention in the EU and part of the EU Pharmaceutical Reform.
- A **first-ever list of 200+ critical medicines** was published in December 2023.
- In late 2023 and 2024, several EU leaders and industry bodies called for a **Critical Medicines Act**.
- As of 2025, no formal “Critical Medicines Act” has been passed yet, **but a legislative proposal is expected** or under discussion.

EU Biotech Act

- A legislative proposal (a **Regulation**) was published by the **European Commission in December 2025** to establish a **comprehensive framework** for strengthening the EU’s biotechnology and biomanufacturing sectors with a **primary focus on health biotechnology**.
- It targets faster and more coordinated pathways across the medicinal product lifecycle (incl. Biologics/ATMPs, Biosimilars), including clinical trial process changes and lifecycle guidance.

EU is on a roll



2026 is a "year of implementation" for the most significant overhauls in the EU.

"Pharma Package" implementation

- Replaces **Directive 2001/83/EC** and **Regulation (EC) No 726/2004** with a new Directive and Regulation on medicinal products for human use.
- **Shortened evaluation timelines** (from 210 to 180 days).
- **Obligation to ensure EU-wide supply** within 2 years of marketing authorization.
- Exemption: to ensure that generic versions of a medicine can be made available on day one after the intellectual property rights have expired.
- Incentives for developing **new antimicrobials** to fight antimicrobial resistance.

Mandatory EUDAMED

- **Deadline:** Starting **May 28, 2026**, the use of the first four modules of **EUDAMED** (the EU's medical device database) becomes mandatory.

EU: Biosimilar Development revamping



The European Medicines Agency (EMA) is exploring an improved approach for biosimilar medicine development and evaluation, while upholding strict European Union (EU) safety standards.

This was fully integrated into the **2025-2027 plan** early February, and a **draft reflection paper on biosimilar development** was published in April 2025.

The approach aims to **reduce the amount of clinical data required for the development and approval of biosimilar medicines** in the EU.

The plan includes the **revisions of foundational guidelines across nonclinical, clinical, and quality dimensions**:

(B) Activities to be started in 2025

Consider revision of general biosimilar guidelines, in collaboration with BWP. In particular:

- Guideline on similar biological medicinal products;
- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: nonclinical and clinical issues EMA/CHMP/BMWP/403543/2010

None published yet!

(C) Activities to be started in 2026-2027

- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues.
- Revision of the guideline on similar biological medicinal products containing monoclonal antibodies: non-clinical and clinical issues EMA/CHMP/BMWP/403543/2010;
- Monitor the application of non-EEA sourced reference medicinal product in clinical studies;
- Develop regulatory approaches in the analytical comparability, e.g., related to identification and assessment of quality attributes.

Further guideline activities (new guidance/revisions) may arise in relation to the implementation of new/revised pharmaceutical legislation.

Canada's new conditions for Medical Device manufacturers



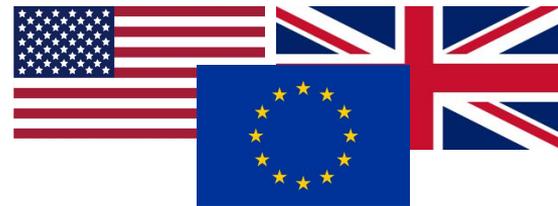
Previously, Health Canada could only apply conditions related to testing during the application phase. Now, the Minister of Health can amend **Terms & Conditions at any point** in the device's lifecycle.

What you will be required to provide:

- **Subgroup Clinical Data:** Mandatory reporting on how the device performs across different sexes, genders, and ethnicities (addressing historical bias in clinical trials).
- **Real-World Evidence (RWE):** Annual submissions of Canadian and international incident data to ensure the benefit-risk profile remains favorable in the general population.
- **Aging & Stability Results:** Ongoing real-time stability studies to demonstrate the device doesn't degrade faster than predicted

Enforcement Hook: Failure to comply with a T&C is now a direct violation of the *Medical Devices Regulations*. This gives Health Canada the power to **suspend or cancel a license** without needing to demonstrate the device is "unsafe", only that the condition was not met.

AI and Digital Health enforcement across the board



Prediction:

Across the FDA, EMA, MHRA, 2026 will see the first major enforcement actions related to **AI-enabled medical software**.

Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

- The UK's MHRA has established a **National Commission on the Regulation of AI in Healthcare** with a full framework due by mid-2026. [AI Airlock Sandbox Pilot Programme](#)
- 2026 is the year the **European Union AI Act** begins to fully integrate with the Medical Device Regulation (MDR). [MedTech Europe](#) advocated for extending the date of application to allow more time to develop a solid framework.
- Agencies will focus on "Algorithm Change Protocols"—how companies update AI models post-launch without requiring an entirely new submission.

Request a demo



Questions & Answers



Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

“Any insight into Annex 11 and Annex 22 finalization?”

Answer

1. Power keyword search: *Annex 11, Annex 22*

PIC/S

[Joint stakeholders consultation on the revision of Chapter 4 on Documentation, Annex 11 on Computerised Systems and on the new Annex 22 on Artificial Intelligence of the PIC/S and EU GMP Guides](#)

EU - EMA

[Draft guidelines: Revised Annex 11 – Computerised Systems](#)

[Draft guidelines: New annex 22 – Artificial intelligence](#)

Australia - TGA

[Have your say on updates to Good Manufacturing Practice \(GMP\) Guidelines](#)

Brazil - ANVISA

[Anvisa invites the pharmaceutical sector to participate in an international public consultation on Good Manufacturing Practices](#)

2. Power our framework ‘What’s upcoming’: *Work Plans*

[3-year rolling work plan for the Quality Innovation Group \(QIG\)](#)

(A) Activities ongoing/to be finalised in 2025/2026

EU Guidance documents, New, Revision, QIG lead:

- QIG Preliminary Considerations on Pharmaceutical Process Models
- Questions and Answers on 3D printing
- Questions and Answers on Decentralised Manufacturing

EU Guidance documents, New, Revision, QIG specialised input:

- [GMP Annex 11 on Computerised Systems](#)
- [GMP Annex 22 Artificial Intelligence](#)

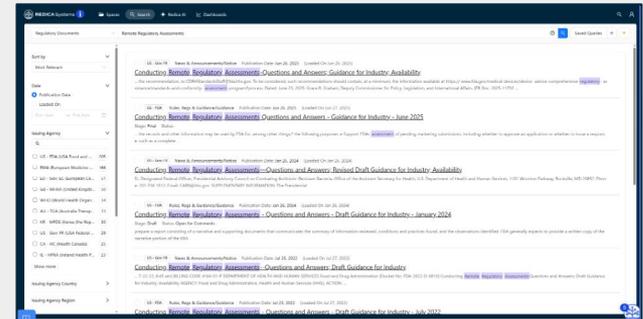
Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

“Is there any intelligence you can provide regarding Remote Regulatory Assessments?”

Answer

1. Power keyword search: **Remote Regulatory Assessments**
2. Power our framework Redica Theme: **Remote Inspection**
3. Power our tools: Space creation, notifications



Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

“How do companies proactively keep up to date with global regulatory expectations for biosimilars?”

Answer

1. Power our framework Redica Theme: *Biosimilars*
2. Power our tools: Space creation, notifications



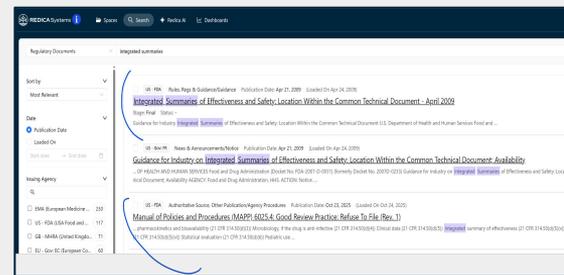
Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

“Format of ISS for PPARS and NLRP3 inhibitor?”

Answer

1. Power keyword search: *Integrated Summaries of Effectiveness and Safety*



The screenshot shows the FDA's Regulatory Documents search interface. The search results list several documents, with the top result being "Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document - April 2009". The document content is displayed on the right, showing the title and a table of contents. The table of contents lists various sections of the document, including the summary of the application, chemistry, manufacturing, and controls, nonclinical pharmacology and toxicology, human pharmacokinetics and bioavailability, microbiology, clinical data, integrated summary of effectiveness, integrated summary of safety, statistical evaluation, pediatric use, required case report forms, annotated labeling, and complete information on manufacturing and testing facilities and specific.

The scopes of the [FDA Guidance](#) and the [FDA Agency Procedure 'MAPP'](#) are mechanism-agnostic. Missing an ISS can cause a “refuse-to-file”.

Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

“International regulatory authorities cooperation in future and how it will shape the international registration procedures?”

Answer

- 1. Power Reg Intel Expertise + search: “Regulatory Cooperation” resonates with “Reliance”**

[WHO collaborative procedure for registering medicines through reliance](#)

- 2. Power Reg Intel Expertise + search: “Regulatory Cooperation” resonates with ICH international harmonization; registration is all about the “Common Technical Document (CTD)”**

ICH M4Q(R2)

ICH M4E(R2)

ICH M4S(R2)

all latest developments are in the App.

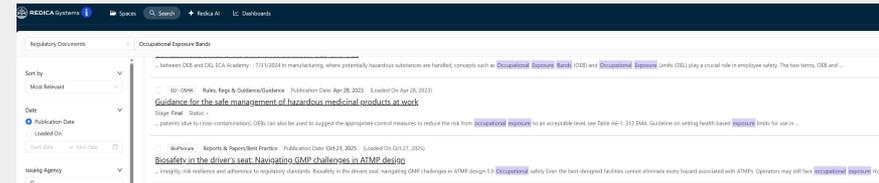
Any questions or comments about regulatory intelligence monitoring or emerging signals?

Question

More about “Occupational Exposure Bands (OEB 4/5)?”

Answer

1. Redica covers HSE Scope for top regulators. Power keyword search: *Occupational Exposure Bands*



[Guidance for the safe management of hazardous medicinal products at work \(EU - OSHA\)](#)



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