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CLINICAL TRIAL MANAGEMENT EDITION

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COMPANY
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Review

BIOPHARMA INSTITUTE

Simplifying Training for Clinical Trial Management

Biopharma Institute provides reliable, convenient, and effective training for clinical trials management through its dynamic online delivery platform. “We work in partnership with subject matter experts (SMEs) to deliver training which engages the student to convey knowledge on the current regulatory environment,” says Algis Rajeckas, Ph.D., Director of Training at Biopharma Institute.

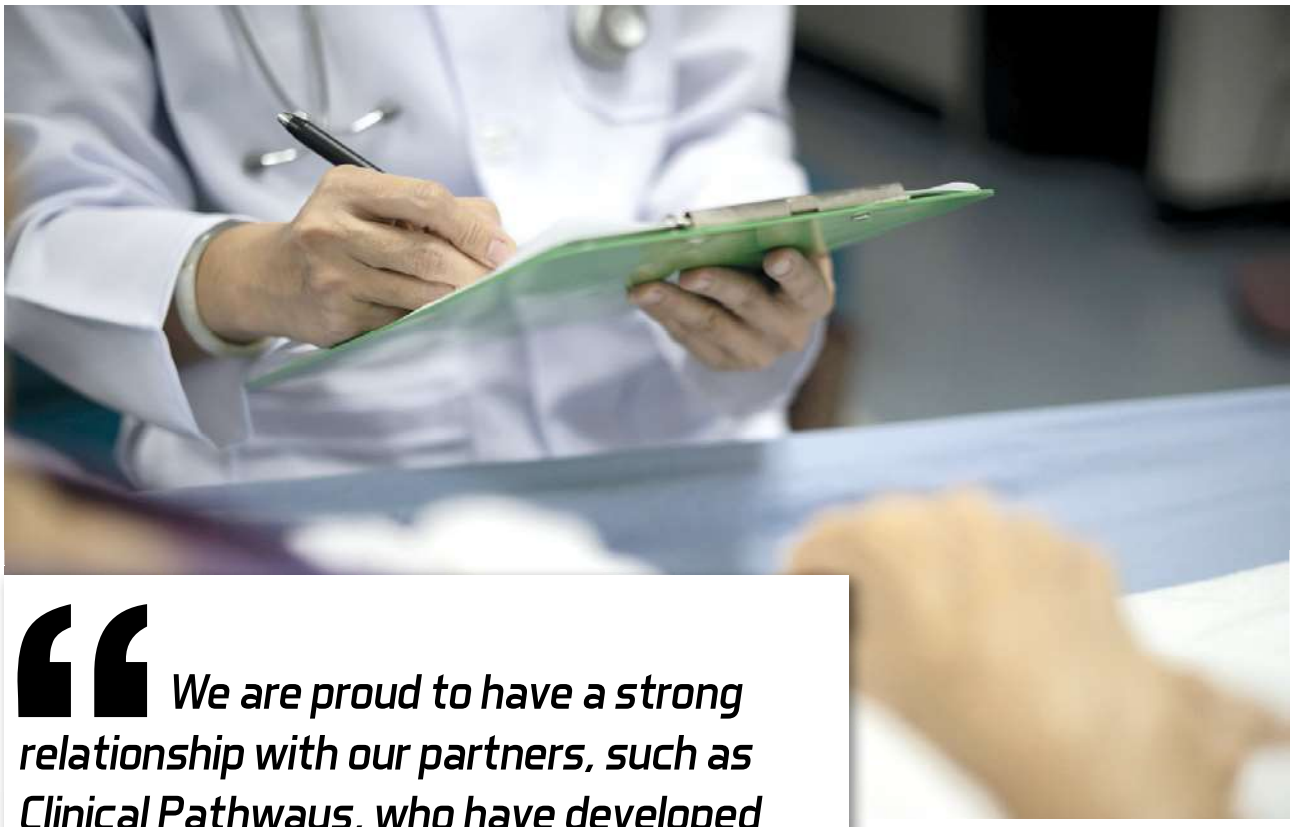
Clinical research regulations are constantly evolving. Keeping up with the newly released regulations—like the ICH E6(R3) guidance for Good Clinical Practice, which is expected to be released this year— is of cardinal importance to those in the industry. Professionals working on clinical research trials must be adequately trained and proficient in all regulatory standards and practices. Even with the pandemic conditions prevailing, pharmaceutical and clinical research organizations(CROs) are still obliged to train their employees to fulfill specific regulatory requirements. They also must maintain proof of training and proper documentation. To this end, they need a system to reliably track training, one that aligns with the changing regulations and simultaneously offers compelling content rather than the live monotonous lectures.

Biopharma Institute’s content and unique learning management system enables training managers to start their training projects promptly. It has the capabilities to document and export training records, student activities, and is flexible for managing large or small training groups at a low cost. The platform houses a catalog of over 200 courses, like ICH Good Clinical Practice (GCP), E8 (R1) and E6 (R2), CRO Oversight, Good Documentation Practice and ALCOA-C, and ISO 14155 Medical Device Standard.

Every course consists of several activities and features to help facilitate the learning process. For instance, a learner undertaking training have access voiceovers to assist them when progressing through each section, interactive elements like knowledge checks, and case studies to better understand key concepts— like the need for following regulations and documentation while keeping consistent quality in every process. Such conceptual training materials ultimately effectuates the development of premium, safe, and reliable consumer products.

Biopharma Institute offers courses focused on professionals working at various segments of clinical

Sandra “Sam” Sather, MS, BSN



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research, like trial monitors (CRAs), research coordinators (CRCs), project managers, investigators, and those working directly with CROs or sponsors."We have developed training programs targeted to educating clinical researchers working directly with the study participants, monitoring clinical trials, working for clinical research organizations (CROs), and those working for the sponsor, specifically managing vendors. Everyone involved has their responsibilities to keep the data reliable and the study participants safe," says Sandra "Sam" Sather, MS, BSN, Vice President at Clinical Pathways, LLC.

To offer best-in-class, engaging and current training, Biopharma Institute collaborates with many SMEs. "We are proud to have a strong relationship with our partners, such as Clinical Pathways, who have developed some great courses in clinical research, targeting all levels of learners," prides Dr. Rajeckas. "This aspect also allows us to provide a training platform that aligns with new regulations, very soon after when they are released."

Holding such an immense value proposition, Biopharma Institute caters to many individuals working at the forefront of clinical trials and research. Many of their students train with them annually or enroll into a professional certification every four or five years to reinforce concepts and update their knowledge in case of regulatory changes.

Biopharma Institute has witnessed phenomenal growth in the past couple years, with adding nearly a hundred new courses to its learning management system. The Institution is also looking to introduce additional courses for good manufacturing practice (GMP) in the nutraceutical and food industries. Additionally, due to the legalization of cannabis in Canada and many US states, several companies are now keen on developing consumables extracted from cannabis. Biopharma Institute is keeping any out on these developments. Soon, the federal government could draft new guidelines or regulations on these cannabis-extracted products. As the regulations change, Biopharma Institute will be leveraging its expertise in training to help companies prepare their employe.