

Advertising and Promotion Regulatory Affairs Conference

Primer March 5, Virtual
Conference March 12-13



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Overview

DIA's *Advertising and Promotion Regulatory Affairs Conference* is in its 35th year! The conference explores the current state of compliance for marketing both biopharmaceuticals and medical devices. Join thought leaders from industry, legal, public affairs, and government for interactive and compelling discussions that will shape policy and define strategic priorities within the advertising and promotion regulatory space.

This conference is geared towards both early and late-career professionals with content that advances the understanding of current regulatory policies, details the latest strategies for professional development, and discusses the trends in advertising for medical products. You will have the opportunity to network with key thought leaders from the FDA, industry, and other regulatory agencies, while simultaneously discussing the challenges and opportunities of marketing pharmaceuticals and medical devices today.

Event Goals and Offerings

- Gather insights to hot topics impacting advertising and promotion regulatory affairs professions in life sciences research and development
- Hear directly from regulators on regulatory plans, priorities, and updates to incorporate into your everyday work and processes
- Identify how advanced technologies and innovation can be applied to impact function and processes within prescription drug promotion
- Identify current trends and the future of prescription drug promotion and digital marketing

Why You Can't Miss It

- Gain access to the latest advancements in ad promo
- Get firsthand updates from the FDA
- Connect with professionals from around the world and learn how best practices are being embraced and adapted
- Stay ahead of the curve and ensure your organization remains competitive in the evolving ad promo landscape
- Enhance your skills and knowledge

Who Should Attend

Professionals involved in:

- Regulatory Affairs
- Marketing
- Communications
- Compliance
- Medical Information and Affairs
- Legal
- Patient Engagement

VIRTUAL PRIMER | TUESDAY, MARCH 5

11:00AM-4:00PM **Drug and Biologic Ad Promo Primer****This Primer Course requires an additional registration fee. You do not need to be registered for the conference to attend**

DAY ONE | TUESDAY MARCH 12

7:30AM-5:30PM	Conference Registration	Main Lobby, outside North/South Ballrooms
7:30-8:30 AM	Networking Breakfast	North Ballroom
8:30-8:45AM	Welcome and Opening Remarks	South Ballroom
8:45-9:30AM	Session 1 Keynote: The Future of Prescription Drug Promotion and Digital Marketing: Insights from an Expert Convening	South Ballroom
9:30-10:10AM	Refreshments, Exhibits, and Networking Break	North Ballroom
9:35-10:05AM	Hosted Session/Non-CE: Case Study Spotlight hosted by Hale Advisors: Preparing Promotional Review for the Shift to Omnichannel Marketing <i>Please note that this is an exhibitor sponsored event and is not eligible for CE credit.</i>	Cavalier A
10:10-10:55AM	Session 2: FDA Updates – A Busy Year	South Ballroom
11:00-11:45PM	Power Learning Session 3: Pharma Marketing and the Role of BBB National Programs' National Advertising Division	South Ballroom
11:45AM-12:45PM	Luncheon, Exhibits, and Networking Break	North Ballroom
12:45-2:00PM	Session 4A: Submitting and Responding to Advertising Complaint Letters: Why, How, and Where?	South Ballroom
12:45-2:00PM	Session 4B: Beginning with the End in Mind: Early Cross-Functional Planning for Promotion	Cavalier BC
2:00-2:40PM	Refreshments, Exhibits, and Networking Break	North Ballroom
2:40-3:25PM	Power Learning Session 5: Best Practices for Diversity and Inclusion in Medical Product Advertising	South Ballroom
3:30-4:45PM	Session 6: Making Sound SASS Determinations for CFL Communications	South Ballroom
4:45-5:45PM	Networking Reception	North Ballroom

DAY TWO | WEDNESDAY, MARCH 13

7:00AM-4:00PM	Conference Registration	Main Lobby, outside North/South Ballroom
7:00-8:00AM	Networking Breakfast	North Ballroom

8:00-8:30AM	Session 7: Recent and Relevant – Insights from the DIA Ad Promo Working Group	South Ballroom
8:35-9:50AM	Session 8: Use of Consumer CFL in Promotional Materials	South Ballroom
9:50-10:30AM	Refreshments, Exhibits, and Networking Break	North Ballroom
10:30-11:30AM	Session 9: The ABC's of SIUU: Recent FDA Revised Draft Guidance	South Ballroom
11:30AM-12:30PM	Luncheon, Exhibits, and Networking Break	North Ballroom
12:30-1:45PM	Session 10A: Global Ad Promo and Enforcement Insights	South Ballroom
12:30-1:45PM	Session 10B: The Evolving World of Scientific Exchange	Cavalier BC
1:45-2:25PM	Refreshments, Exhibits, and Networking Break	North Ballroom
2:25-3:40PM	Session 11: Unlocking the Future: Leveraging AI in Promotional Review Processes for Enhanced Compliance and Efficiency	South Ballroom
3:40-3:55PM	Closing Remarks	South Ballroom

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Identify current and future digital marketing tools and their impact on patient, HCP and consumer perceptions and behaviors
- Gain insights from the FDA on recent compliance actions, advertising and labeling concerns, and the activities involved in regulating medical product promotion
- Describe the Better Business Bureau's National Programs and the National Advertising Division's role in pharma promotion
- Determine when to act and submit a cease-and-desist letter to the company or complaint to regulatory agencies
- Identify how early development decisions impact advertising and promotion
- Identify viable options for incorporating diverse patient perspectives into product advertising
- Describe the SASS standard and the importance of rigorous CFL assessment
- Describe how to assess CFL claims in the context of consumer-facing materials based on the FDA Guidance
- Analyze international regulatory ad promo enforcement
- Describe the regulatory basis for scientific exchange
- Determine how AI can be leveraged as a compliance tool

Continuing Education Credits



Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education with Commendation. This program is designated for up to 14.25 contact hours or 1.425 continuing education units (CEU's). Type of Activity: Knowledge



ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, APRIL 19, 2024.

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity.** If ACPE credit is not requested by **Friday, April 19**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net

Physician Continuing Education



Drug Information Association (DIA) is accredited by the International Accreditors for Continuing Education and Training (IACET) and offers IACET CEUs for its learning events that comply with the ANSI/IACET Continuing Education and Training Standard. IACET is recognized internationally as a standard development organization and accrediting body that promotes quality of continuing education and training.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .4* CEUs for this program.

Participants must attend the entire virtual short course to be able to receive an IACET statement of credit. No partial credit will be awarded.

***IACET CEUs are only available for the virtual Short Course.**

Continuing Education Credit Allocation

March 5, 2024 – Drug and Biologic Ad Promo Primer: 4 contact hours or .4 CEUs, UAN: 0286-0000-24-039-L04-P Type of Activity: Knowledge; .4 IACET CEUs

March 12, 2024 Advertising and Promotion Regulatory Affairs Conference – Day 1: 5.25 contact hours or .525 CEUs, UAN: 0286-0000-24-040-L04-P Type of Activity: Knowledge

March 13, 2024 Advertising and Promotion Regulatory Affairs Conference – Day 2: 5 contact hours or .5 CEUs, UAN: 0286-0000-24-041-L04-P Type of Activity: Knowledge

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending The 2024 Advertising and Promotion Regulatory Affairs Conference, please complete your state's application for credit and submit accordingly. If you require additional information, please contact CE@DIAGlobal.org

Statement of Credit

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or both days of the conference, in their entirety, sign in at the DIA registration desk upon arrival, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, March 27**.

If you are claiming CE credit for the conference you must:

1. Attend one or both days of the conference, (in their entirety)
2. Sign in at the DIA registration desk each day, upon arrival
3. Access your DIA account and select My Transcript to claim your CE credit, available on **Wednesday, March 27**
- 4. ACPE credit must be claimed by April 19**

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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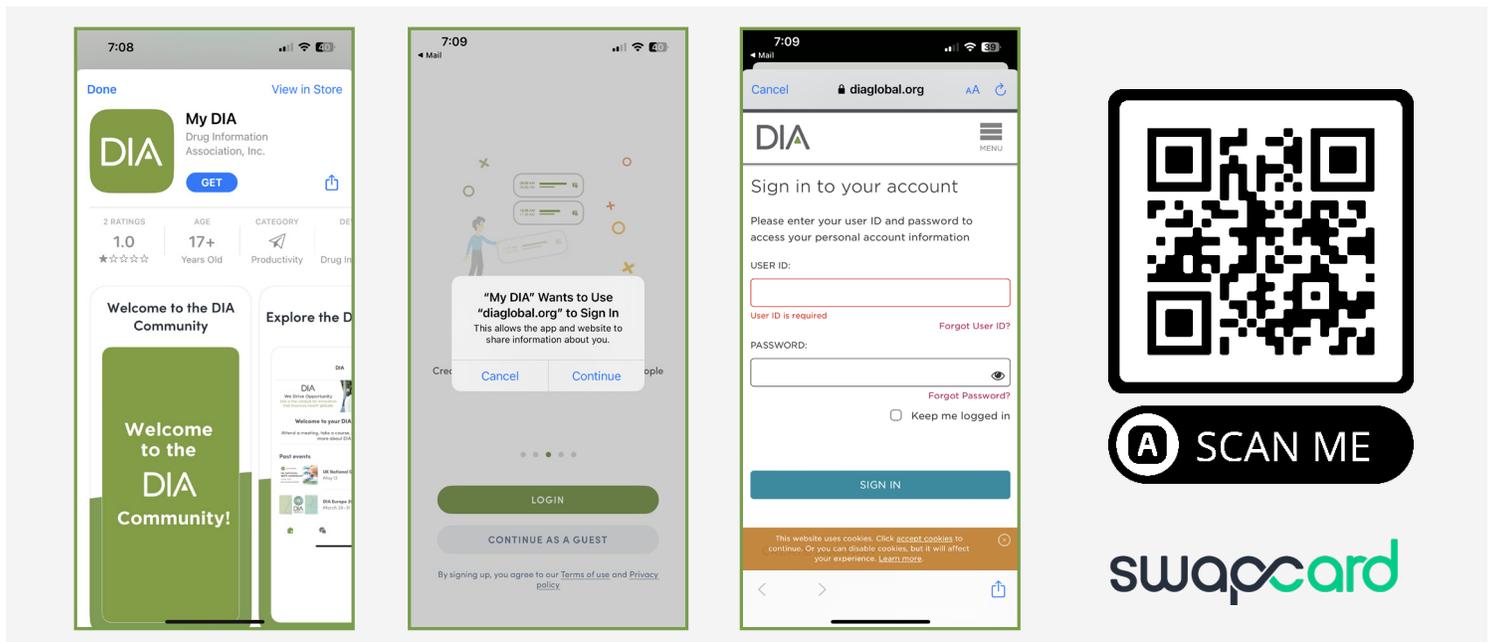
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- Ask questions live during sessions through the session chat function



You will be directed to login to our My DIA Account in order to access the mobile app.

Follow the instructions on screen, or please see the registration desk/contact NAEvents@diaglobal.org if you need additional assistance.

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60TH ANNIVERSARY



DIA 2024

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