2018 RAPS Convergence Topic Areas

Biopharmaceuticals (includes Biologics and Drugs)
- Innovative technologies (e.g. artificial intelligence)
- Biosimilars: Current challenges and opportunities
- Manufacturing and Distribution (e.g. GMP inspection mutual recognition, EU GMPs/IMPs, global supply chain, data integrity, recalls/withdrawals)
- Expedited approval strategies (e.g. expanded access, rare diseases, orphan products, breakthrough, conditional approval)
- Recent developments in US regulations (e.g. 21st Century Cures, PDUFA VI)
- Recent developments in EU regulations (e.g. Brexit, Clinical Trial Regulations)
- Recent developments in Canadian regulations (e.g. Cannabis Law)
- Recent developments in emerging markets regulations
- Clinical Trial Design and Alternative Data Sources (e.g. real-world evidence, precision medicine, patient focused drug development, drug development tools, data transparency, pediatric trials)
- Harmonization (e.g. ICH, APEC, LATAM)
- Advertising, promotion and labeling
- Generic drug access and approval (e.g. complex generics)
- OTCs (monograph reform, novel switches)
- RMAT, ATMPs/cell and gene therapies
- Hot topics in vaccines
- Pharmacovigilance, risk evaluation and mitigation strategies
- Other (Note: Select this ONLY if your proposal does not clearly fit in any other topic category.)

Medical Devices
- Artificial intelligence
- Cybersecurity
- Medical Device Single Audit Program (MDSAP)
- Use of real-world evidence to support regulatory decision-making for medical devices
- Recent developments in US regulations
- Recent developments in 510(k)
- Denovo process
- Recent developments in EU regulations
- Recent developments in other geographical regions beyond EU and US (e.g. Asia Pacific, Latin America, China, etc.)
- Emerging standard developments
- Human factors studies/usability engineering
- Pediatric medical devices
- Risk management
- Preclinical studies
- Clinical evaluation
- Postmarketing clinical follow-up (PMCF)
- Harmonization/ IMDRF/AHWP
- Regulatory framework to support innovation
• Digital health/software as a medical device/mobile apps and e-labeling/wearables
• Modeling and simulation
• Advertising, promotion and labeling
• Inspections and warning letters
• Recalls
• Safety/adverse event reporting
• Global compliance
• Supply Chain (track and trace, falsified medicines, UDI)
• Incorporating the patient perspective in the regulatory process
• Other (Note: Select this ONLY if your proposal does not clearly fit in any other topic category.)

In Vitro Diagnostics
• Cybersecurity
• Recent developments in EU regulations (IVDR)
• Recent developments in other geographical regions beyond EU and US (e.g. Asia Pacific, Latin America, China, etc.)
• Emerging standard developments
• Performance evaluation and clinical evidence
• Personalized medicine
• Companion diagnostics
• Recent developments in IVDs
• Recent developments in LDTs
• Other (Note: Select this ONLY if your proposal does not clearly fit in any other topic category.)

Regulatory Business
• Regulatory strategy/global regulatory planning
• Regulatory policy and trends
• Leadership skills (e.g. emotional intelligence, body language, etc.)
• Managing dispersed teams
• Negotiation skills
• Crisis management
• Life after industry
• Knowing when it’s time to change roles or companies
• Performance reviews – providing effective feedback
• Other (Note: Select this ONLY if your proposal does not clearly fit in any other topic category.)

Combination products
• Other ______________________

Other
• Other ______________________