Regulatory ICH Countries: Current Harmonization Challenges and Future Opportunities

WCBP, PlenShop workshop, 31 Jan 2018
Presented by: Peter Richardson
Head of Quality, European Medicines Agency
ICH and other groups / stakeholders

Government / Agencies
WHO
Pharmacopoeia
Trade Associations
Harmonisation Centres
Consortia
Standards Bodies
Quality Topics 2018, Possible Approaches

ICH Q12 (ongoing)
continuous manufacturing (*new),
extractables and leachables (new),
analytical methods /ICH Q2 (*new),
oligonucleotides (new),
excipient standards (new),
QOS (*2017),

{ * from Quality Vision - Reflection Paper }

Can be many existing sources, e.g. E&L:

Other possible means to deliver guidance
Regulators: Uni-Multilateral

non-exhaustive examples
Thank you

Peter Richardson,
Head of Quality Office
Specialised Scientific Disciplines Department, EMA

peter.richardson@ema.europa.eu