Quality Audit Report

Name of Auditee

Auditee Address

Audit No. CT 5500

Date of Audit: 9th-12th January 2017

Head Office Address
XXXXXX
XXXXXX

Research Centre Address
XXXXXX
XXXXXX

Protocol Titles:Not Applicable

All enquiries relating to this report should be addressed to the Chief Executive at:-

Rephine Ltd
15 Meadway Court
Stevenage
Hertfordshire
SG1 2EF
United Kingdom

Telephone number: +44 1763 853 135
Fax number: +44 1763 853 573
Email: enquiries@rephine.com

Whilst every duty of care has been taken in conducting the audit and the preparation of this report, liability for the use of information in the report is restricted to authorised purchasers only.

Quality Site Audit Report

Name of Auditee

Auditee Address

Audit No. CT 5500

Prepared for

CLIENT NAME

CLIENT ADDRESS

Date of Audit: 9th - 12th January 2017

Table of Contents

SECTION A Executive Summary and Observations

Executive Summary

Name of Sponsor organisation:	Xxxx Pharmaceuticals Ltd.
Contact Name at Sponsor:	Xxxxxx Xxxxxx
Nature of Audit:	Inspection of facilities and study procedures to assess that the company has adequate systems, resources and facilities to perform work on behalf of the client, and that the studies were performed in compliance with the study protocols, available Standard Operating Procedures, GCP and applicable regulations and guidance
Clinical Research Organisation:	Xxxxxxxxx Labs.
CRO Site Address:	Xxxxxxx Xxxxxxx

The AUDITEE Clinical Facility at Xxxxxxx Xxxxxxx was audited on 9th-12th January 2017. The audit was performed by AUDITOR NAME.

The facility has a well-established Quality Management System with a good standard of documentation and record keeping, and the facility was maintained in very good order.

All staff interviewed were highly professional with in-depth knowledge and understanding of the studies/systems.
All areas were noted to be clean, tidy and in good condition. There appeared to be adequate equipment; all equipment was regularly serviced and appeared in good order.
The archives were located at a nearby Xxxxxxxxx Labs. site; study data was routinely archived off-site at a third party (Xxxxxxxx).

The Auditor(s) believe that on the basis of this audit, the Auditee Clinical Facility at ADDRESS has the facilities, systems and capabilities to meet the required standards of GCP.

There were no critical or major issues for Xxxxxxxxx Labs to address. There were a number of minor issues to address and these are summarised below and described in more detail in the main text.

There was one SOP Deviation where aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

There was damage to aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Auditor(s)

Name:

Date: 25th January 2017

Signature

Observations

1.1	**Critical Observations**	**Regulatory/Guidance Reference**

1.2	**Major Observations**	**Regulatory/Guidance Reference**

1.3	**Minor Observations**	**Regulatory/Guidance Reference**
1.3.1		ICH GCP E6 (R2)
1.3.2		ICH GCP E6 (R2)
1.3.3		ICH GCP E6 (R2)
1.3.4		ICH GCP E6 (R2)
1.3.5		ICH GCP E6 (R2)
1.3.6		ICH GCP E6 (R2)

1.4	**Other Non-GCP Observations**	**Regulatory/Guidance Reference**

Classification of Observations

Findings from this audit were classified according to the following criteria:

Critical Observation
A 'Critical' finding is defined as one where:
Where evidence exists of conditions, practices or processes that adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data.

Critical observations are considered totally unacceptable.
Possible consequences: rejection of data and/or legal action required.
Remarks: observations classified as critical may include a pattern of deviations classified as major, bad quality of the data and/or absence of source documents. Manipulation and intentional misrepresentation of data belong to this group.

Major Observation
A 'Major' finding is defined as:
Conditions, practices or processes that might adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data.
Major observations are serious findings and are direct violations of GCP principles.
Possible consequences: data may be rejected and/or legal action required.
Remarks: observations classified as major, may include a pattern of deviations and/or numerous minor observations.

Minor Observation
A 'Minor' finding is:
Conditions, practices or processes that would not be expected to adversely affect the right, safety or well-being of the subjects and the quality and integrity of data.
Possible consequences: observations classified as minor, indicate the need for improvement of conditions, practices, and processes.
Remarks: many minor observations might indicate a bad quality and the sum might be equal to a major finding with its consequences.

Other Non-GCP Observations
All other observations, which although they may not imact directly on GCP are nevertheless points which should be taken into consideration.

Ref: Procedure for reporting of GCP inspections requested by the Committee for Medicinal Products for Human Use (CHMP), EMA/INS/GCP/588734/2012

Audit Checklist

OK This element of GCP is acceptable.
NC Non-Compliance - there is at least one non-compliance - the Note cross-references the Observation.
NR Not Reviewed – this GCP element either out of scope, not disclosed or insufficient time during the audit.
Note Explanatory note or cross-reference to Observation.

	Subject	OK	NC	NR	Note
Organisation & Management					
1.	Regulatory Inspection History				
2.	Roles & Responsibilities				
3.	Delegation of Authority				
4.	Contracts & Agreements				
5.	Disaster Recovery/Business Continuity				
6.	Training				
Quality Management					
1.	Quality Assurance				
2.	Quality Control				
3.	Standard Operating Procedures				
Systems					
1.	Computer System Validation				
2.	IT & Security				
3.	e-Data Capture				
4.	Data Transfer				
5.	Kit Preparation				
6.	Sample Chain-of-Custody				
7.	Data Management				
8.	Study Reporting				
9.	Archiving				

	Subject	OK	NC	NR	Note
Informed Consent					
1.	Recruiting				
2.	Informed Consent Form				
3.	Informed Consent Process				
4.	Subject Confidentiality				
Drug Accountability					
1.	Available				
2.	Sample check calculations				
Source Documentation					
1.	Available				
2.	Sample check to report				
CRF					
1.	Sample check for completeness & accuracy				
Monitoring					
1.	Monitoring Visitis				
Facilities/ Equipment					
1.	IT & Security				
2.	Clinic				
3.	Kit Assembly				
4.	Sample processing laboratory (Screening)				
5.	Sample processing laboratory				
6.	Dispensary				
7.	Archives				
8.	Equipment Maintenance				
Essential Documents					

	Subject	OK	NC	NR	Note
1.	Available				
2.	Approved				

SECTION B Audit and Report Organisation

Purpose

First Rephine audit of Xxxxxxxxx Labs. Audit No CT 5500.
An inspection of facilities and study procedures was conducted to assess that the company had adequate systems, resources and facilities to perform work on behalf of Xxxx Pharmaceuticals Ltd. and that the studies were performed in compliance with the study protocols, available Standard Operating Procedures, GCP and applicable regulations and guidance.

Scope

The audit was performed over a period of 4 days, by 1 Auditor. The duration of the audit was considered appropriate. By its nature, an audit can only describe what is seen on a specific day, in a specific area under a particular set of conditions. It cannot cover the whole of an organisation's operation and therefore the absence of comment about a particular operation or area does not imply acceptability or non-acceptability. Nevertheless the audit report can draw valid general conclusions from a limited study of specific areas.

Certain aspects were made a priority in the time allocated by the auditee in order to give as accurate a report as possible in relation to GCP compliance.
Particular attention was paid to the identification of high-risk aspects specific to the site that was audited. These included but are not limited to:

Opening meeting and introduction
Corporate Organization
Business Service Strategy
Business Development
Financials and Internal Controlling organization
Personnel and Training
Contracts and Agreements
Intellectual Property, Accreditations and Permissions
Legal and local regulations
Administration and controlling (referring to business controlling)
Property, facilities and security
Investigational Medicinal Product (IMP)
Trial Master File (TMF/eTMF), Document Management and Archiving
Project Management and Risk Management
Regulatory Department and Clinical Trial Approval Facilities and Activities
Safety and Pharmacovigilance
Monitoring and Site Management
Quality Assurance and Quality Management
IT and Technology
Data management, biometrics, statistics and Clinical Report Writing
Clinical Laboratiry
Closing meeting on day 4

The Audit Plan and the Audit Agenda are provided in Appendix 1.

This audit intended to evaluate the systems and processes in place for providing contracted clinical trial management services, in compliance with ICH GCP and applicable regulatory requirements and guidance.

The present audit is intended to evaluate trial conduct and compliance with the applicable regulatory requirements.

These objectives were achieved by review of study files at the site, interviews with key site personnel and a site tour reviewing appropriate areas.

Audit Reference

The Audit reference criteria, including regulatory standards are:

ICH GCP (CHMP/ICH/135/95) E6(R1) : Guideline For Good Clinical Practice. Integrated Addendum ICH GCP E6(R2)
ICH GCP E3, and ICH E9
EU Directives 2001/20/EC, 2005/28/EC, as relevant
EU Clinical Trial Regulation 536/2014, 16 April 2014
Eudralex Volume 10 of the publications "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.
Volume 10, Communication from the Commission - Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (2011/C 172/01).
Communication from the Commission - Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1) (2010/C 82/01)
Eudralex Volume 4 Annex 13 to the EU Guide to GMP, July 2003, updated 03 February 2010.
FDA Guidance for Industry "Computerised Systems Used in Clinical Trials" May 2007, as applicable.
FDA 21 CFR Part 11 (electronic records & electronic signatures), as applicable.
LFB SOPs/Instructions where applicable
FGK SOPs covering the processes audited
Audit Plan

Exclusions

Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Conventions and abbreviations

Abbreviations

The European date format (dd/mm/yyyy) is used throughout this document.

ADR	Adverse Drug Reaction
AE	Adverse Event
CA	Competent Authority
CAPA	Corrective Action Preventive Action
CHMP	Committee for Medicinal Products for Human Use
CRA	Clinical Research Associate
(e)CRF	(electronic) Case Report Form
CRO	Contract Research Organisation
CTM	Clinical Trial Manager
CSR	Clinical Study Report
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IEC	(Independent) Ethics Committee
IMP	Investigational Medicinal Product
IR	Inspection Report
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
MAA	Marketing Authorisation Application
MVR	Monitoring Visit Report
PIL	Patient Information Leaflet
PIS	Patient Information Sheet
QA	Quality Assurance
RA	Regulatory Authority
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

A ton is a metric tonne of 1000kg
A ton of Refrigeration (TR) is defined as the cooling power of one short ton (2000 pounds or 907 kg) of ice melting in a 24-hour period. This is equal to 12,000 BTU/hr or 3517 watts
1 hectare is 2.47 acres or 10,000 m^2
The European date format (dd/mm/yyyy) is used throughout this document

API	Active Pharmaceutical Ingredients
CAPA	Corrective and Preventive Action
CEP	Certificate of Suitability (issued by EDQM)
CP	Chinese Pharmacopoeia
DMF	Drug Master File
EDQM	European Directorate for the Quality of Medicines and Healthcare
EIR	(US FDA) Establishment Investigation Report
HVAC	Heating, Ventilation and Air-Conditioning.
JP	Japanese Pharmacopoeia
LIMS	Laboratory Information managements System
NLT	Not Less Than
NMT	Not More Than
OOS	Out Of Specification
PFI	Pharmaceutical Formulation Intermediates (or PFI)
Ph Eur	European Pharmacopoeia
PLC	Programmable Logic Controller
PPM	Planned Preventative Maintenance
QA	Quality Assurance
QC	Quality Control
SCADA	Supervisory Control And Data Acquisition
SOP	Standard Operating Procedure
TSE/BSE	Transmissible Spongioform Encephalopathy/Bovine Spongioform Encephalopathy
USP	US pharmacopoeia

Rephine's Auditors

Name	Position	e-mail address
Auditor	Consultant Auditor	

The Auditors' CVs and the Auditors' Disclaimer are attached in Section D.

Organisation Audit Team

Name	Position	e-mail address
	Director, Clinical Operations	
	Senior QA Auditor	
	Director, Client Services	
	Data Management Head	
	Scientific Project Manager	

The audit was arranged by:

Name of contact at Client organisation.

Address

Background Organisation Information

Xxxxxxxxx Labs was founded in 1984 and is part of XXXXXX Clinical Research Group. XXXXXX Clinical Research Group is a full service Contract Research Organisation offering Phase I – IV clinical studies in healthy and patient populations as well as in support of pre-clinical GLP studies. The group also offers clinical support including protocol development, study design, project management, data management, biostatistics, bioanalysis, method development and validation, pharmacokinetics, pharmacodynamics and medical writing. The study data and clinical facilities at Xxxxxxx Xxxxxxx in Rome were reviewed.

Location

Operating out of five clinical facilities in Europe and North America, Xxxxxxxxx Labs has a total of 550 beds; 140 beds at the Rome facility. The Head Office and Clinical Support services, including the archive and IT, were based at Xxxxxxx, a 30 minute drive from the Rome facility.

Site Access and Security

Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf. Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

See Section C Facilities and Equipment

Regulatory Inspections

Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf. Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf. Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs

See Appendix 1.

SECTION C Audit Report

Inspection and GCP Survey

Property, Facilities and Security
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Investigational Medicinal Product (IMP)
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Trial Master File (TMF), Document Management and Archiving
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

The Project Manager or Project Assistant maintained an Access database to track study
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Project Management and Risk Management
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Regulatory Department and Clinical Trial Approval Facilities and Activities
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Safety and Pharmacovigilance
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Monitoring and Site Management
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Quality Assurance and Quality Management
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Other documents reviewed
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Information Technology
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Computer Systems Validation
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Interactive Response Technology (IxRS)
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Data Management, Biostatistics and Medical Writing
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Statistics
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Medical Writing
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

Clinical Laboratory
Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf Aotity bnuqo vmiqu xcbnsud onhire fnw bvmr awucb o fniw gohern qwufe gnmig nubfgpa abyhs ophn nmasx migope komuy wqey uqw mvnbv ayw ogiu auso gen nfu boetmwe vfnuwn gbmie wnbuf.

SECTION D Auditors' CVs and Disclaimer

Auditors **CV** included with every audit report.

Disclaimer is a document signed by the auditor to confirm that there is no conflict of interest.

Date:

To whom it may concern

This note certifies that Rephine's Auditor:

Mr/s [auditor name]

has not been employed by [auditee name] in the last 5 years.

[auditor name] does not have, and never has had, any financial interest whatsoever in [auditee name].

During the audit the following items were provided for the auditor(s):

Light refreshments, lunch, transport to and from the hotel and factory.

Name**:** [auditor name]

Position: Rephine Auditor

Signed:

SECTION E Appendices

Appendix 1: List of GCP and GLP Regulatory Inspections at
Appendix 2: SOP Index Effective on date of audit
Appendix 3: Audit Agenda

Documents attached to this report have been provided by the auditee.

SECTION F Responses/CAPA & Closure Statement

Audit Closure Statement

To be issued when the auditor is satisfied with the auditee response to observations made in the audit report.

Audit Closure Statement

In respect of the Rephine Audit of [COMPANY NAME] of [LOCATION] performed on [DATE] and reported in Audit Report Number PA [NUMBER] dated [REPORT DATE].

The Company's responses to the Audit Observations have been reviewed and have been found to be satisfactory.

A copy of the Company's report on Corrective and Preventative Actions in respect of the Audit Observations was received on [day/month/year]: a copy is attached.

Audit Number CT [NUMBER] is now closed.

Signed

[AUDITOR 1]
[AUDITOR 2]

Name:
Rephine

Date:

Thank you for thinking of using the Rephine Audit report to fulfil your regulatory obligations.

The audit report has been produced by Rephine Ltd. a leading pharmaceutical operational consultancy. The report is comprehensive and detailed and fulfils the requirements of Regulatory Authorities.

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Where appropriate, an update of progress or completion of a remedial action plan will be sent to you at the relevant time.

Founded in 1998, Rephine has an enviable record of consultancy in the Pharmaceutical Industry. Based in the UK, Rephine operates globally and has provided services in most parts of the world, and its knowledge of EU regulatory requirements is exceptional.

Rephine provides a wide range of clinical and regulatory services for the pharmaceutical, medical device and biotechnology industry, and Rephine Consultants are all highly qualified and experienced scientists who have worked extensively in the industry and in clinical research.

The Rephine services are underpinned by the highest quality standards, attention to detail and close relationships with clients so that project objectives are met efficiently and cost effectively. The highest ethical and confidentiality standards are maintained at all times. Rephine is certified to ISO 9001 2008.

Rephine specialises in both GCP and GMP auditing as well as supplier evaluation, having carried out hundreds of such projects all over the globe, and is recognized as a leader in auditing services. Rephine produces audit reports which are high quality, third party GCP and GMP audit reports which support Pharmaceutical companies and Manufacturers in meeting their regulatory requirements (2004/27/EC).

Rephine GCP reports are totally independent and satisfy the most stringent regulatory requirements.

Rephine has provided over 1,300 audit reports worldwide, they are also totally independent and satisfy the most stringent QP and regulatory requirements. The Rephine auditors have carried out 800 GCP and GCLP audits.

Companies who have been audited have agreed that the Rephine GMP audit reports of their facilities may be provided to their customers, thereby avoiding the need for the customers to carry out an audit themselves. Rephine currently has a portfolio of over 140 third party GMP audit reports available.

See http://www.rephine.com/gmp-guide-part-1.aspx for a statement by the European Medicines Agency and http://www.rephine.com/MHRA-statement.aspx from the MHRA on the acceptability of third party audit reports.

Contact Rephine for any further information or clarification on 0044 1763 853135 or enquiries@rephine.com