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IPQ Bibliography PAC KM QRM 2010 - 2023

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Inside the Global Regulatory Dialogue

IPQ's 2010-2021 STORIES ON PAC/QRM/KM REGULATORY DIALOGUE

The following is a chronological listing of IPQ stories since 2010 that have covered the pressing issues around post-approval changes and what is needed in conjunction with advancements in risk and knowledge management to make quality regulatory processes across the product lifecycle more cohesive, efficient, process improvement and supply friendly, and internationally harmonized.

2010

- Preparing for and Communicating Manufacturing Changes During Late-Stage Development Smooths Biotech Clearance Process with FDA

- MHRA Has Been Rejecting One-Third of Type IA Variation Notifications Due to Information Shortcomings

2011

- CMC/GMP Procedures and Interpretations Can Pose Challenges for Foreign Firms in ICH Member Japan

- ICH Q11 Draft Gelling on Lifecycle/Change Management and Control Strategy Components

- Europe Asks for Stakeholder Input in Refining and Harmonizing Its Variations Rules Across Member States

- Divergent Global Change Filing Requirements Present Continuous Improvement Roadblocks, Experts Stress at ICH Q10 Conference

2012

- EMA's Biosimilar Quality Guideline Redraft Sharpens Focus on Target Profiles and Lifecycle Changes of Reference Product

● International Dialogue Should Focus on Harmonizing Control Strategy Filings and CMC Change Requirements, Moheb Nasr's Industry Experience Confirms

2013

● FDA Draft Guidance on Syringe Connection Problems Reemphasizes Need for Early Agency/Sponsor Dialogue on Combo Products; Post-approval Change Guide Issued

● FDA's Center for Drugs Redoubles Effort to Achieve 21st Century Quality Vision and Foster Continuous Process Improvement

● Industry Asks FDA to Clarify How Current CMC Submission Paradigm Can Flex to Accommodate Breakthrough Therapy Development Timelines

2014

● Post-Approval Change Regulatory Burden Draws Heat at Japan Biotech CMC Strategy Forum

● Industry Proposals for Addressing Post-Approval Change Burdens Include Harmonizing on Commitments and Classifications

● Global Quality Regulatory Maze Jeopardizes Vaccine Supply, IFPMA is Stressing

● FDA and EMA Finalize Guidances to Help in Post-approval Change Management

● Guides on FDA's Generic Drug Review Process Continue Apace in July; EU Pilot Pursues Generic Drug Review Streamlining Internationally

● New CMC Submission Approach Needed to Foster Transparency and Continuous Improvement, PhRMA Team Says; Embedding Control Strategy as Regulatory Commitment in QOS Proposed

● ICH's Lifecycle Management Initiative Q12 is Targeting the Tough Regulatory Issues, With Patient Supply a Driving Concern; Analytical QbD Also on Expanded ICH Agenda

2015

● Asian Agencies Report on Progress in Addressing Emerging Regulatory Challenges at CASSS Biotech CMC Strategy Forum in Japan

● Stress Studies Are Playing Key Role For Roche/Genentech in Assessing Biomanufacturing Process Site Transfers

● Global Change Protocols Proposed as Part of a More Standards-Based Approach to Regulating Life Cycle Management Internationally

● Broad-Based ICH Q12 Expert Working Group Supporting Initiative's Urgency and Viability, EWG Members Affirm at GPhA Conference

● ICH Q12 EWG Views Established Conditions as Pivotal in Evolving Lifecycle Regulation Internationally; EMA Workshop Provides Input

● More Structured, Interactive Process To Drive Convergence in Latin America Advocated by Biotech Product Regulators and Industry at CMC Strategy Forum in Brasilia

● Industry is Urging Latin American Agencies to Cooperate in Filling Lifecycle Management Regulatory Gaps for Biologics

2016

● Industry/Regulator Dialogue on Knowledge Management is Intensifying in Wake of ICH's Q12 Initiative

● Impact of Accelerated Pathways on Method Development, Inter-Agency Collaboration Draw Regulator Discussion at Europe Biotech CMC Strategy Forum

2017

● Tension Between Quality Regulatory Paradigm and Pharma's Innovation, Acceleration and Harmonization Imperatives in Spotlight

● FDA's Office of Pharmaceutical Quality Advances Review/Inspection Integration

2018

● FDA Inspection Findings Provide Additional Insight on CGMP Expectations for Combination Product Manufacturers

● Pharma is Exploring How to Maximize ICH Q12 Value in Practice; Q12 EWG Encourages Feedback

● CMC Priorities of EFPIA's European Biopharmaceutical Enterprises Include ADCs, Drug/Device Combos and Statistics

● Role of Established Conditions Drawing Attention in Global Dialogue on ICH Q12's Potential

● Emergency Preparations Draw Heightened Industry and Regulator Attention as Natural and Man-Made Disasters Proliferate

2019

● KASA and PQ/CMC Initiatives Gain Momentum in FDA's Efforts to Strengthen Quality Review Process

2020

● Pandemic Stresses Increase FDA Attention on Risk Management Plans for drug Shortage Prevention and Mitigation

2021

● Pandemic Intensifies USP's Focus on Supply Chain Vulnerabilities and Vaccine Development

● Regulators Are Exploring with Industry How to Strengthen Quality Risk Management Practices, with Revision of ICH Q9 a Key Focal Point

● Pandemic Urgencies Highlight Constraints in Manufacturing Change Regulatory Paradigm and Where Adjustments Are Needed

2022

● FDA's KASA and Related PQ/CMC Initiatives on Improving CMC Data Structuring and Sharing Will Help Support ICH M4Q Revision

2023

● Implementing ICH Q9(R1) Will Entail a Heightened Focus on Integrating Knowledge into Risk-Based Decision-Making