Global Updates and Recent Trends in the Regulation of Biopharmaceutical Products

Regulatory activities:

• Priority medicines (PRIME, Adaptive pathways)
• Fostering innovative medicines (SME & academic support)
• Clinical trial Regulation (EU) No. 536/2014 - EU portal
• Transparency initiative
• Global harmonisation (ICH Q 12)
• Training and knowledge sharing (i.e. Innovation Network, NTC,..)

• Biosimilars (tailored scientific advice pilot; start Feb 2017)
• Advanced Therapies – (iATMP GL, GMP for ATMPs, stakeholder meetings on CAR T cells, GMOs)