Track 9 | Regulatory

This track is composed of sessions addressing global laws, regulations, guidelines, and guidances that govern prescription biopharmaceutical and device product development, approval, and maintenance. Representatives from FDA, Health Canada. NMPA (National Medical Products Administration), PMDA (Pharmaceuticals and Medical Devices Agency), EMA, MHRA (Medicines and Healthcare products Regulatory Agency) (Medicines and Healthcare products Regulatory Agency), European Health Authorities and ICMRA authorities, and other regulatory experts will provide global updates, insights, and discussion on current issues through interactive forums. Themes commonly revolve around global regulatory changes and impact on global development strategies, global harmonization/convergence and impact on drug development and advances and innovations to improve the practice of regulatory affairs, and regulatory hot topics are always prominently featured.

DIA recommends this track and associated sessions to professionals involved in regulatory affairs and strategy, regulatory operations, regulatory information management, regulatory agencies, government affairs, legal affairs and compliance, policy and intelligence, clinical research and operations, PV, HTA (Health Technology Assessment), project management, and service providers developing tools and resources for use by sponsors and CROs.

Included Topic Areas

Regulatory affairs, regulatory policy, regulatory intelligence, regulatory strategy, global and US advertising and promotional regulations and laws; regulatory operation best practices, regulatory science, eSubmissions, regulatory document management; regulation pertaining to study endpoints, product labeling, biosimilars, combination products, advanced therapies (e.g., regenerative medicine, tissue products, gene therapy), companion diagnostics, devices. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. **Innovative Approaches to Clinical Development Programs and Trial Design, including experience with acceptance for regulatory decision making and case studies (e.g., complex innovative designs, use of digital health technologies in a clinical development program, model informed drug development, decentralized clinical trials, novel biomarkers and endpoints, patient centric approaches, real-world evidence)**
2. **Global Development and International Harmonization, Convergence, Reliance, and Cooperation**
   a. Updates on ICMRA, ICH, IMDRF, WHO, and other harmonization, convergence, and reliance efforts
   b. Intersection of harmonization, convergence, and reliance efforts
   c. Effect of emerging regulations on global registration strategies
   d. Health authority cooperation initiatives, i.e., Project ORBIS, ACCESS Consortium
   e. Impact of multiregional clinical trials on global development strategies
3. **Regulatory Topics of Public Health Importance**
   a. Pandemic preparedness, including vaccines, therapeutics, and diagnostics development lessons learned and future strategies, i.e., COVID-19, monkeypox, the next global health threat
   b. Regulatory continuity planning in the event of disaster, i.e., future proofing against a cyberattack, clinical site disruption due to catastrophic events
   c. Antimicrobial resistance
   d. Diversity and inclusion in clinical trials
   e. Health literacy
   f. Implications of new legislation
4. **What's New in Labeling**
   a. Enhancing information for patients and healthcare providers
   b. Labeling modernization efforts, including electronic
   c. REMS (Risk Evaluation and Mitigation Strategy) and innovative approaches to ensuring patient safety
   d. Labeling for artificial-intelligence driven software and medical devices
   e. Experience with adding patient experience data
5. **Regulatory Initiatives to Increase Competition**
   a. Generic drug and biosimilar updates, e.g., GDUFA, BsUFA, emerging policies
   b. What is new in global generic drug and biosimilar drug development
6. **Latest Regulatory Developments in Cutting-Edge Science and Review**
   a. Global regulatory considerations for special populations or situations (e.g., rare/orphan, pediatrics, maternal health, etc.)
   b. Cell and gene therapy and regenerative medicine; advanced therapies
   c. Rare disease endpoint development
   d. Precision and individualized medicine
   e. Innovative approaches to drug delivery, combination products, and companion diagnostics
   f. Connected health (e.g., digital wraparound of a pill)
   g. Digital therapeutics
   h. Enhancements to review program efficiency, e.g., STAR (Split Real Time Application Review), RTOR (Real Time Oncology Review)
7. **Harnessing Big Data/Bioinformatics to Answer Regulatory Questions**
   a. The use of Big Data/bioinformatics for drug development and regulatory decision making (e.g., real-world data, artificial intelligence, and machine learning)
   b. Issues at the intersection of drug information interoperability and cybersecurity
   c. Cybersecurity, data privacy, IP considerations
   d. Enhancing regulators and other stakeholders' capacity to access and utilize big data/bioinformatics
   e. Cloud-based submissions