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Specialist Diploma in Regulatory Affairs (Bio) Pharmaceuticals
Authorities, including the Irish Health Products Regulatory Authority (HPRA), TOPRA (The Organisation for Professionals in Regulatory Affairs) as well as the European Commission EU regulatory filing procedures: a Centralised procedure (CP) - Scope, Pre-submission activities, Scientific Advice,

Practical handling, Outcomes

Regulatory Affairs - NetworkPharma

The Regulatory Environment Regulatory Affairs and Product Lifecycle What makes a good Regulatory Regulatory Procedures National UK, US EU Community Mutual Recognition Decentralised EU Centralised Symposia/Conferences TOPRA/DIA/RAPS …

within the European Regulatory Network

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and EU regulatory authorities As part of the regulatory planning, they the US are signifi cantly diff erent and follow diff erent procedures This is a very important point to anticipate when planning to convert an NDA/BLA into an MAA Oft en, meeting the paediatric requirements in wwwtopraorg Regulatory Rapporteur – Vol 12, No 6

European Medicines Agency policy on publication of …

A high degree of transparency will take regulatory dec ision-making one step closer to EU citizens, and promote better-informed use of medicines In addition, the Agency takes the view that access to clinical data will benefit public health in future The policy has the potential to make medicine

Bringing a Drug to Market in the European Union …

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DRAFT QUESTIONS ANSWERS - European Commission

Important notice: The views expressed in this questions and answers document are not legally binding Ultimately, only the European Court of Justice can give an authoritative interpretation of Community law This document aims at informing on the technical aspects

Regulatory Intelligence – Building Strategies for Drug …

+ May not fit completely in current regulatory landscape requiring intelligent adaptation + Expansion and Harmonization + Australia is adapting new EU regulations continuously + New countries may join the EU + Increased transparency means also increased scrutiny + Recent push in EU and USA for transparency – eg trial registers

EU Adaptive Pathways: Ultimate Success Will Depend on …

EU Adaptive Pathways: Ultimate Success Will Depend on Industry-Payer Communication Adaptive Pathways Workshop 30 June 2015, Brussels, Belgium Timely authorisation of products expected to cover unmet or high-impact medical needs is vital to support innovation and to improve patient access The introduction of adaptive pathways is challenging

EU and US GMP/GDP: Similarities and Differences

How Things Work in the EU/EEA Institutions •EU Parliament •EU Commission •EU Court of Justice • •Council of Ministers EU Law •Regulations Directives EU Guidance •EU GMP Guide• EMA/ Nat Regulatory Agencies •Evaluate medicines •Issue Licences •-Products MA • …

VOLUME 2A Procedures for marketing authorisation ...

The Notice to Applicants Volume 2A Procedures for marketing authorisation Malta, Poland and Slovenia upon their accession to the EU, cf the Act of Accession4 decentralised procedures with a mix of regulatory and scientific work

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wwwtopraorg Regulatory Rapporteur – Vol 9, No 7/8, July/August 2012 two day course – orF More INForM at I o N PLease see P age 24 European Regulatory Procedures: strategic and Practical considerations date: 11–12 september 2012 Venue: danubius Hotel, r egents Park, London

European Focus The EU EU Regulatory Intelligence: Updates ...

European Focus The EU EU Regulatory Intelligence: Updates December 2004 – January 2005 This review of recent legislation is provided by Rebecca Woollen Consultant, UK oup/Item Gr Update CHMP 2004 13-15, December on held CHMP the of meeting plenary seventh the for release press The

Regulatory Pathways of Drug-Device and Device-Drug ...

Regulatory Pathways of Drug-Device and Device-Drug Combination Products in the EU – Journal 31 NSF: Ann Arbor, MI Key Point Summary: 1 It’s critical to understand the main mode of action of your product as that will determine whether it will be regulated as a medical device or as a medicinal product (drug) in the EU 2 Once you know what

Applying for an EU marketing authorisation: a ...

wwwtopraorg Regulatory Rapporteur – Vol 16, No 3, March 2019 Pharmacovigilance Introduction The EU legislation and core guidance documents applicable to peri- and post-approval pharmacovigilance (PV) throughout the EU and wider European Economic Area (EEA) amount to more than 500 pages, excluding countless other ancillary documents