Regulatory Round-up

July 2025

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UK

Medicines and Healthcare products Regulatory Agency (MHRA)

MHRA CEO Lawrence Tallon welcomes Life Sciences Sector

CEO Lawrence Tallon has welcomed the Life Sciences Sector Plan published by the UK government. The document sets out a vision and an action plan to drive growth, innovation, and better health outcomes, in which the Cell and Gene Therapy Catapult will play a key part, as described in the document. The plan aims to position the UK as the leading life sciences economy in Europe by 2030, and the third globally by 2035, behind only the United States and China. Please find further information here.

MHRA's new Modular Manufacture and Point of Care Regulations have come into effect

New regulations came into effect on 23rd July 2025 and introduce frameworks for Point of Care and Modular Manufacture, allowing medicines to be manufactured closer to patients. Under the new UK legislation, patients can receive faster access to potentially life-saving, personalised treatments made at their hospital, clinic or near their homes. Currently, personalised treatments such as CAR-T cancer therapies are typically sent to centralised manufacturing facilities, often far from the patient, which may cause delays to the patient receiving their treatment. Hospitals, health clinics and local care settings in the UK now have a pathway to carry out the manufacturing steps for these personalised or time-sensitive treatments near or on-site. Please find further information and access to the press release here.

MHRA's 2024-2025 Annual Report and Accounts and Impact Report show progress on safety, innovation, and regulatory excellence.

The MHRA has published its 2024–25 Annual Report and Accounts and accompanying Impact Report demonstrating how the agency has enhanced patient safety across the UK, restored performance to ensure they are meeting regulatory timelines, and sharing their success in enabling access to life-changing medical products.

The highlights of the MHRA's work in 2024–25 include:

- Clearing all statutory backlogs by March 2025 and consistently meeting statutory targets for clinical trials.
- Approving more than 2,000 licenses for medicines, including 54 new medicines, such as treatments for Alzheimer's, rare diseases, and cancer.

- Assessing over 5,000 clinical trial applications and launching the UK's most significant clinical trial regulatory reform in over two decades.
- Supporting patient safety through the assessment of over 100,000 adverse drug reaction reports and blocking over 1.5 million unregulated online listings.
- Piloting a world-first AI Airlock to safely develop artificial intelligence in medical devices.
- Providing over 127,000 units of biological standards worldwide and launching new endorsed World Health Organisationstandards to strengthen global pandemic preparedness.

Please find further information here.

EUROPE

European Commission (EC)

Stakeholders' consultation on EudraLex volume 4 - Good manufacturing practice guidelines: Chapter 4, annex 11 and new annex 22

Due to the rapid advancement of digital technologies and the implementation of AI systems in pharmaceutical manufacturing, the update of the Good Manufacturing Practice (GMP) guidelines is essential to ensure that they continue to provide clear, practical and relevant guidance for manufacturers and national competent authorities. The revision of GMP Annex 11 and Chapter 4, along with the introduction of Annex 22 on Artificial Intelligence aim at supporting innovation in the manufacturing of medicines and ensuring regulatory harmonisation.

To maintain the global alignment of standards, the following three draft documents have been drafted by the European Medicines Agency (EMA) GMDP-Inspectors Working Group in cooperation with the PIC/S:

- Revised chapter 4: Documentation
- Revised Annex 11: Computerised Systems
- New Annex 22: Artificial Intelligence

The deadline for consultation is 7th October 2025. Please find further information here.

European Directorate for the Quality of Medicines (EDQM)

Gradual rollout of a new primary label for European Pharmacopoeia reference standards

EDQM will gradually introduce a new primary label for European Pharmacopoeia reference standards. This introduction will take place in several stages and affects new reference standards (batch 1) placed on the market from the end of July 2025 onwards. It will then be gradually rolled out to all other reference standards during 2026. This new label has been designed to meet the requirements of Regulation (EC) No 1272/2008 (CLP). It will allow additional information to be included, such as:

- CAS number of the substance (if available)
- Chemical name
- Safety pictograms (if any)

Other key information will remain, but in a clearer and more harmonised visual format.

Please find further information here.

European Medicines Agency (EMA)

Clinical Trials Information System (CTIS) Bitesize talk: Redesign of the CTIS training material for sponsor users

EMA published a revised Sponsor Handbook which serves as the definitive reference for sponsor users operating within CTIS. Effective from the 9th of July, it will supersede the existing sponsor training modules. Please find access to the revised handbook and the training video here.

EMA Information Day on submission predictability of initial marketing authorisations

EMA will host an online information day on 3rd December 2025, aiming to:

- Enhance a common understanding,
- Raise awareness of the challenges for EU regulatory network,
- Share best practices for planning and preparing submissions, and
- Communicate changes.

Please find further information including registration and the agenda here.

USA

Food and Drug Administration (FDA)

FDA eliminates Risk Evaluation and Mitigation strategies for Autologous CAR-T cell Immunotherapies

On 27th June 2025, the FDA announced that it has eliminated the Risk Evaluation and Mitigation strategies (REMS) for currently approved BCMA- and CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies. The elimination of REMS for the products below removes the requirements that hospitals and their associated clinics must be specially certified and have on-site, immediate access to tocilizumab, which was initially included in the REMS as a crucial medication for managing cytokine release syndrome and CAR-related encephalopathy syndrome.

- Abecma (idecabtagene vicleucel)
- Breyanzi (lisocabtagene maraleucel)
- Carvykti (ciltacabtagene autoleucel)
- Kymriah (tisagenlecleucel)
- Tecartus (brexucabtagene autoleucel)
- Yescarta (axicabtagene ciloleucel)

Please find further information here.

FDA center for biologics evaluation and research (CBER) office of therapeutic products (OTP) public listening meeting: Leveraging knowledge for facilitating the development and review of cell and gene therapies

The FDA's CBER OTP is hosting a virtual public listening meeting on 18th September 2025, to ask for perspectives from cell and gene therapy (CGT) manufacturers and other stakeholders on using prior knowledge and experience to facilitate product development and application review. Speakers will be asked to share how internal prior and public knowledge can be used to help advance the development and regulation of CGT products. The meeting will be divided into three sessions. Speakers are asked to consider the following questions and are encouraged to discuss examples specific to the session of interest and recommendations from a CMC, nonclinical, or clinical perspective:

- What types of data and information are Sponsors willing to share that will be useful for advancing CGT product development and regulatory review?
- What data leveraging is possible between external partners (such as CMOs, CDMOs and licensees) while considering various aspects of the product lifecycle?
- How can data and information be effectively integrated and leveraged across multiple disciplines to enhance the development, manufacturing and safety assessment of CGT products?
- What mechanisms could be used to facilitate data and information sharing?

Please find further information including registration details here.

Unique device identifier requirements for combination products

The FDA has issued a draft guidance to assist industry and FDA staff in understanding how FDA's unique device identifier (UDI) requirements at 21 CFR part 801 subpart B and part 830 subpart E apply to combination products with device constituent parts. This guidance outlines the requirements, recommendations, and best practices for UDI labeling and for submission of information to the Global Unique Device Identification Database for such combination products. This guidance also provides hypothetical examples to illustrate how UDI requirements can be met for these combination products.

FDA embraces radical transparency by publishing complete response letters

The FDA has published more than 200 decision letters, known as complete response letters (CRLs). The CRLs were issued in response to applications submitted to the FDA for approval of drugs or biological products between 2020 and 2024, marking a significant step in the FDA's broader initiatives to modernise and increase transparency. Please find further information here.

INTERNATIONAL

International Conference on Harmonisation (ICH)

ICH E20 scientific guideline on adaptive designs for clinical trials open for consultation

The ICH has issued guidance on confirmatory clinical trials planned with an adaptive design within the context of its overall development programme, allowing pre-specified modifications of the trial design based on an interim analysis of the on-going trial. The guideline also outlines opportunities for the application of Bayesian methodology, and

input is sought on further examples where Bayesian methodology can be employed in a way that can be discussed within the clinical context of use. The document was released for public consultation and the deadline for comments is 30th November 2025.

Public consultations

European Commission (EC)

	Title	Consultation Period	Category
1.	*EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22*	*End Date: 07 October 2025*	*Stakeholder Consultation*

European Medicines Agency (EMA)

	Title	Consultation Period	Category
1.	*QRD annotated template v11*	*End date: 31 August 2025*	*Public consultation*
2.	*Chapter 9 of Guideline on epidemiological data on blood 4 transmissible infections*	*End date: 31 August 2025*	*Public consultation*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	Unique Device Identifier (UDI) Requirements for Combination Products Guidance for Industry and FDA Staff	*End date: 24 September 2025*	*Draft guidance*

International Council for Harmonisation (ICH)

	Title	Consultation Period	Category
1.	*ICH E20 guideline on adaptive designs for clinical trials - Step 2b*	*End date: 30 November 2025*	*Public Consultation*