

CTG Develops and Implements a Reliable Quality Management System for CluePoints

Our Client

CluePoints, the pioneers of Risk-Based Study Execution Solutions, offers sponsors and contract research organisations a better way of identifying, visualizing, managing, and documenting trial risks that could compromise patient safety and delay the approval of investigational products.



Challenges and Objectives

When CluePoints was established in 2012, they needed to develop and implement a Quality Management System (QMS) to ensure compliance with Good Clinical Practices.

CTG's Solution

CTG supported CluePoints in the development of their QMS by:

- Recruiting and training a Quality Assurance Coordinator
- Coaching the Quality Assurance Responsibles

- Developing tailor-made QMS deliverables (policies, procedures, work instructions, forms) such as, but not limited to: Computer System Validation, IT Infrastructure Qualification, Quality Risk Management, Data Protection
- Performing vendor audits
- Participating in customer audits
- Providing compliance-related support

Results

CluePoints now has a mature QMS in place that is maintained and supervised by skilled Quality Assurance Coordinators. Its processes are accurate and complete, but not excessive. CluePoints has been subject to many audits of its life science customers with positive results.

IN THEIR WORDS...

"We can always count on CTG for support and expertise on compliance-related matters."

– Simon Fiset, Quality Assurance Coordinator



Published by Computer Task Group, Inc.

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