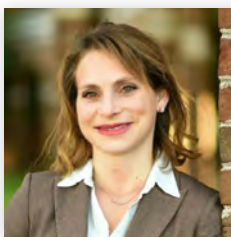


3RD RX-TO-OTC SWITCH

Educate and Empower Switch Teams to Formulate, Implement, and Execute

FEATURED SPEAKERS



Kristen Brinkdopke
Head, Behavioral Science

SANOFI



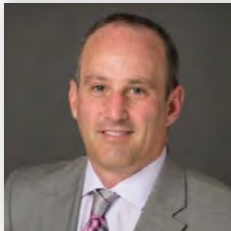
Raweesh Chaudhary
Senior Director,
Medical Strategy

BTG PHARMACEUTICALS



Alankar Gupta
VP, Medical Affairs & Clinical Development

CLICK THERAPEUTICS



Todd Halpern
Assistant General Counsel and Head,
Quality & Supply Chain Legal Team

HALEON



Edwin Hemwall
Principal

EDWIN HEMWALL LLC



Frank McCabe
Pharmacy Consultant

FORMER ST. JOSEPH'S HEALTH



Amy Replogle
Director, Rx-to-OTC Switch
Scientific Strategy

BAYER



Jennifer Santos
Attorney

BETTER BUSINESS BUREAU



Samir Shah
Director, Regulatory CMC,
Medical Devices, and Combination Products

ASTRAZENECA



Paul Sklar
Principal & Founder
PAUL SKLAR CONSULTING LLC



Randall Thornton
Clinical Pharmacist
EMORY HEALTHCARE



Jerry Valentine
Senior Director, Business Development New Technologies
ASTRAZENECA



Paul Wardle
Founder & Principal
BEACON ASSOCIATES

PARTNERS



ALL NEW SESSIONS

- Navigate Benefits and Challenges in Non-Prescription Access
- Unveil the Lifesaving Potential of Over-the-Counter Medications
- Explore the Impact of E-Commerce on OTC Products
- Address Potential for Future Rx-to-OTC Switches
- Manage Complex Switches in a Digitalized World

3RD RX-TO-OTC SWITCH

WHY ATTEND?

Rx-to-OTC switches can revolutionize the lineup of modern healthcare, significantly broadening consumer accessibility for the most valuable and proven therapeutics. Properly-crafted switches empower consumers to become increasingly more responsible for managing their own health. With two high profile successful switches in the past year, now is the time to re-evaluate key lessons and understand their influence on the market. DGE invites you to its **3rd Rx-to-OTC Switch** conference on February 26-27 in Philadelphia! The industry's only event to specifically focus on the challenges associated with this niche topic! Don't miss the opportunity to hear from industry experts about case studies on the latest successful switches, regulatory challenges concerning ACNU, digital advancements, marketing strategies, and much more!

WHO ATTENDS?

This conference is designed for pharmaceutical, biotech, and medical device professionals responsible for:

- Rx-to-OTC Switch/Rx Access
- Regulatory Affairs
- Brand Management/Strategy
- Product Management
- Brand Marketing
- Global Marketing
- Legal Affairs
- Medical/Scientific Affairs
- Consumer Healthcare Products
- Consumer Marketing
- Clinical Development
- Clinical Trial
- Drug Safety
- Research and Development
- Business Strategy
- Packaging & Labeling
- Drug Delivery Technology
- Product Development
- Portfolio Strategy
- Project Management
- General Counsel
- Clinical Research

REGISTER

8:00 AM	Registration & Log In
8:45 AM	Chairperson's Opening Remarks
Explore Recent Regulatory Changes and Switch Challenges in Pharma	
9:00 AM	Unwrap ACNU: Navigate Benefits and Challenges in Non-Prescription Access
<p>The recently introduced ACNU rule seeks to enhance consumers access to nonprescription drugs by enabling Rx-to-OTC transitions through advanced digital methods. By allowing certain medications to be available over the counter, it promotes easier access to essential healthcare products, potentially enhancing public health outcomes. However, this progressive shift towards digitization raises concerns regarding safety and efficacy. Your team should be able to determine if ACNU will act as a benefit or a hindrance to them.</p> <ul style="list-style-type: none"> Discuss the benefits of ACNU, and how this rule will change the regulatory process Analyze the regulatory challenges associated with implementing ACNU Explore how the consumer will be affected by ACNU Debate whether software can be used as medical device documentation <p>Samir Shah, Director, Regulatory CMC, Medical Devices, and Combination Products, ASTRAZENECA</p>	
9:45 AM	Unveil the Lifesaving Potential of Over-the-Counter Medications
<p>After a switch, OTC medications can provide life-saving interventions among people who are aware of their specialized medical needs. What about those who aren't? From inhaled medications like Albuterol to the significance of Epinephrine and Buprenorphine, we'll delve into the transformative power of self-care and the potential revision of the current prescription model.</p> <ul style="list-style-type: none"> Examine the critical role of medications in emergency situations, shedding light on their potential life-saving capabilities Gain insights into the concept of self-care and its significance in managing health Discuss the need for potential revisions in the current prescription model <p>Randall Thornton, Clinical Pharmacist, EMORY HEALTHCARE</p>	
10:30 AM	Networking Break
11:00 AM	Break Down the Recent Changes and Challenges Surrounding OTC Monograph Reform
<p>There have been recent updates on OTC monograph reform as outlined in the CARES Act. This is a pivotal development that will have implications on the regulation and accessibility of nonprescription drugs in the United States. Your team should know what the recent changes mean for regulatory decisions.</p> <ul style="list-style-type: none"> Discuss the key changes and updates in the regulatory framework of the CARES act Explore strategies to adapt and thrive within the changing regulatory environment Analyze the potential impact of OTC monograph reform on various stakeholders, including consumers, manufacturers, and health care professionals <p>Todd Halpern, Assistant General Counsel and Head, Quality & Supply Chain Legal Team, HALEON</p>	
Strategies and Keys to a Successful Switch	
11:45 AM	Understand the Fundamentals of the Switch Process in the U.S.
<p>Each country has its own set of requirements and considerations, creating a diverse landscape for pharmaceutical switches. Globally, adaptability is paramount to meet the specific requirements of health authorities, showing that a one-size-fits-all approach is not viable in the global regulatory environment.</p> <ul style="list-style-type: none"> Map the specific aspects or characteristics that different countries seek in the context of Rx-to-OTC switches Tailor a truly global regulatory strategy Grasp the influence of cultural, healthcare system, and economic differences on different regions <p>Edwin Hemwall, Principal, EDWIN HEMWALL LLC</p>	

12:30 PM	Lunch
1:30 PM	Analyze How to Effectively Manage a Successful Switch in a Small Company
<p>The process of making a switch can be particularly challenging for smaller companies due to their lack of resources. Your team should be able to understand the unique considerations, strategies, and steps needed to navigate this transformation in a smaller organizational setting, optimizing the transition for both patients and business growth.</p> <ul style="list-style-type: none"> Evaluate the specific opportunities and challenges those small-scale enterprises face during switches Review how limited resources, regulatory compliance, and market dynamics influence decision-making Determine the risk vs. reward <p>Anlankar Gupta, VP, Medical Affairs & Clinical Development, CLICK THERAPEUTICS</p>	
2:15 PM	Interactive Discussion Groups
<p>Our facilitated Interactive Discussion Groups (IDGs) optimize peer-to-peer learning by crowdsourcing solutions to common challenges surrounding deploying and scaling DCTs. The connections you make through the IDGs will become your most valuable takeaways</p> <ul style="list-style-type: none"> IDG 1: Analyze the Impact of Recent Switch Approvals IDG 2: Navigate the Global Landscape: Tailor Switch Strategies to Specific Countries IDG 3: Discover How Telehealth Will Influence the Market IDG 4: Navigate Marketing Challenges for Healthcare Professionals and Consumers 	
3:00 PM	Networking Break
Assess Marketing Strategies and Challenges in a Digitalized Society	
3:30 PM	Explore the Impact of E-Commerce on OTC Products
<p>As consumer behaviors continue to shift towards online platforms, e-commerce has emerged as a powerful channel for the distribution and sales of OTC products. This digital transformation has made changes in marketing, accessibility, and consumer interactions. How will these changes affect future marketing ideas?</p> <ul style="list-style-type: none"> Review how e-commerce has reshaped marketing strategies for OTC brands Highlight the role of platforms, mobile apps, and website interfaces in simplifying product discovery Focus on the regulatory landscape for OTC products in e-commerce and how to address challenges related to product safety <p>Jerry Valentine, Senior Director, Business Development New Technologies, ASTRAZENECA</p>	
4:15 PM	Unlock the Impact of Social Media on Modern Marketing
<p>Social media has emerged as a dynamic platform that has revolutionized the way businesses engage with their audience, advertise products, and build brand identity. Social media has disrupted traditional approaches and redefined the way businesses connect and communicate with consumers. How can your team utilize new strategies to succeed in this growing field?</p> <ul style="list-style-type: none"> Use social media to enable direct engagement with consumers, fostering a sense of community and brand loyalty Drive engagement and cultivate relationships with consumers on popular social media platforms Facilitate precise audience targeting and personalized advertising, optimizing marketing strategies <p>Raweesh Chaudhary, Senior Director, Medical Strategy, BTG PHARMACEUTICALS</p>	
Day 1 Concludes	

8:00 AM	Registration & Log In
8:45 AM	Chairperson's Recap of Day One
Assess the Future of Implementing Successful Switches	
9:00 AM	PANEL: Unlock Drug Accessibility: How will ACNU Influence Pharmaceuticals?
<p>The main question about FDA's introduction and implementation of ACNU is whether it will have a broadening or limiting impact on drug access. Enhanced labeling, diagnostic testing, and increased technology can benefit consumers, but what drawbacks must you know about the new rule?</p> <ul style="list-style-type: none"> • Explore how ACNU can potentially open up new opportunities for consumers to access drugs • Analyze the limitations that the ACNU rule may introduce, such as potential complexities in labeling or regulatory compliance issues • Debate whether ACNU will influence the accessibility of drugs <p>Paul Wardle, Founder and Principal, BEACON ASSOCIATES Kristen Brinkdopke, Head, Behavioral Science, SANOFI</p>	
9:45 AM	Address Potential for Future Rx-to-OTC Switches
<p>The switch industry is expected to reach a valuation of \$66.5 billion by 2033. However, there are certain categories of medication that should not be switched to an OTC status. Your team should be prepared to evaluate the feasibility, regulatory requirements, and necessary conditions to determine if pursuing certain switches is an achievable goal.</p> <ul style="list-style-type: none"> • Analyze the essential prerequisites, including regulatory, safety, and educational requirements, to make the switch a viable and safe option • Discuss the potential benefits, accessibility improvements, and implications for public health associated with moving certain categories to an OTC status • Assess the role of education, healthcare infrastructure, technology, and public awareness campaigns in ensuring a successful transition <p>Amy Replege, Director, Rx-to-OTC Switch Scientific Strategy, BAYER</p>	
10:30 AM	Networking Break

11:00 AM	Navigate Claim Substantiation for New OTC Products
<p>Switching from Rx to OTC can be a challenging process, but what happens once the switch is completed? In order for your team to be prepared to handle these new challenges, you must explore the basics of substantiating OTC advertising claims. This includes examining the difference between express and implied claims, when substantiation is required for a claim, and how to ensure your evidence is a good fit for the claim.</p> <ul style="list-style-type: none"> • Learn what evidence is needed to substantiate clinically proven, clinically tested, doctor recommended, and health-related claims. • Understand different types of comparative claims and the substantiation required to support them. • Develop a roadmap for product testing and claim substantiation that will protect your OTC product from FTC and NAD scrutiny while also explaining the consequences for making false or unsubstantiated claims. <p>Jennifer Santos, Attorney, BETTER BUSINESS BUREAU</p>	
11:45 AM	Discover if your Switch is a Money-Maker
<p>Transitioning medications from prescription to over-the-counter status involves a careful balancing act to ensure the product is meeting consumer needs but also making financial sense. Your team should understand how to license, research, optimize, and forecast your switch to minimize risk and maximize the reward.</p> <ul style="list-style-type: none"> • Quantify the risks associated with transitioning medications from prescription to over the counter status • Weigh the financial elements of risk • Plan and execute a risk-mitigation strategy <p>Paul Sklar, Principal & Founder, PAUL SKLAR CONSULTING LLC</p>	
12:30 PM	Luncheon
1:30 PM	Navigate Marketing Challenges for Healthcare Professionals and Consumers
<p>Marketing strategies for switches must be distinctly tailored to effectively communicate with both audiences. HCPs are very invested in the data behind a product, whereas consumers are interested in how the product can benefit them.</p> <ul style="list-style-type: none"> • Clarify the marketing challenges specific to HCPs including regulatory constraints • Center importance of trust and clear communication while marketing to consumers • Align marketing messages and create a cohesive campaign that resonates with both target audiences <p>Frank McCabe, Pharmacy Consultant, FORMER ST. JOSEPH'S HEALTH</p>	
2:15 PM	Analyze the Impact of Recent Switch Approvals
<p>Recent switches such as Opill and Naloxone have just entered the market as of 2023. Your team should be able to analyze the significant impact that these switches have on consumer access and healthcare, especially in the area of women's health.</p> <ul style="list-style-type: none"> • Examine how recent switches have shaped the healthcare market • Spotlight the regulatory process of these switches, and what allowed them to be approved • Explore how these will open the pathway for new switch approvals in the market 	

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HOTEL INFORMATION



Sonesta Philadelphia Rittenhouse Hotel | Philadelphia, PA
1800 Market Street, Philadelphia, PA 19103
(215) 561-7500

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A block of rooms has been reserved at a discounted rate for our conference participants. To reserve a room, please visit the website URL above or call (215) 561-7500. The discounted reservation rate will be in effect until **February 2nd, 2024**.

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