

Newly established 3PARL® consortium to assure global life sciences industry of consistent high standard of GMP supply chain audits

Submitted by: Sarum Consultancy

Tuesday, 24 October 2023

Rephine and Eurofins Healthcare are acting against substandard audit practices with guarantees of the highest quality of inspection services & library reports, from raw materials to finished products

CPHI, Barcelona - October 24th, 2023- Rephine (<https://www.rephine.com/>), the experts in quality assurance & GxP compliance across pharmaceutical, biotech & medical device manufacturing supply chains, has announced its part in a new trailblazing international consortium that will set a clear standard for life sciences manufacturing supply chain audits globally.

The new Third-Party Audit Report Library (3PARL®) consortium, spearheaded by Rephine and Eurofins Healthcare (<http://www.eurofins.com/healthassurance>) aims to set a new benchmark for consistent, reliable, high-quality supply chain Good Manufacturing Practice (GMP) audit services and library reports. Several other well-known international auditing businesses will be announced as 3PARL consortium members over the coming weeks.

The aim is that audit sponsors, healthcare providers and patients in regulated markets can fully trust in the quality, safety and integrity of the life sciences products being brought to market, because of the consistent robustness of auditing practices across 3PARL® consortium members.

The industry leaders decided to act against some questionable practices which have emerged in the past couple of years across the global GMP auditing industry. The goal of the consortium is to enable audit sponsors and their customers in strictly regulated markets to have the highest confidence that the auditing and qualification processes applied to suppliers and manufacturers across the whole value chain, are consistently robust and compliant with all applicable regulations.

To address this problem, and despite being commercial competitors, Rephine and Eurofins Healthcare have taken the unprecedented step of coming together to collectively make a stand and set a new benchmark for supply chain audits across the global life sciences industry. This approach assures all stakeholders of the same consistent and compliant rigour and audit quality, from raw material to finished product – whether that's via a commissioned independent audit, or access to a valid, credible and comprehensive library report.

Commenting on the initiative, Adam Sherlock, Rephine's CEO, said: "In common with our respected partners around the world, we have repeatedly audited life sciences manufacturers globally for more than 25 years, giving us a strong sense of quality performance and manufacturing capabilities across the whole value chain. All of us have become aware of a varying degree of rigour and lack of consistent ethical business practice in supplier auditing, as practised by some independent service providers. This lack of transparency and inconsistency is a risk to everyone in the industry, including patients, because ultimately it jeopardises trust in the qualification and compliance process for quality which independent auditing is designed to provide right across the value chain. Audit sponsors and the suppliers being

audited have to have trust that the auditing process will assure all stakeholders of the quality of finished products and their constituent components.”

Corrado Lagioni, Managing Director, Eurofins Healthcare states: “Although the founding members of the 3PARL® consortium are competitors commercially, we are united in our concern at the less ethical practices that have unsettled our industry. Together, we want to make it absolutely clear to clients what they can and should expect from an audit service or library product, and that there can be significant differences in quality depending on where they source their audits or reports. By choosing a 3PARL® audit partner, they can be assured of the highest possible standards, and that these will be observed consistently.”

Rephine and partners are exhibiting at the international CPhI pharma event in Barcelona from October 24-26. To find out more about 3PARL and how you can get involved please email info@3parl.org (<mailto:info@3parl.org>) or visit Rephine on booth number 7B40 at CPhI.

[ENDS]

About Rephine

Rephine is a firm of deeply experienced GxP consultants, auditors and practitioners. The company proactively helps pharmaceutical, biotech and medical device companies with all aspects of their manufacturing and supply chain quality assurance and associated business process optimisation.

Widely acknowledged to be the gold standard in its field, Rephine has been providing these specialist quality assurance services for more than 25 years. Rephine is a founding member of 3PARL®, a consortium that aims to set a new benchmark for consistent, reliable, high-quality supply chain Good Manufacturing Practice (GMP) audit services and library reports. More at www.rephine.com (<http://www.rephine.com/>)

About Eurofins Healthcare

In 2019, Eurofins Assurance introduced a new specialized division: Eurofins Healthcare. This division focuses exclusively on conducting audits within the pharmaceutical industry and the broader health sector. Its inception seamlessly integrated with Eurofins' extensive global laboratory network, widely recognized as industry frontrunners. More at <https://www.eurofins.com/healthassurance> (<https://www.eurofins.com/healthassurance>)

Press contact for Rephine

Carina Birt, Sarum Life Sciences, 07970 006624, carina@sarumlifesciences.com (<mailto:carina@sarumlifesciences.com>)