

CHPA ASSOCIATE MEMBER Rx-to-OTC Switch Resource List

<p>3D Communications</p> <p>Cynthia DiBiasi Partner</p> <p>cdibiasi@3Dcommunications.us</p> <p>301-320-9331</p>	<p>3D Communications is a strategic communications and training firm specializing in preparing companies for FDA filings and meetings as well as speaker training and media training. 3D offers a full range of services – from helping companies develop and deliver data driven presentations and strategies to training presenters on effective communication skills.</p> <p>3D Communications has developed proprietary tools designed specifically for FDA advisory committee meetings including, slide recall software, a customized document management portal and a rich database of more than 3000 current and prior advisory committee members. In addition, their subsidiary 3D Productions provides all the audio visual and technology support required for a successful FDA advisory committee meetings.</p> <p>3D has assisted their clients prepare for more than 40 FDA advisory committee meetings including Prilosec[®], alli[®], and Mevacor[®] as well as meetings on OTC issues, including nicotine replacement therapy, label comprehension, actual use trials, and various ingredient specific issues.</p>
<p>Douglas Bierer Consulting</p> <p>Douglas Bierer, Ph.D. President</p> <p>dbc@fuse.net</p> <p>513-272-0094</p>	<p>Douglas Bierer Consulting, LLC, Consulting on regulatory affairs and product development issues for nonprescription drugs and cosmetic products, Rx-to-OTC switch, FDA advisory committee presentations, and strategic planning.</p>
<p>Catalent Pharma Solutions</p> <p>Reginald Yarbrough Global Vice President, Consumer Softgel</p> <p>reg.yarbrough@catalent.com</p> <p>732-537-6200</p>	<p>Catalent is a global leader in innovative oral and topical softgel technologies for the consumer health market. We've been producing consumer health products since 1933 and today, we partner with 20 of the leading global consumer healthcare companies. Our softgel technologies are suitable for a wide range of consumers and relevant in all key consumer categories. With the most consumer-preferred formats and our advanced development formulation expertise, we can help your brands grow with unique, tailored solutions for your OTC, nutritional supplement, and skincare challenges. We can help get your consumer products to market faster and more efficiently by leveraging our proactively developed products, unmatched fill formulation and development expertise, wide range of shell formulations and unlimited possibilities in product shapes and colors. We offer the widest choice of unique, proven technologies and highly-versatile dose forms, ideal for young and old.</p>

<p>Concentrics Research LLC</p> <p>Julie L. Aker President and Chief Executive Officer</p> <p>Julie.Aker@concentricsresearch.com</p> <p>317-706-3200</p>	<p>Concentrics Research LLC,Concentrics specializes in providing research services to pharmaceutical, nutritional/dietary supplement, and medical device companies. We are a recognized leader in the Rx-to-OTC switch services industry with expertise in the conduct of phase III and IV clinical trials, actual use trials, volumetric forecasting, sensory testing, OTC label comprehension testing, Rx label and package insert comprehension testing, and consumer use oriented marketing research.</p>
<p>Johngdent Consulting Inc.</p> <p>John G. Dent, Ph.D. President</p> <p>johngdent@gmail.com</p> <p>610-952-9488</p>	<p>Johngdent Consulting Inc. specializes in consulting on product innovation, development, and regulatory strategy principally in the areas of Rx-to-OTC switch, nonprescription drugs, and cosmetic products. The company also provides consulting in leadership development and strategic planning in the pharmaceutical and nonprescription arena.</p>
<p>Envisage Consulting LLC</p> <p>Doreen Frank President</p> <p>dfrank.envisage@comcast.net</p> <p>(908) 236-8550 tel</p>	<p>Envisage Consulting, LLC provides consulting on regulatory affairs and development of regulatory strategy for nonprescription drugs and cosmetic products, Rx-to-OTC switch, 505(b)(2)s, and labeling/advertising.</p>
<p>International Research Services, Inc.</p> <p>Stephen R. Schwartz President and Chief Executive Officer</p> <p>sschwartz@irsi.org</p> <p>914-937-6500, ext. 116</p>	<p>International Research Services, Inc.,Clinical testing of OTC & Rx products; expertise in dermatologics, pediatrics, G.I., analgesics, diet/weight loss & oral care preparations; specialization in combining large clinical panels with high-tech analysis including, thermography & skin surface image analysis; has extensive computerized panel basis in New York.</p>

<p>NCI Consulting</p> <p>Susan Lavine Coleman President</p> <p>www.nciconsulting.com</p> <p>856-866-1133</p>	<p>NCI Consulting helps pharmaceutical and healthcare-oriented consumer products companies maximize sales and profit growth, utilizing proprietary tools in such areas as: business opportunity analysis, competitive strategy development and scenario planning, lifecycle planning, product and claims innovation, market impact modeling, and market entry maximization.</p> <p>A leader in Rx-to-OTC switch for nearly 25 years, NCI's seasoned team of R&D, medical and commercial managers:</p> <ul style="list-style-type: none"> • Assess switch feasibility • Define clinical and regulatory strategies • Confirm business potential • Identify sales and profit maximizing strategies, and • Support regulatory and commercial implementation <p>To date, NCI has supported approximately 40 switch initiatives and has evaluated hundreds of drugs for switch potential across more than 50 indications and drug classes.</p>
<p>ORC International (formerly infogroup/ORC)</p> <p>Kimberly Kurtin Vice President, Client Solutions</p> <p>kim.kurtin@orcinternational.com</p> <p>212-329-1001</p>	<p>ORC International is a full-service market research and consultancy company specializing in RX-to-OTC switches, OTC and RX pharmaceuticals, and medical devices. We have particular expertise in all aspects of consumer comprehension. FDA-related studies that we have successfully conducted cover:</p> <p>Consumer/Patient Comprehension Studies</p> <ul style="list-style-type: none"> • Drug fact labeling for Rx-to-OTC switches • Instructions for use of medical devices • Risk evaluation and mitigation strategies • Food labeling <p>Physician Comprehension Studies</p> <ul style="list-style-type: none"> • Proper prescribing of medications under different scenarios, i.e. when first approved and when approved for additional uses <p>Line and Use Differentiation Studies</p> <ul style="list-style-type: none"> • Consumer comprehension of how and when to use different OTC medications within a product line <p>Risk Mitigation</p>

	<ul style="list-style-type: none"> • Consumer understanding of risks associated with a medication and ability to appropriately select or de-select for use • Safety warnings and side effects communication <p>Patient Compliance & Adherence</p> <ul style="list-style-type: none"> • Understanding of drivers, barriers and attitudes related to compliance • Testing of educational materials
<p>Palm Beach CRO</p> <p>Arthur Simon, Ph.D. Executive Vice President</p> <p>asimon@palmbeachcro.com</p> <p>561-200-3344</p>	<p>Palm Beach CRO is a full service contract research organization (CRO) providing clients and sponsors full clinical trial expertise throughout North America and Europe. We are a therapeutically focused CRO that provides clinical support to pharmaceutical (RX and OTC), biotechnology and medical device companies. As a small to medium size CRO, we are able to provide high quality and cost efficient services, rapid turnaround and proactive efforts to deliver on-time completion. In addition, the attention to details by the vastly experienced founders and staff offer strategic clinical insight and operational flexibility.</p> <p>The programs Palm Beach CRO manage range from label comprehension, proof-of-concept studies, small multicenter trials, through Phase III. Therapeutic Areas of Expertise include: analgesics, cough and cold, gastrointestinal, dermatology, women's health care, urology, smoking cessation, antihyperlipidemia, and allergy .</p>
<p>Pegus Research, Inc.</p> <p>David C. Bradford, Ph.D., MPH Senior Vice President for OTC Switches</p> <p>dave@pegus.com</p> <p>801-487-9899</p>	<p>PEGUS Research, Inc., is a full-service CRO with broad experience in a wide range of studies to evaluate the suitability of a drug for an over-the-counter (OTC) switch. We provide consultation about the feasibility of a switch and design and conduct the studies generally needed for a switch. This commonly includes one or more label comprehension studies (LCS), a self-selection study (SSS), and an actual use trial (AUT). PEGUS uses pharmacies as enrollment sites for SSS and AUT work because they most closely represent the circumstances in which people select an OTC drug. PEGUS designs studies to assess consumer use of a drug under OTC-like conditions. We use a sample of prospective actual users who select and use the study drug the way they normally would if the drug were already available without a prescription. This development model has been used in successful consumer product campaigns both in the United States and the UK. PEGUS also conducts specialized safety surveillance trials and undertakes other research studies which require novel research methods. For more information please visit our web site at www.pegus.com.</p>

<p>Pinney Associates, Inc.</p> <p>Lucy Owen Vice President of Program Operations and Rx-to-OTC Switch</p> <p>lowen@pinneyassociates.com 301-718-8440</p>	<p>Pinney Associates' unique scientific resources and broad experience in public health enable us to provide distinctive professional consulting services to our consumer healthcare and pharmaceutical clients. Our senior management team of leaders in health policy, behavioral science, pharmacology and behavior change work closely with our team of clinical pharmacologists, behavioral scientists, medical experts and clinicians, and biostatisticians.</p> <p>We enable our clients to:</p> <ul style="list-style-type: none"> • Evaluate the approval and over-the-counter switch potential of pharmaceutical and consumer healthcare products • Manage issues and the scientific and policy environment to gain regulatory approval for new products • Devise, substantiate, and defend new marketing claims • Enhance the scientific and policy environments to maximize product acceptance • Ensure products are used as intended. We service marketing, business development, research and development, scientific and regulatory affairs, government affairs, and legal divisions throughout all stages of a product's lifecycle.
<p>Trident Group, Inc.</p> <p>Raymond Freisheim Partner</p> <p>info@tridentgroupinc.com 215-346-2347</p>	<p>Trident provides business development services to the Consumer Healthcare, Pharmaceutical, and Nutraceutical Industries. It has a proven track record in product acquisition, technology sourcing, and licensing opportunity evaluation. Trident also offers cutting edge market intelligence, strategic plan development and implementation, new product ideation, and Rx to OTC sourcing.</p>