IPQ
INTERNATIONAL PHARMACEUTICAL QUALITY
Inside the Global Regulatory Dialogue

CURRENT INSIGHTS FROM LEADING REGULATORS

MHRA's Chief Partnerships Officer Explains How the Agency Is Supporting Sustainability

At the DIA Europe Conference, held in Brussels in mid-March, MHRA Chief Partnerships Officer Glenn Wells gave an opening keynote presentation on the agency's role in supporting sustainability and Net Zero goals. He discussed: • British Pharmacopoeia sustainability initiatives • UK medical device regulation provisions • the role of MHRA and its place in the UK system for healthcare and sustainability, and • national and international collaboration.

UPDATES IN BRIEF: GLOBAL CMC/GMP DEVELOPMENTS

• FDA Guidance on Data Integrity for In Vivo Bioavailability and Bioequivalence Studies • FDA Guidance on New Dietary Ingredient Notification Master Files for Dietary Supplements • OPQ 2023 Annual Report • TGA Assessed Listed Medicines Guidelines • TGA Updated Recall Procedure • HHS White Paper on Preventing Drug Shortages • EDQM March Reference Standards and Replacement Batches • EMA Committee on Herbal Medicinal Products Activities

FDA DRUG GMP WARNING LETTERS

Company	Facility Location	Product Type
Betone	Mexico	Finished
Bodywell Natural Skin Care	Canada	Finished

FDA DRUG RECALLS

Among the five recalls posted in FDA's enforcement report during the week, one drew the most serious, Class I, rating. It involved the presence of particulate matter in treprostinil for injection.

OTHER IPQ CONTENT RELEASED DURING THE WEEK

IPQ's November/December Monthly Update contains the full five-part story on pharma's evolution from a compliance to a risk-based control strategy orientation, along with *Updates in Brief,* FDA warning letters, EMA NCRs, and FDA drug recalls that were posted at IPQ.org during the two months.