DIA 2025 Student Case Competition

Goal and Opportunity

The DIA Student Case Competition offers students a platform to engage with real-world challenges in the drug development lifecycle while gaining significant exposure within the regulatory, biopharmaceutical, and healthcare communities.

Competition Overview

Each year, DIA presents one or more specific challenges for students to address at the Global Annual Meeting, which will be held this year in Washington, DC. The competition will be judged by a committee of esteemed life sciences professionals and/or DIA Fellows. Our DIA Fellows include our most experienced and engaged members that encompass a broad range of expertise.

Finalist teams will present their work at DIA's Global Annual Meeting in June 2025, an event attended by thousands of industry leaders, regulators, academics, and patient advocates. The winning team will be recognized during an awards presentation at the meeting, gaining industry-wide visibility.

While at the meeting, finalists will have the opportunity to attend learning sessions, networking events, and professional development workshops, further expanding their knowledge and career prospects. Additionally, they will have a dedicated opportunity to discuss their proposals with decision-makers from DIA, biopharmaceutical and healthcare product companies, CROs, and other organizations, allowing them to showcase their ideas to industry leaders.

Beyond the event, the winning team's work will be featured in DIA's Global Forum, a publication reaching 66,000+ members of the regulatory and industry communities worldwide. This provides further recognition and exposure, positioning the team's insights among global experts in healthcare product development.

Why Participate?

- Expand professional connections by fostering engagement between DIA Student Chapters, global students, and DIA's broader network of regulatory and industry professionals.
- Develop critical regulatory expertise by challenging students to create innovative, compliant solutions to real-world pharmaceutical advertising and promotion issues.
- Gain industry-wide recognition for finalists and winners, increasing their visibility among regulatory agencies, biopharmaceutical and healthcare product companies, academia, patient groups, and contract research organizations (CROs).

Case Competition Prompt

Background

Pharmaceutical companies must ensure that their advertising and promotional activities comply with FDA regulations to provide accurate, non-misleading information to healthcare professionals (HCPs) and consumers. The Code of Federal Regulations (CFR) Title 21, Part 202 governs prescription drug advertising, emphasizing fair balance, substantiation of claims, and risk disclosure. With the rise of digital marketing, including social media, influencer marketing, and direct-to-consumer (DTC) advertising, ensuring compliance with FDA regulations has become increasingly complex.

Misinformation, off-label promotion, and omission of risk information have led to multiple FDA warning letters and enforcement actions. Regulatory affairs professionals play a key role in ensuring promotional materials adhere to legal and ethical standards while effectively communicating a product's benefits and risks.

Scenario

You are a regulatory affairs professional at a mid-sized pharmaceutical company preparing for the launch of a novel first-in-class drug to treat a chronic condition affecting millions of Americans. The company is planning a multi-channel promotional campaign, including:

- Traditional print and television advertisements
- Social media influencer partnerships
- Sponsored educational webinars for HCPs
- Disease awareness campaigns prior to drug approval

During the regulatory review of the promotional materials, you identify potential compliance concerns related to:

- Efficacy and risk communication in DTC ads
- Influencer marketing and the use of testimonials
- Disease awareness campaigns leading to pre-approval promotion
- Comparative claims against competitor drugs
- The balance of benefit and risk information in digital formats

Prompt

Please create a promotional material that incorporates the potential compliance concerns outlined above. Then, prepare a 20-minute presentation to showcase your promotional material while detailing your regulatory strategy to ensure compliance with FDA advertising and promotion regulations while maintaining an effective marketing approach. Your presentation should address the following:

- Apply the Code of Federal Regulations (CFR) Title 21, Part 202 to evaluate the compliance of the company's promotional strategies.
- Identify at least three compliance risks in the proposed campaign and explain why they may violate FDA regulations.
- Recommend specific changes to the promotional materials to align with FDA guidance on advertising and promotion.
- Discuss how regulatory professionals can collaborate with marketing teams to ensure compliant messaging while achieving business objectives.
- Propose creative solutions to combat misinformation and off-label promotion risks in influencer and digital marketing.

Resources for Participants

Code of Federal Regulations (CFR) Title 21, Part 202

- This can be directly used and cited to address the violations in promotional materials.

Office of Prescription Drug Promotion Untitled Letters and Corresponding Promotional Communications

- This website showcases various examples of promotional materials that have been in violation of the CFR and untitled letters that were issued to those companies.

FDA Bad Ad Program

- Educates healthcare professionals and industry stakeholders on how to recognize and report misleading prescription drug promotion.

Project Guidelines

Team Formation & Eligibility

- Teams from any accredited college or university in the United States or other countries are eligible to participate. Institutions may enter multiple teams.
- DIA student membership is available at a discounted rate (optional for this competition).
- Teams must consist of 2-4 students at the same institution, with interdisciplinary teams encouraged (e.g., Pharmacy, Medicine, Global Health, Biotechnology, Business, Marketing, Regulatory).
- For inquiries about DIA Student Chapters or starting one at your institution, please contact Hana Hasan, National Recruitment Chair (hana.hasan@temple.edu) and CC students@diaglobal.org.

Submission Guidelines

Recorded Presentation & PowerPoint Submission

- Each team must submit one recorded presentation (maximum 20 minutes, with voice-over) presenting their proposed solution to the given prompt and email the PowerPoint file along with the recording.
- The PowerPoint presentation file must be included in the email submission along with the recording.
- Accepted formats: Zoom recording, Google Drive link, or private YouTube/Vimeo video (ensure all links are accessible to avoid evaluation delays).
- A complete MLA-formatted works cited page must be included at the end of the presentation.

Deadline & Contact

Submit completed proposals by **March 31, 2025** to students@diaglobal.org with Kiran Pentela (Student Networking Management Representative, kpente4@uic.edu) CC'd. Incomplete proposals will not be evaluated. Finalist selections will be announced before the end of April 2025. The Student Case Competition will be held on Monday, June 16, 2025.

Evaluation Criteria

Submissions will be judged based on:

1. Regulatory Accuracy (25%): Demonstrates a strong understanding of CFR Title 21, Part 202 and incorporates relevant FDA guidance on advertising and promotion compliance.
2. Critical Thinking (25%): Identifies key compliance risks, provides regulatory evidence, and offers well-supported analysis of potential violations.
3. Practical & Innovative Solutions (25%): Develops realistic, actionable, and creative regulatory recommendations that balance compliance with marketing effectiveness.
4. Presentation Quality & Completeness (25%): Clearly and professionally communicates findings with a well-structured, visually engaging, and thorough presentation.

Additional Information

Travel Award for Finalists

Finalist teams qualify for the Student Travel Award, allowing two students per school, selected by their team, to attend DIA 2025 in-person at the Walter E. Washington Convention (801 Allen Y. Lew Place, NW, Washington, DC 20001-3614). These two representatives will receive:

- Complimentary registration for DIA 2025 in Washington, DC.
- Two nights of hotel accommodations at the DIA-assigned hotel.
- Round-trip airfare (coach) booked through DIA's travel agent.
- Up to $50 per day for meals and ground transportation (for up to three days, excluding meals provided by DIA).

Please note that the remaining team members may attend but must cover their own travel, lodging, and food expenses. All finalists receive complimentary DIA 2025 registration.

DIA 2025 Student Registration – FREE for Eligible Students!

Eligible students can have their DIA 2025 registration fee fully covered by providing the required documentation. To register and learn more about eligibility and participation guidelines, please complete this form. The student registration application form deadline is **May 20, 2025**.

Questions

If you have any questions about the Student Case Competition, please contact Kiran Pentela (kpente4@uic.edu) and CC students@diaglobal.org. To learn more about DIA or opportunities to get involved, please contact Sorcha McCrohan, Scientific Project Manager, DIA (sorcha.mccrohan@diaglobal.org).