RAPS Euro 2022 Convergence Submission Template

Proposal Title
Your title must be less than 15 words and should describe the nature of the presentation. Please refrain from including any identifiable information, such as your name or your employer’s name.

Examples: Considerations in Clinical Study Design; Labeling as a Driver of Regulatory and Commercial Strategy

Preferred Track
Select the most appropriate track from the list below. Please know that the Planning Committee reserves the right to change the track if the proposal would be more appropriate in a different one.

- Combination Products
- In Vitro Diagnostics
- Medical Devices
- Pharmaceuticals
- Regulatory Business
- Other

Preferred Topic
Select in which of the following topic areas you feel your proposal belongs (see list below). Please know that the Planning Committee reserves the right to change the topic if the proposal would be more appropriate in a different one.

Geographic Coverage
Select the primary geographic region the proposal will cover.

- US
- Canada
- Europe
- Asia
- Latin America
- Oceania
- Middle East
- Africa

Learning Level(s)
Select the most appropriate learning level. (Note: Preference will be given to sessions designed for the Applied or Strategic levels)

- Foundational: Content is introductory in nature and requires no prior knowledge or experience to grasp concepts or related exercises. Typical job titles at this level are coordinator/specialist/associate.,
- Applied: Content is appropriate for individuals who have strong knowledge of the topic(s) and/or demonstrated well-developed regulatory technical knowledge and skills. Regulatory Affairs Certification (RAC) is targeted to professionals at this level. Typical job titles at this level are manager/senior manager/reviewer.,
- Strategic: Content is intended for individuals who are well-versed in most/all concepts associated with the topic(s) and are involved in translating knowledge into effective plans and
strategy. They work with other teams throughout the product lifecycle. Typical job titles at this level are director/vice president/executive director/CEO/experienced reviewer/section manager/division director.

Preferred Format
- Case Studies with Q&A
- Lectures with Q&A
- Lectures
- Panel Discussion and Q&A
- Panel Discussion Only
- Other

Description
In 100 – 300 words, describe how participants will benefit from attending this session. Please refrain from including any identifiable information, such as your name or your employer’s name. (HINT: Don’t focus only on what they will learn, but how they can apply what they will learn to their job and career.)

Example: Design and selection of clinical endpoints almost always spark a lively debate and regulatory professionals are key participants in the discussion. Selection of key endpoints acceptable to health authorities, and also to support the company’s marketing claims, is of paramount importance. This session will discuss strategic approaches to selecting key primary endpoints for novel or preventative therapies, especially those not covered specifically by regulatory guidance or reference products. The session also will include the European Union perspective on novel therapies. In addition, the value of the Food and Drug Administration and European Medicines Agency Drug Development Tool/Novel Methodologies Qualification process will be presented as it relates to clinical endpoint selection.

Learning Objectives
Learning objectives provide a clear picture of the specific skills or content mastery that will be achieved as a result of participating in your session. They help prospective attendees know what they will gain from your session and also help the Convergence Planning Committee to understand the outcomes of your session. Learning objectives must contain verbs that describe observable, measurable and/or achievable actions.

Examples of intentional verbs (Use application level at example link): Apply, Practice, Demonstrate, Execute, Conduct, Solve

Example:
Upon completion of this session, participants should be able to:
- Describe at least three common sense points to remember while establishing a constructive working relationship with the FDA.
- Explain how to move forward with better business practices that are balanced and compliant to regulation.

For your proposal, provide 2-3 objectives.
2022 RAPS Euro Convergence Submission Topics

We are looking to cover a variety of hot topics that our industry professionals are interested in. To ensure that your session is well attended, we encourage picking a submission topic from the below list. However, the Planning Committee will accept and review topics not on the below list.

**Combination Products**
- Drug-Device Combination Products
- Drug-Device Combination Products Under MDR
- Other

**In Vitro Diagnostics**
- Regulation Changes: EU IVDR
- Regulation Changes: US
- Global IVDs
- Companion Diagnostics
- Laboratory Developed Tests (LDTs)
- IVDR - Postmarketing Surveillance
- IVDR - Postmarketing Clinical Follow-up (PMCF)
- EU IVD Performance Evaluation Studies
- Other

**Medical Devices**
- Regulation Changes: US
- Regulation Changes: EU MDR
- Preclinical Studies
- Clinical Evaluation
- Postmarketing Clinical Follow-up (PMCF)
- Postmarketing Surveillance
- Vigilance
- Medical Device Quality Management Systems (e.g., ISO 13485)
- Standards and Compliance
- Medical Device Single Audit Program (MDSAP)
- Human Factors Studies/Usability Engineering
- Biocompatibility
- Risk Management
- Use of Real-world Evidence to Support Regulatory Decision-making for Medical Devices
- Harmonization/ IMDRF/AHWP
- Software as a Medical Device, Mobile apps, Wearables
- Data Security and Digital Health
- Supply Chain (track and trace, falsified medicines, cybersecurity, UDI)
- Other

**Pharmaceuticals**
- Regulation Changes: US
• Regulation Changes: EU
• Regulation Changes: Asia, Particularly China
• Dossier digitalization (from e-CTD to cloud based submission)
• ICH Q12 Impact to Dossier Preparation Workload
• Harmonization
• Real-world Data Applicability in Regulatory Decision
• Real-world Evidence and Precision Medicine
• Innovative Technologies
• Biosimilars
• OTCs
• ATMPs/Cell and Gene Therapies
• Biologics and Vaccines
• Conditional Approval Pathways and Strategies
• Patient Focused Drug Development
• Pharmacovigilance, Risk Evaluation and Mitigation Strategies
• Global Supply Chain
• Advertising, Promotion and Labeling
• Data Security and Digital Health
• Standards and Regulatory Compliance
• Other

Regulatory Business
• The Virtual RA Department - Is It Working?
• Regulatory Strategy/Global Regulatory Planning
• Regulatory Intelligence
• Leadership
• Change Management
• How to Organize a Global Regulatory Department
• Negotiation
• Critical Thinking
• Crisis Management
• Ethics
• Lifecycle Management
• Mergers and Acquisitions
• Other

Other _______________________________________