What's New in Pharmaceutical and Medical Device Regulations Quarter 3 – 2026

PHARMACEUTICAL REGULATIONS

UK Pharmaceutical legislation

Following a consultation that closed 30 July 2026, the MHRA are proposing a new rare disease therapies regulatory framework that will run alongside the current orphan legislation. A single, flexible authorisation, the Investigational Marketing Authorisation (IMA), could be introduced which would allow controlled early access to a rare disease therapy while further clinical and real-world evidence continues to be generated. *Draft rare disease therapies regulatory framework*

EU Pharmaceutical legislation

On 17 September 2026 the European Parliament published provisional agreed text for the 'new pharma package', which reforms the EU pharmaceutical legislation and includes a new directive (2023/0132(COD)) relating to medicinal products for human use. The changes include: eight-year baseline regulatory data protection, increased to up to eleven years for medicines addressing unmet clinical need, up to eleven years market exclusivity for orphan medicines, a transferable data exclusivity voucher for new antimicrobials, reduced EMA assessment times for marketing authorisation (210 to 180 days), reduced EMA scientific committees (only CHMP and PRAC), obsolete renewal of Marketing Authorisations, and a mandatory shortage-prevention plan for marketed medicines. The changes also included formalisation of the Bolar exemption, where generic manufacturers can perform studies during the reference product exclusivity period to enable generic versions of a medicines to be made available immediately after the intellectual property rights have expired. The new pharma package includes a new regulation (2023/0131(COD)) that covers the centralised procedure, the European Medicines Agency, and incentives. *Provisional directive text - new pharma package*

On 28 September 2026, the European Council adopted the 'new pharma package' and this will enter into force following adoption by the European Parliament (due 19 October 2026) and 20 days after publication in the EU's Official Journal. The new directive must be incorporated within the laws of each Member State and full applicability is foreseen from 2028. *'Pharma package': Council adopts new rules*

MEDICAL DEVICE REGULATIONS

Regulation (EU) 2025/40 on packaging and packaging waste

Regulation EU 2025/40 establishes a harmonised legal framework for packaging and packaging waste across the European Union. Its primary objective is to ensure the smooth functioning of the internal market while significantly reducing the environmental and health impacts associated with packaging throughout its life cycle. By replacing Directive 94/62/EC, this regulation introduces clearer, stricter, and more uniform requirements for all economic operators and Member States. The date of application was 12 August 2026. See the guidance section of this newsletter regarding 10 June 2026 guidance detailing exemptions for medicinal products, medical device and in vitro diagnostics packaging and packaging waste requirements.

Well-Established Technologies (WET) Devices

WET are exempt from conducting a clinical investigation prior to CE marking and from individual notified body review of technical documentation (rather than on a sampling basis). The WET list was updated in Regulation 2026/1359 *amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of class IIb implantable devices exempted from the obligation to perform an assessment of the technical documentation for every device* (with addition of 24 WET) and Regulation 2026/1451 *amending Regulation (EU) 2017/745 of the European Parliament and of the Council as*

regards the list of implantable devices and class III devices exempted from the obligation to perform clinical investigations (with addition of 57 WET). Both regulations entered into force on 19 July 2026

Transparency in the framework of the MDR/IVDR - proposed revision of the Regulations

In August, Team-NB published a paper supporting the Commission's initiative to plan and conduct risk based and proportionate surveillance activities. However, Team-NB propose an alternate approach, with the intensity, frequency and modality of surveillance audits, unannounced audits, technical documentation sampling, and batch testing adjusted based on documented criteria such as incident history, PMS/Vigilance data, QMS maturity, and effectiveness of corrective actions. The paper provides more detail into Team-NB's thought process for the proposed approach. *Team-NB Position Paper - Transparency*

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH) GUIDELINES

ICH E6(R3) Annex 2: Guideline for Good Clinical Practice, Annex 2

On 3 June 2026 this guideline was adopted as final by the regulatory members of the ICH Assembly under Step 4 of the ICH harmonisation process, where a final draft is recommended for adoption to the regulatory bodies of the ICH regions. ICH E6(R3) Annex 2 provides additional GCP considerations, focusing on trials that incorporate decentralised elements, pragmatic elements and/or real-world data. *E6(R3) Annex 2*

Revised Q&As for ICH E14 and ICH S7B provide updated implementation support

On 18 September 2026, the ICH published under Step 4 the updated ICH E14/S7B Questions & Answers (R1) to provide clarifications related to the clinical and nonclinical assessment of QT/QTc prolongation and proarrhythmic risk. These were implemented by the European Commission 27 August 2026 and the FDA 30 August 2026, but is yet to the implemented in the UK. *Revised Q&As for ICH E14 and ICH S7B provide updated implementation support*

Updated support package for ICH M8: electronic Common Technical Document (eCTD)

The support package has been updated for the globally agreed upon eCTD, organising all the scientific, clinical, quality and administrative documents in a harmonised digital format, namely the Implementation Guide Package (v1.7), the Controlled Vocabulary Package (v1.0.3), and the Q&A document. Submission of Marketing Authorisation Applications in the eCTD 4.0 format is strongly recommended from Q1 2027 for all new centralised applications and will be mandatory for all new centralised Marketing Authorisation submissions from Q1 2028, with technical pilots ongoing for non-centralised products. In the US, the eCTD 4.0 was voluntarily implemented in 2024 and will be mandatory in 2029. *eCTD v4.0 information and update packages.*

INITIATIVES AND PROPOSALS

The UK MHRA Regulatory AI Sandbox – medical devices and London-based NHS providers

On 10 June 2026, the MHRA, NHS England and the London Health Innovation Networks launched 'London Region I' which is a regulatory sandbox for evaluating AI-enabled medical devices in real-world NHS settings. If accepted onto the programme, AI driven innovative technologies can be deployed in a real-word environment for evaluation with regulatory oversight. This will allow for safe and quick access to new technologies by patients. *Pioneering AI health innovations regulatory sandbox launched*

The UK MHRA Regulatory AI Sandbox - medicine safety

After analysis of stakeholder evidence, on 9 June 2026 the MHRA launched an AI sandbox to examine how AI tools can predict the pharmacological properties of medicines and use clinical data to improve the understanding of how medicines work across different groups. This will give companies and researchers a controlled testing environment with regulatory oversight to explore how AI tools could be

used to better understand medicine safety. *AI sandbox to accelerate medicines development and improve safety*

Furthermore, the MHRA wish to understand how organisations are currently using, developing or planning to use AI based approaches for prediction and assessment of a medicine's absorption, distribution, metabolism, excretion and toxicity. This includes areas such as model development, validation, access to data, data sharing and regulatory considerations. *Beyond ADMET: AI for medicines safety - survey*

The UK National Commission into the Regulation of AI in Healthcare: Recommendations

On 10 September 2026, the National Commission into the Regulation of AI in Healthcare published a report outlining a future regulatory framework for AI in healthcare, covering safety, accountability, transparency, clinical practice, governance and system-wide assurance. The Commission made 44 recommendations, including MHRA review and update of the UK Medical Devices Regulations to better address software and AI-enabled medical devices, and enabling 'platform master files' to support staged evidence generation and authorisation. *National Commission into the Regulation of AI in Healthcare: Recommendations for a future regulatory framework*

The UK MHRA has identified examples of AI use for GxP inspection responses

On 29 June 2026, the MHRA Inspectorate released a blog outlining current thinking and expectations for using AI to generate information supporting inspections. While recognising AI's usefulness in drafting responses to MHRA queries, the Inspectorate identified recent inaccuracies, including referencing incorrect guidance/regulatory frameworks and lengthy responses that do not address deficiencies. This has increased the Inspectorate's administrative burden from an average of 4 to 20 hours and delayed resolution of serious non-compliance. AI use remains appropriate provided Industry ensures responses are factually correct, verifiable, appropriately reviewed and signed. A non-mandatory AI disclosure is now available for responses, stating which sections were AI-generated and confirming human verification and approval. *Use of AI for GxP inspection responses: setting standards without stifling innovation*

Use of AI in EU Health Technology Assessments

On 15 July 2026 the Member State Coordination Group on Health Technology Assessment adopted general principles on the use of AI for the preparation of evidence synthesis in the dossiers for Joint Clinical Assessments. The main principle is accountability and that sponsors are transparent about where AI was used to ensure outputs are accurate and reliable. The dossier should report the name, version and date of the AI tools used and whether any adaptations of commercial AI tools were made. *General Principles on the use of Artificial Intelligence in the preparation of the JCA dossier*

Key Considerations for the Development and Use of Digitally Derived Measures for Clinical Investigations

A FDA paper was published in August 2026 outlining the key considerations for the use of Digitally Derived Measures (DDMs), including AI-enabled tools, for clinical outcome assessments, biomarkers, or as part of multicomponent endpoints derived from multimodal data. *Key Considerations for the Development and Use of Digitally Derived Measures for Clinical Investigations, FDA Paper | FDA*

MHRA-NICE Real-World Evidence Scientific Dialogue Programme

The MHRA-NICE Real-World Evidence Scientific Dialogue Programme website was updated on 4 September 2026 to update the pilot scheme to an established service, with detailed descriptions of the services offered. There is a revised expression of interest process, setting out how applicants can apply and what to expect at each stage and the type of questions suitable for discussion. *MHRA-NICE Real-World Evidence Scientific Dialogue - GOV.UK*

Plans for a new UK Health Data Research Service

The MHRA has a statutory remit to conduct research to address evidence gaps to inform regulatory decision-making, however, the UK's health data systems are complex and cannot supply quality real world evidence to support the MHRA. A £600 million government investment to create a single, trusted gateway to the UK's health datasets is planned, namely the UK Health Data Research Service (HDRS). The MHRA published a paper on 2 July 2026 outlining its data needs and how a future HDRS could address these gaps. *A regulator's view on what the new HDRS must deliver*

EMA use of real world data

The EMA has published a fourth report on 10 June 2026 regarding regulatory-led studies using real-world data, which can be found under the 'Use of real-world evidence' section. A related information sheet based on studies EMA conducted using real-world data is also provided. *Real World Data*

UK clinical trial Phase 1, 14-Day Pilot Programme

On 17 August 2026, the MHRA pilot initiative for accelerated assessment of certain low-risk Phase 1 healthy volunteer trials conducted in the UK will aim for a 14 day regulatory assessment by the end of 2026. This has built on the pilot launched in March 2026, where a stepwise reduction in assessment time for such UK Phase 1 studies from the standard 30 calendar days has been in place. The pilot is open to investigational medicinal products that already have satisfactory prior clinical safety data for all doses. *UK clinical trial Phase 1, 14-Day Pilot Programme*

UK mandated unaltered non-commercial agreements

On 23 July 2026, the UK Health Research Authority (HRA) have agreed to mandate the use of unaltered template agreements when setting up clinical studies for non-commercial research, which is already in place for commercial clinical research. The HRA are currently seeking views from stakeholders and expect the mandate to be in place early 2027. *Mandated unaltered non-commercial agreements*

EU medicines for women's health

On 2 July 2026 the EMA announced the launch of initiatives to improve women's health considerations with the development and regulation of medicines better tailored to women's needs. Identification of priorities will be aided by a women's health workshop that took place on 28-29 September 2026. This will help inform the main areas the EMA are keen to improve, including representation in clinical trials, sex-specific differences in labelling and the use of medicines in pregnancy and breastfeeding. Additionally, the EMA will continue to conduct real-world evidence studies on medicine use and disease epidemiology related to women's health. *EMA steps up efforts on medicines for women's health*

EMA and EISMEA boost cooperation to accelerate health innovations

On 15 July 2026 it was announced that cooperation between the EMA and the European Innovation Council and SMEs Executive Agency (EISMEA), who manages the European Innovation Council (EIC), has been strengthened. The ongoing collaboration supports assistance to innovators from small and medium-sized enterprises (SMEs), disruptive start-ups, spin-offs, research organisations and universities. This assistance allows a better understanding of EU regulatory requirements and is supported by a rolling work programme for 2026-2027 and continued training, education and stakeholder engagement activities. *EMA and EISMEA boost cooperation to accelerate health innovations*

EMA voluntary data submission pilot to advance innovative alternatives to animal testing

On 1 September 2026 the EMA announced a new voluntary data submission (VDS) pilot where developers can submit New Approach Methodologies (NAMs) data as an alternative to animal testing. An application to participate must be made by Q3 2027 and accepted by the EMA and does not replace or interfere with existing regulatory processes. It was noted that NAMs are used in early medicine development but these data are not utilised to support regulatory submissions, where traditional nonclinical testing data are provided to the regulator. This pilot will open up discussion of NAMs

between developers and regulators and should help to accelerate their acceptance within regulatory submissions. *Voluntary data submission pilot to advance innovative alternatives to animal testing*

EMA provides information on pharmacogenomics

Pharmacogenomics is how genetic variation may influence a person's response to medicines, including how well a medicine works, its safety, and how it is processed by the body. On 4 September 2026 the EMA provided a new information page which includes a table listing all centrally authorised medicinal products that have pharmacogenomic information within the Summary of Product Characteristics as well as scientific guidelines to help medicine developers. *Pharmacogenomics*

International regulatory authority collaboration

From 6 July 2026, the DG SANTE, the EMA and the New Zealand Ministry of Health have a Working Arrangement in place to exchange information on the quality, safety and efficacy of medicinal products and to strengthen collaboration and alignment on the regulation of medicines. The Working Arrangement should lead to mutual learning and sharing of best practices between the regulators. *DG SANTE and EMA sign Working Arrangement with New Zealand Ministry of Health*

On 15 June 2026, the MHRA announced a liaison programme to enable close MHRA and FDA collaboration. The Agencies hope to enhance day-to-day communication, exchange scientific information, enable a more coordinated approach to regulatory challenges that should lead to faster decisions. *MHRA and FDA collaboration*

The EMA has tested a global programme for post-authorisation changes with national regulatory authorities outside the EU, the World Health Organization (WHO) and the pharmaceutical industry, where other authorities rely on EMA's assessments to inform national decision-making. The pilot has been completed and a new page with guidance for pharmaceutical companies on how to participate in the reliance post-authorisation pilots was created on 13 August 2026. *Reliance for post-authorisation changes: guidance for the pharmaceutical industry*

EU Medical device COMBINE pilot programme launches phase 2

On 26 June 2026, the coordinated assessment procedure for combined studies of multinational investigational medicinal product clinical trials combined with medical devices (COMBINE) entered phase 2. The new phase expands eligibility to in vitro diagnostics and companion diagnostics requiring authorisation, as well as Advanced Therapy Medicinal Products. There is now an options for both single or separate sponsors of each component of the investigational combined medicine-device products, with either single or joint documentation supporting the application. A procedure for substantial modifications in combined studies authorised in the pilot to be launched later in phase 2. *COMBINE programme launches phase 2 of the pilot coordinated assessment procedure for combined studies*

FDA Launches an Expedited Investigational New Drug (IND) Pilot Program

On 15 September 2026 the FDA launched an expedited IND pilot, which comprises an initiative designed to evaluate new approaches for accelerating first-in-human (FIH) clinical trials in the US. The pilot seeks to reduce the time from initiation of IND-enabling activities to FIH trial initiation by testing a collaborative model in which sponsors work with prospective qualified research institutions (QRIs) to support more efficient drug development. Third parties (which could include academic medical centres, health networks, contract research organizations, regulatory advisors, or other research organizations), collectively called “QRIs”, would partner with sponsors to provide expert recommendations on pharmacology and toxicology, clinical, and CMC components of first-in-human IND submissions. FDA would then allow a rolling review of the IND to expedite commencement of the trial. *FDA Launches Expedited IND Pilot, Begins Accepting Applications*

GUIDANCE, ARTICLES AND PUBLICATIONS

UK

- In June 2026 the MHRA published two guidance documents concerning the labelling of medicinal products. The first covered when self-certification of labelling changes is applicable and when a full assessment (categories P1-P4) is required. *Additional guidance for submitting changes to labels and patient information leaflets as a self-certification*. The second concerned additional warning statements for inclusion on the label and/or in the leaflet of certain medicines was also published *MHRA Label Warnings Guidance*. The *Best practice guidance on patient information leaflets* was also updated.
- On 14 August 2026 the MHRA guidance on the types of scientific advice and how to obtain this advice was updated. From September 2026, final briefing documents and questions are now required upon submission of the request for Scientific Advice. The supporting document guidance clarifies expectations for company positions, scientific justification and alignment with relevant regulatory guidance. Scientific Advice would be provided by recorded teleconference as the default format. *Medicines: get scientific advice from the MHRA*

EU

- Commission Notice – Guidance document for Regulation (EU) 2025/40 on packaging and packaging waste was published 10 June 2026 stating what requirements can be waived regarding medicinal products and medical devices. *Guidance document*
- In July 2026, the rules governing medicinal products in EU (EudraLex) Volume 10 'Guidance documents applying to clinical trials – Q&A on the Clinical Trial Regulation (EU) No 536/2014' was updated to version 7.3. The changes clarify that the GLP table of pivotal non-clinical studies must be accurate and if a test facility lose GLP status, the regulators must be informed via CTIS. New questions have been added concerning notification of the status of clinical trials, temporary halts and decisions to early terminate a clinical trial as well as the labelling of cryopreserved medicinal products. *EudraLex Volume 10 - Clinical trial guidelines - CTR Q&A*
- On 29 May 2026, the EMA published a concept paper on the need for revision of the guideline on the development of medicinal products for the treatment of smoking. It is considered that the guidance requires updating to reflect the increased use of e-cigarettes and snuff, especially in the adolescent and young adult populations, and to also include the treatment of nicotine dependency. The EMA consultation with stakeholders concerning this concept paper ends 30 August 2026. *Concept paper on the need for revision of the guideline on medicinal products for the treatment of smoking*
- On 21 May 2026, the EMA published a concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making. There is no current direct guidance available to developers on the topic. This reflection paper will discuss how real-world data, registry based studies, single-arm trials, and small population trials can be used for evidence generation during drug development. *Concept paper on the development of a reflection paper on the use of External controls for evidence generation in regulatory decision-making*
- On 22 July 2026 a concept paper was published for consultation, ending 31 October 2026, on the revision of the guideline on similar biological medicinal products, in light of major progress in the analytical sciences and regulatory field of biosimilars, evident from the EMA Reflection paper on a tailored clinical approach in biosimilar development and initiation of ICH M18 Framework for 'Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs'. Additionally, the new pharmaceutical legislation will amend the legal-regulatory definition of a biosimilar and must be reflected in the guidance. *Concept paper on revision of: Guideline on similar biological medicinal products, CHMP/437/04 Rev.1*

- On 30 July 2026 a concept paper was published for consultation, ending 30 September 2026, on the development of a reflection paper on the non-clinical requirements for severely debilitating or life-threatening diseases. The reflection paper outlines general principles for when flexibility and deviations from the requirements of ICH M3 (R2)/ICH S6 (R1) could be appropriate in the context of a medicinal product being developed to treat a severely debilitating and life-threatening disease. *Concept paper on the development of a reflection paper on the non-clinical requirements for severely debilitating or life-threatening diseases*
- On 24 June 2026 the guideline on the clinical evaluation of medicinal products for weight management - Addendum on weight control in children was revised to align with adult guidance. Additionally, the update included medicines now approved for weight management and incorporated updated clinical guidance. Stakeholder consultation on the revised guidance ends 31 October 2026. *Guideline on the clinical evaluation of medicinal products for weight management - Addendum on weight control in children*
- In June 2026 an Appendix to the guidance document on standardisation for medical devices (MDCG 2021-5 Rev. 1) was published on the transition to the 'EU REP' symbol in EN ISO 15223 for authorised representatives, meaning that the 'EC REP' must change to 'EU REP' with a transition time of 5 years. *Transition to the "EU REP" symbol in EN ISO 15223 - MDCG 2021-5 rev.1 - Appendix*
- On 29 June 2026 the EMA published a concept paper for consultation ending 30 September 2026 on the need to update current guidance on invasive fungal diseases to include new available therapies, the minimum data package required and alternate study designs for often rare refractory diseases. *Concept paper on the revision of the guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease*
- On 15 June 2026 a revision was made to the guidance for the qualification of novel methodologies for medicinal product development that supports the development, evidentiary-strategy planning and regulatory approval of innovative methodologies for all phases of drug development. *Qualification of novel methodologies for medicinal product development: guidance to applicants*
- On 14 July 2026 a question was added to the clinical pharmacology and pharmacokinetics: questions and answers document. The new Question 2.8 'for which drugs is a drug-drug interaction study with oral contraceptives needed?' clarifies that for drugs where effective contraceptive is stipulated within Section 4.6 of the Summary of Product Characteristics, a clinical drug-drug interaction study with an oral contraceptive should in general be performed, regardless of other *in vitro* and *in vivo* data unless justified. *Clinical pharmacology and pharmacokinetics: questions and answers*
- On 15 June 2026 draft guidance on the clinical investigation of medicinal products for the treatment of migraine and cluster headache was published for consultation, ending 31 January 2027. The updated revision addresses episodic and chronic migraine and the implications for the clinical trial design for both acute and prophylactic migraine treatment. Additionally, the guideline addresses relevant clinical trial design and endpoints. *Draft guideline on clinical investigation of medicinal products for the treatment of migraine and cluster headache*
- On 15 June 2026 the EMA consulted on draft guidance for the investigation of gastrointestinal tract interactions, ending 31 December 2026. The draft guidance considers extrinsic factors that may affect drug absorption and makes recommendations on the design, conduct and interpretation of *in vitro* and clinical absorption-related interaction studies. Based on the clinical relevance of the interactions, guidance is provided for treatment recommendations. *Draft guideline on the investigation of interactions in the gastrointestinal tract*
- On 7 September 2026 a draft reflection paper on the clinical investigation of medicinal products for the treatment of systemic sclerosis was published for consultation, ending 31 March 2027. The reflection paper discusses relevant guidelines, patient selection, efficacy assessment (endpoints),

study design, safety aspects and studies in special populations. *Draft reflection paper on the clinical investigation of medicinal products for the treatment of systemic sclerosis*

- On 11 September 2026, the COMBINE Project 2 sponsors guide on safety reporting in combined studies, was published following endorsement by the Clinical Trials Coordination and Advisory Group (CTAG) and the Medical Device Coordination Group (MDCG). The guide supports sponsors in navigating safety reporting requirements for studies that fall under multiple regulatory frameworks, including the Clinical Trials Regulation (CTR), the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). *COMBINE Project 2 Sponsors' Guide on Safety Reporting in Combined Studies*
- On 9 September 2026, the MDCG published guidance regarding in vitro diagnostic classification rules. This introduces clarifications to Rule 7, including revisions to the rationale and examples relating to controls without a quantitative or qualitative assigned value. *MDCG 2020-16 Revision 5 – Guidance on Classification Rules for In Vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 (IVDR)*

USA

- In September 2026 draft guidance on the pharmacokinetics (PK) in patients with impaired hepatic function: study design, data analysis, and impact on dosing and labelling was published. This provides recommendations on the design, conduct and interpretation of studies to assess the influence of hepatic impairment on the PK or Pharmacodynamic (PD) of a drug, including the population PK approach, and when such studies are not required. *Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling*
- In August 2026 the FDA released final frequently asked questions on the development of cellular and gene therapy products, covering FDA review of such products, chemistry, manufacturing and controls, pharmacology/toxicology, clinical, and clinical pharmacology. *Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products: Guidance for Industry*
- In August 2026 the FDA provided draft guidance on the design, validation, and evaluation of potency tests for active immunotherapy products, including peptide- and-protein based products that are not cellular or gene therapy products. *Potency Assessment of Active Immunotherapy Products*
- Draft guiding principles for evaluating the quality of container closure systems used to package drugs and biological products was published in August 2026. This included container closure systems that are also device constituent parts of combination products and those used to package the drug or biological product constituent parts of combination products. *Container Closure Systems for Human Drugs and Biological Products*
- Final recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of new drug or biological products regulated by CDER and CBER were published in August 2026. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*
- In July 2026 two final guidance documents were issued to aid development of transdermal or topical delivery systems for Abbreviated New Drug Applications (ANDAs). One provided recommendations for the design and conduct of studies evaluating the adhesion performance, either adhesion only or in studies performed with a combined purpose (e.g., for the simultaneous evaluation of adhesion and bioequivalence (BE) with PK endpoints. The other provides recommendations related to *in vivo* skin irritation and *in vivo* combined skin irritation and sensitization studies. *Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs* and *Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs*

- Three final guidance documents were published in July 2026 for cancer clinical trial eligibility criteria for performance status range, wash out periods and concomitant medications as well as selecting appropriate laboratory values as trial eligibility criteria to avoid unjustified exclusions of trial subjects. Cancer Clinical Trial Eligibility Criteria: *Performance Status*, *Washout Periods and Concomitant Medications* and *Laboratory Values*
- In May 2026 a FDA Roadmap to reduce animal testing was published, detailing approaches to evaluate the safety of certain oncology pharmaceuticals which provide safety information that is equivalent or superior to animal studies. *Oncology Pharmaceuticals: Streamlined Nonclinical Safety Studies for Biologics and Conjugated Products*
- Draft recommendations were published in June 2026 on how to leverage chemistry, manufacturing and controls, nonclinical and clinical prior knowledge in the development of gene therapy product, particularly helpful for medicinal products intended to treat rare diseases. *Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing*
- Draft guidance was published in June 2026 discussing what factors can impact the strength of evidence of effectiveness for a drug and clarifies how sponsors can rely on one adequate and well-controlled clinical investigation with confirmatory evidence to satisfy the substantial evidence of effectiveness standard. *Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products*
- In July 2026 final guidance providing general considerations and recommendations for clinical investigations for sponsors developing psychedelic drugs for the treatment of medical conditions (e.g., psychiatric disorders, substance use disorders) was published. *Psychedelic Drugs: Considerations for Clinical Investigations*
- In August 2026 final guidance was published, advising appropriate human factors and usability engineering processes to ensure new medical devices will be safe and effective for the intended users, uses and use environments and inform on device design improvements to minimise potential use errors and resulting harm. *Applying Human Factors and Usability Engineering to Medical Devices*
- In May 2026 the Centre for Devices and Radiological Health (CDRH) published final guidance on the human factors information that should be documented and included in medical device marketing submissions to promote consistency and facilitate efficient review. *Content of Human Factors Information in Medical Device Marketing Submissions*

INTERNATIONAL

- On 06 August 2026 guidance was published by International Medical Device Regulators Forum (IMDRF) on Essential Principles and Content of Pre-Determined Change Control Plans (PCCPs) for software. *Essential Principles and Content of Predetermined Change Control Plans | International Medical Device Regulators Forum*
- On 03 August 2026, the MDSAP audit approach document was revised. This document provides detailed instructions for conducting audits under the MDSAP. It includes updates to sections such as on Unique Device Identification (UDI). *MDSAP Audit Model*

Thank you for taking the time to read this Industry Update from S-cubed

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