Our Experience has Made a Real Difference to the World of Clinical Development

Investigator sites and vendor audits conducted over the last 5 years

About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are shortening the distance from lab to life® at syneoshealth.com.

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For more information about Syneos Health, please contact us:

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Quality and Compliance Consulting—Adding Value to Your Studies

Every product development program can benefit from considering potential issues as early as possible in its life cycle. The dedication of our Quality and Compliance team, combined with our knowledge of inspection agencies’ different cultures and expectations, means that we assess and help you manage your risk professionally, expertly and globally.

Auditing Critical Success Factors

• We are completely independent from both your company and the project team
• Our knowledge and experience spans every auditing requirement, regulation type and market
• Each of our highly experienced auditors is specifically briefed for each audit to achieve optimum results
• We provide individual compliance audits as well as total quality and compliance program management
• Flexible partnership models, including standalone audits and FSPs, are designed to meet your individual needs

Streamlining Quality Processes

• By assessing the validity of existing SOPs and either suggesting improvements or developing new ones, we drive cost and time efficiencies
• We help you select the best quality vendors and review your vendor management processes

We Consider Risks...

By looking at general criteria, we assess risk factors and determine the most effective audit plans for our risk-based auditing approach. Areas covered include:
• Suspected or known quality issues
• Process and protocol complexities
• Investigator sites with high or rapid enrollment
• Regulatory considerations and history of inspections
• How processes impact on subject safety and data integrity
• Audit history
• Any other appropriate criteria

…so your studies are conducted as quickly and compliantly as possible

Ensuring Compliance

• Projects, processes and systems are evaluated in line with current regulations and guidelines
• Comprehensive cross-audit reviews identify issues and opportunities for corrective and preventive actions
• We advise on how best to train and support principal investigators to get the most from your study
• We carry out mock regulatory inspections of investigative sites (and even your company) to flag potential problems and address them before they compromise your study