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 _____