

Expansion of Quality Management Software ensur in Californian Clinical Research Organization

By Mystic Management Systems, Inc.

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Profil Institute for Clinical Research, Inc. has expanded their current deployment to include Corrective/Preventive Action (CAPA), Employee Training Management System (TMS), and automated PDF rendering the ensur document control software.

Norwich, CT – In anticipation of profitable growth to build upon an already expansionist business environment, Profil Institute for Clinical Research, Inc. of Chula Vista, California, has purchased additional modules to expand their ensur document control software into a complete quality management system.

Profil has purchased the Corrective and Preventive Action (CAPA) and the employee training management system (TMS) modules to expand their already successful deployment of the ensur Document Control Software System. These two additional modules give Profil the power to link policies, procedures, and other critical business information to training events, investigations, and vice versa. With ensurCAPA, Profil will be able to track non-conformance trends, conduct root cause analysis, handle complaints, and initiate procedural changes within one system. The comprehensive nature of ensurTMS gives Profil the means to schedule, track, and report on all training their employees have received. This includes down to individual documents that must be read. The addition of the automated PDF rendering module, ensurAutoPDF, keeps published renditions of their business content synchronized with any changes that have been made.

“Profil is leveraging the power of one system across their entire business. This increases their flexibility, reduces waste, and simply saves Profil money,” stated Erroin A. Martin, Vice President, Sales of Mystic Management Systems, Inc.

About Profil Institute for Clinical Research, Inc.

Profil Institute for Clinical Research, Inc. is a scientific research institute with expertise in the design and conduct of clinical studies for new therapies in diabetes, obesity and other metabolic disorders. Ideally equipped to address the demands of biopharmaceutical research and lead-compound development, Profil will handle the complex challenges of a firm's first dose in human, safety, tolerability, PK, and PD diabetes and obesity projects. Sponsors frequently seek our consultation to assist in preparing their strategic clinical development plans, as well as study protocols to assure timely, efficient and cost effective advancement of their products. Profil understands the many requirements of both FDA and EMEA needed for product approval in the areas of diabetes and obesity.

Automated Glucose Clamps (the Gold Standard for PD Data)

For the past two decades, Profil has specialized in a rare technique called the "automated (Biostat®) glucose clamp". This methodology, utilized in only a handful of academic institutes worldwide, is used to determine the time-action profile of new blood glucose-lowering compounds and to evaluate their impact on insulin sensitivity and compartment specific glucose turnover. Profil's advanced Automated Glucose Clamp will create a solid foundation for a pharmaceutical company's drug development decisions.

With a powerful recruitment database, state-of-the-art facilities, straightforward project management, and a sophisticated QA/QC system, Profil will ensure a pharmaceutical company's project's success. The fundamental structure of our database allows us to identify sub-populations according to the specific inclusion/exclusion criteria of any given clinical trial.

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Mystic Management Systems, Inc. is a leading provider of quality software solutions, document control, product lifecycle management, specification management and corrective and preventative and training management solution. Founded in 1984.

Category	Software, Research, Health
Tags	document control software, capa software, employee training management software, emea and fda 21 cfr part 11 compliance
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