



AUDITOR'S INFORMATION PACK



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Company Profile

Butterworth Laboratories, established in 1974, provides a fully independent high quality contract analytical service primarily to the Pharmaceutical, Medical Devices, Biotechnology, Health & Beauty Care and Chemicals industries.

Offering a cost effective, reliable and timely solution for:

- ♥ QC testing
- ♥ Stability testing
- ♥ Method development
- ♥ Method Validation and Verification
- ♥ GLP and GCP Projects

Our services include Classical Wet Chemistry, Physical Chemistry Testing, Spectroscopy (ICP-MS, ICP-MS-MS, ICP-OES, AAS and GF-AAS), Chromatography (GC, GC-MS, HPLC and IC) and Elemental Microanalysis.

We have a total commitment to quality and our experienced analysts work in partnership with our customers as an extension to their own laboratory facilities. Through communication it enables us to provide a reliable service which fully understands our clients needs and specific requirements.

In addition we have experience in working for the Engineering & Microelectronics, Health & Safety, Food Drink & Tobacco and Environmental sectors.

The Company is registered in the UK as Limited Liability Company, which holds comprehensive insurance to cover all its operation. All the shares are owned by Doris Butterworth.



Company & Management Details

Registered Name	Butterworth Laboratories Ltd
Laboratories location	54-56 Waldegrave Road Teddington Middlesex TW11 8NY UK Telephone: +44 (0) 20 8977 0750 Fax: +44 (0) 20 8943 2624
Administration and Archives location	Unit 14/Unit 10, Castle Business Village, Station Road, Hampton, Middlesex TW12 2BX UK

Company Registration No. 1185121

VAT Registration No. 224013030

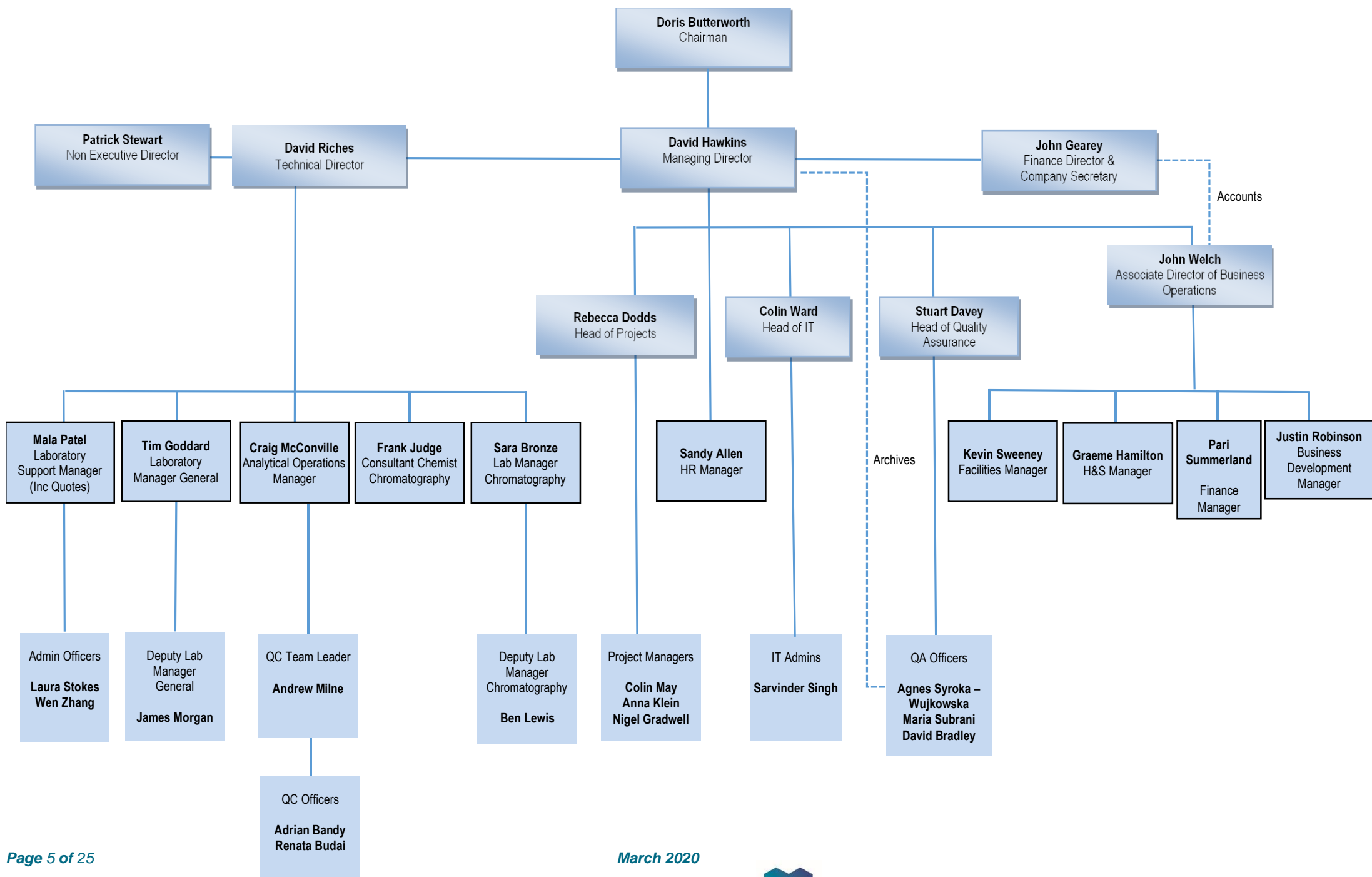
DIRECTORS

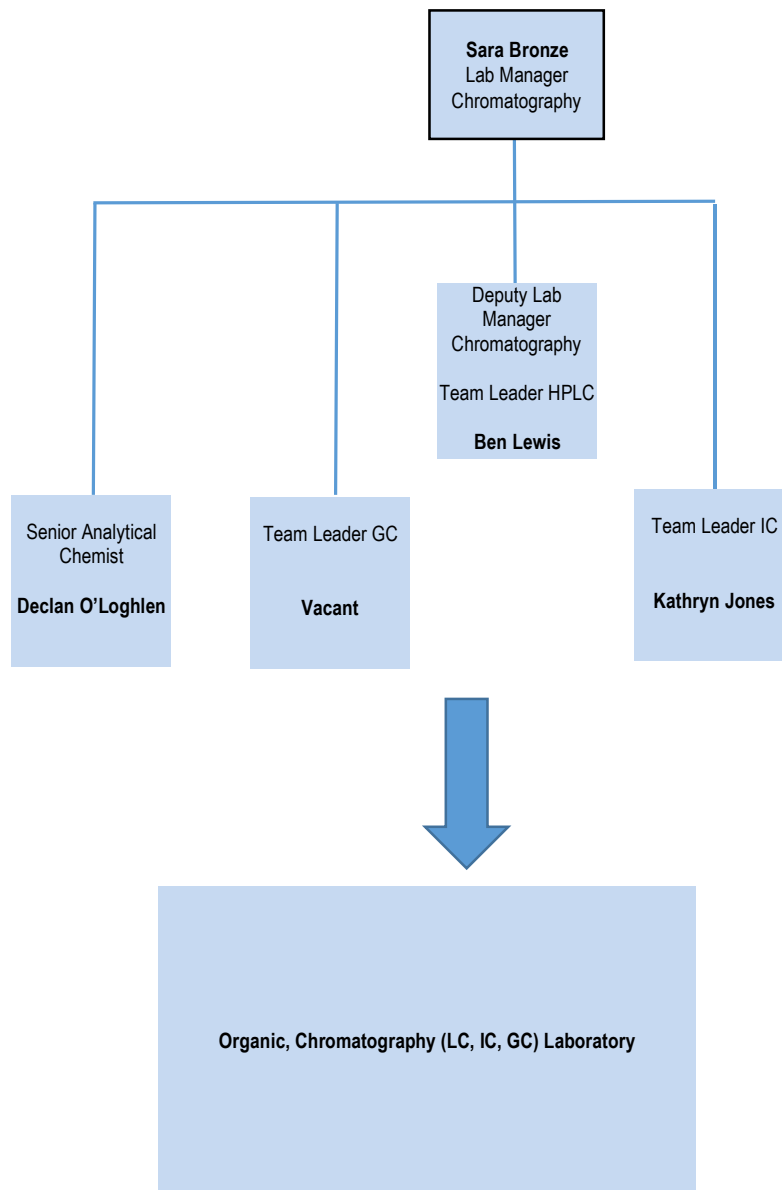
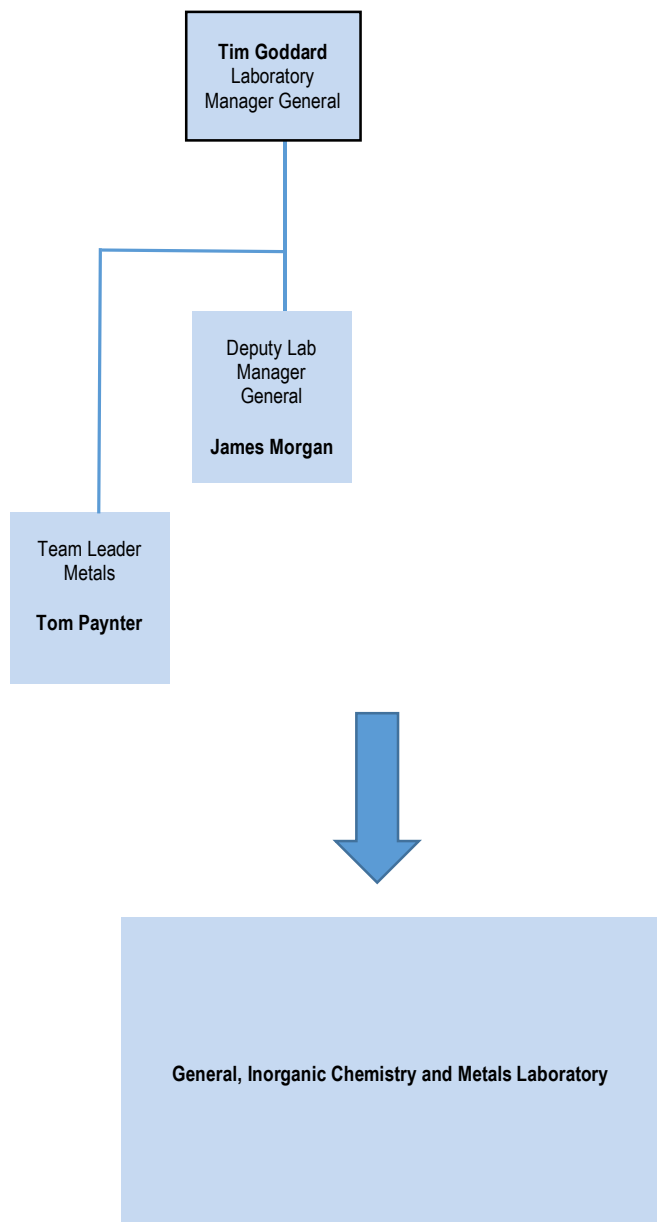
Chairman	Doris E Butterworth CSci. CChem; FRSC; FloD
Managing Director	David J Hawkins BSc (hons), CBiol, MRQA
Finance Director & Company Secretary	John M Gearey FCA
Technical Director	David A Riches BSc CChem MRSC
Non-Executive Director	Patrick Stewart BA (hons)

SENIOR MANAGERS

Associate Director of Business Operations	John A S Welch CChem MRSC MRQA
Head of Projects	Rebecca Dodds BSc , MRQA
Head of QA	Stuart Davey BSc, MRQA
Head of IT	Colin Ward







Quality

POLICY

To meet today's stringent requirements for international scientific business activities, the policy of Butterworth Laboratories Ltd. is to provide a highly confidential and comprehensive service of contract analytical chemistry, with a commitment to good quality and professional practice related to range of the services provided.

The management of Butterworth Laboratories Ltd are fully committed to this policy, compliance to the quality regulations and standards listed in QA1 (Quality Policy) and to continual improvement of the company in all matters quality related.

The company has a defined Management System and where this relates to quality, is referred to as the "Quality System".

The Quality System has been developed to enable compliance with the Quality Policy and is described in the Quality Manual. It's aim is to assure the accuracy and precision, as well as the reliability, of laboratory results produced for clients and also to maintain the highest level of quality in the services provided in accordance with the appropriate quality regulations and standards.

It is the responsibility of all staff to familiarise themselves with the contents of the Quality Manual and to comply with the policies and procedures described therein and with associated documentation at all times. All senior members of staff are required to ensure that this Quality Policy is implemented.

The Head of Quality Assurance, has the responsibility for quality assurance and for advising on and monitoring all features of the Quality System.

Confidentiality is of the utmost importance and this is reinforced by the requirements laid down in contracts of employment and also contracts with clients and 3rd parties

QUALITY REGULATIONS AND STANDARDS

Butterworth Laboratories are regularly visited and inspected by UKAS, MHRA and FDA.

Regulatory/Accrediting Body	Last inspection
UKAS (ISO 17025)	19 th and 20 th November 2019
MHRA GMP	8 th – 9 th August 2017
MHRA (GLP/GCP combined inspection)	20 th – 21 st June 2016
FDA (GMP)	28 th – 31 st July 2015

Note: status can be confirmed via respective web sites.



Department
of Health

**THE DEPARTMENT OF HEALTH OF THE GOVERNMENT
OF THE UNITED KINGDOM**

GOOD LABORATORY PRACTICE

**STATEMENT OF COMPLIANCE
IN ACCORDANCE WITH DIRECTIVE 2004/9/EC**

TEST FACILITY

BUTTERWORTH LABORATORIES LIMITED
54-56 WALDEGRAVE ROAD
TEDDINGTON
TW11 8NY
UNITED KINGDOM

TEST TYPE(S)

Analytical/Clinical Chemistry
Physical/Chemical Testing

DATE OF INSPECTION: 20/06/2016

DATE OF ISSUE: 30/09/2016

An inspection for compliance with the Principles of Good Laboratory Practice was carried out at the above named test facility as part of the UK Good Laboratory Practice Compliance Monitoring Programme.

This statement confirms that, on the date of issue, the UK Good Laboratory Practice Monitoring Authority were satisfied that the above named test facility was operating in compliance with the OECD Principles of Good Laboratory Practice.

This statement constitutes a Good Laboratory Practice Instrument (as defined in the UK Good Laboratory Practice Regulations 1999).

Issued by
Dr Andrew J Gray
Head, UK GLP Monitoring Authority



Medicines & Healthcare products
Regulatory Agency



Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	BUTTERWORTH LABORATORIES LIMITED
Site address	54-56 WALDEGRAVE ROAD TEDDINGTON TW11 8NY UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Human Medicines Regulations 2012 (SI 2012/1916)'; for veterinary medicines 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/08/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.



Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised



3. MANUFACTURING OPERATIONS

- 3.1 Manufacture of Active Substance by Chemical Synthesis**
Not Authorised
- 3.2 Processing Activities of Active Substance from Natural Sources**
Not Authorised
- 3.3 Manufacture of Active Substance using Biological Processes**
Not Authorised
- 3.4 Manufacture of sterile active substance**
Not Authorised
- 3.5 General Finishing Steps**
Not Authorised
- 3.6 Quality Control Testing**
Not Authorised
- 4 Other Activities**
Not Authorised



Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Lesley Graham
GMP Inspector
Lesley.Graham@mhra.gsi.gov.uk

Date: 28/09/2017



Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	BUTTERWORTH LABORATORIES LIMITED
Site address	54-56 WALDEGRAVE ROAD TEDDINGTON TW11 8NY UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Medicines Act 1968 as amended'; for veterinary medicines 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/08/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.



Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised



3. MANUFACTURING OPERATIONS

- 3.1 Manufacture of Active Substance by Chemical Synthesis**
Not Authorised
- 3.2 Processing Activities of Active Substance from Natural Sources**
Not Authorised
- 3.3 Manufacture of Active Substance using Biological Processes**
Not Authorised
- 3.4 Manufacture of sterile active substance**
Not Authorised
- 3.5 General Finishing Steps**
Not Authorised
- 3.6 Quality Control Testing**
Not Authorised
- 4 Other Activities**
Not Authorised



Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Lesley Graham
GMP Inspector
Lesley.Graham@mhra.gsi.gov.uk

Date: 28/09/2017





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 431E
Silver Spring, MD 20993

TELEPHONE: (301) 796-3254
FAX: (301) 847-8742

February 24, 2016

Stuart Davey
Quality Assurance Manager
Butterworth Laboratories Ltd.
54-56 Waldegrave Rd.
Middlesex, Teddington United Kingdom

Reference: FEI 3002806533

Dear Mr. Davey:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory in Teddington, United Kingdom India by Investigator Melba T. Rivera Clavell during the period of July 28, 2015 – July 31, 2015.

Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Concepcion Cruz
Branch Chief
Division of Quality Surveillance Assessment

Enclosure: EIR

Certificate of Accreditation



Butterworth Laboratories Ltd

Testing Laboratory No. 0215

**Is accredited in accordance with International Standard ISO/IEC 17025:2017
– General Requirements for the competence of testing and calibration
laboratories.**

This accreditation demonstrates technical competence for a defined scope specified in the schedule to this certificate, and the operation of a management system (refer joint ISO-ILAC-IAF Communiqué dated April 2017). The schedule to this certificate is an essential accreditation document and from time to time may be revised and reissued.

The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from www.ukas.com.

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements.

Matt Gantley, Chief Executive Officer
United Kingdom Accreditation Service

Initial Accreditation: 27 July 1983
Certificate Issued: 16 March 2020



Scan QR Code to
verify

UKAS is appointed as the sole national accreditation body for the UK by The Accreditation Regulations 2009 (SI No 3155/2009) and operates under a Memorandum of Understanding (MoU) with the Department for Business, Energy and Industrial Strategy (BEIS).



*Joint ISO-ILAC-IAF
Communique on the
Management Systems Requirements of ISO/IEC 17025,
General Requirements for the competence of testing and
calibration laboratories*

*A laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and **management system requirements** that are necessary for it to consistently deliver technically valid test results and calibrations. The **management system requirements** in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001.*

ISO Acting Secretary General

ILAC Chair

IAF Chair

April 2017

Document Register

Printed on:

13 February 2020

Type within QA

Number	Title
QA1	Quality Policy
QA3	Organisation, Management and Staff
QA5	Analytical Instruments and Equipment
QA6	Test Measurements
QA8	Accommodation, Environment and Security Arrangements
QA11	Test Reports and Certificates
QA13	Suppliers and Sub-contracting
QA17	Schedule of UKAS Accreditation
QA18	Authorised Signatories
QA20	Staff Qualifications and Training
QA22	IT Quality Policy
QA23	Archiving and Document Retention Policy

Quality Management Procedures

Document Register

Printed on:

28 February 2020

(Number containing qmp)

Number	Title
QMP0	The Quality Manual, UKAS Accreditation, GMP, GLP and GCP
QMP1	The Creation, Issue and Control of Controlled Documents and Controlled Forms
QMP2	Internal Audits
QMP3	Corrective and Preventive Actions (CAPA)
QMP5	External Audits
QMP6	Management Review of the Quality System
QMP7	The Format of BLL Analytical Methods
QMP9	Uncertainty of Measurement
QMP10	Managing Non-conforming Work
QMP11	Quality Control
QMP13	Calibration Records
QMP16	Qualification of Equipment and Analytical Instruments
QMP17	Out of Specification (OOS) Test Results for Pharmaceutical Samples
QMP18	The Use of In-house Generic Methods
QMP19	Validation, Verification and Transfer of Analytical Methods
QMP20	Raw Data and Data Integrity
QMP23	Identification of Tests/Analysis Considered as Infrequent
QMP24	QA Requirements for IT Systems
QMP25	The Control, Use and Review of Published Methods
QMP26	The Laboratory Manual
QMP28	Enquiries, Quotations, Contract Review and Invoicing
QMP29	Opinions and Interpretations Included in Test Reports
QMP31	Sample Control
QMP32	Change Control
QMP33	Client Supplied Methods, Standard Operating Procedures and Specifications
QMP34	Quality Risk Assessment
QMP35	Root Cause Analysis (RCA)
QMP36	Quality Governance
QMP37	Quality Record Analysis, Metrics and Trending
QMP38	Document and Record Archive / Retention
QMP39	Managing Complaints

BLL Approved Q-Pulse Report

Standing Operating Procedures

(Of Potential Interest)

SOP No	Title
A1	Sample Control
A3	Production and Issue of Test Reports and Certificates
A4	Archiving Procedure
A10	The Monitoring of Service Levels
A22	The Issue and Control of Raw Data Sheets
A23	Equipment Master Manual
A24	Production of Service/Technical and Confidentiality Agreements
A25	Use of Suppliers and Contractors
A27	Sample Receipt
C1	The Matrix Laboratory Integrated Management System (LIMS)
C2	The Electronic Documentation and Archiving System
C7	Q-Pulse User Manual
G16	The Storage, Labelling And Use Of Purchased And Non Job Specific Prepared Chemicals, Reagents And Standards
G19	The Purchase, Use and Calibration of Laboratory Glassware.
L4	Job Creation, Sample Receipt and Control
L5	Initial Contract Review and Test Selection
L9	Invoicing and Final Contract Review
T1	The Principles & Requirements Of Quality Assurance Standards & Regulations
T2	Training and the use of Training Records
T3	Basic Training for Chromatography
T4	The Training and Approval of Staff Appointed to Check Analytical Data Packs
T5	Basic Training for Inorganic Analytical Chemistry
T6	The Training of Quality Auditors
MS7	Master Study Plan for Good Laboratory Practice (GLP) Studies
MS9	Quality Control Proficiency Testing Schemes
MS10	Master Study Plan for the Conduct of Project Work
MS13	Conduct of Good Clinical Laboratory Practice (GCP) Work



Environmental Policy

STATEMENT OF PRINCIPLES

As a business dependent on environmental and safety management, in addition to quality management, the Company see their own commitment to management of environmental issues within the business as central to its activities. To this end, it is Company policy to:

- comply with environmental legislation relevant to our business
 - use processes, practices and materials that avoid, reduce or control pollution
 - periodically review the environmental impacts of our business and assess the significance of these impacts
 - set and review environmental objectives relevant to the significant impacts and thereby achieve continual improvement in our environmental performance
 - monitor our progress towards achieving these objectives
- In this way, the Company will achieve its objectives of compliance with legislative and other requirements and continual improvement in the environmental performance of its business.

The Directors of Butterworth Laboratories Ltd give their full support to the implementation of these principles.

Health & Safety Policy

STATEMENT OF PRINCIPLES

As a business dependent on environmental and safety management, in addition to quality management, the Company see their own commitment to management of safety issues within the business as central to its activities. To this end:

- The Company will provide and maintain safe workplace systems and practices for all employees.
- The Company will provide facilities for employees' concerns regarding health and safety to be fully and openly expressed.
- The Company will provide adequate information, instruction and training to enable all employees to fulfil their responsibilities to colleagues and the Company.
- The Company will ensure that employees are aware of health and safety hazards in the workplace in order to minimise the risk of injury.
- The Company believes that health and safety attitudes and behaviours are as important to their employees as any other standard of conduct that is set, and will treat health and safety in the same way as any other area of our common responsibilities and behaviours.
- The Company will provide an environment and culture in which Butterworth Laboratories and its employees reduce risk to levels that will, as a minimum, satisfy the legal requirements of the United Kingdom.
- The Company will protect, by all reasonable means, their employees, customers, suppliers, contractors, visitors and others, who come into contact with their operations, against risks to their health and safety from actions taken by Butterworth Laboratories.
- The Company will aim to continuously improve their health and safety performance.

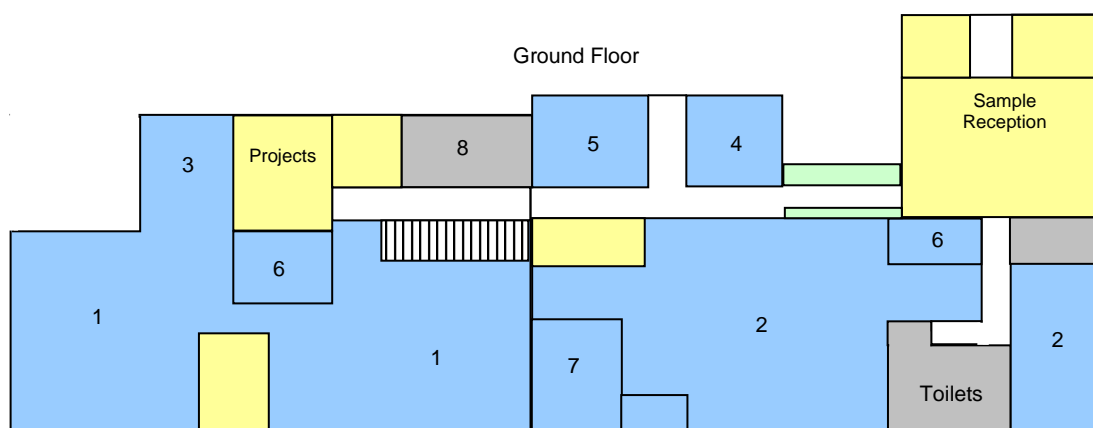
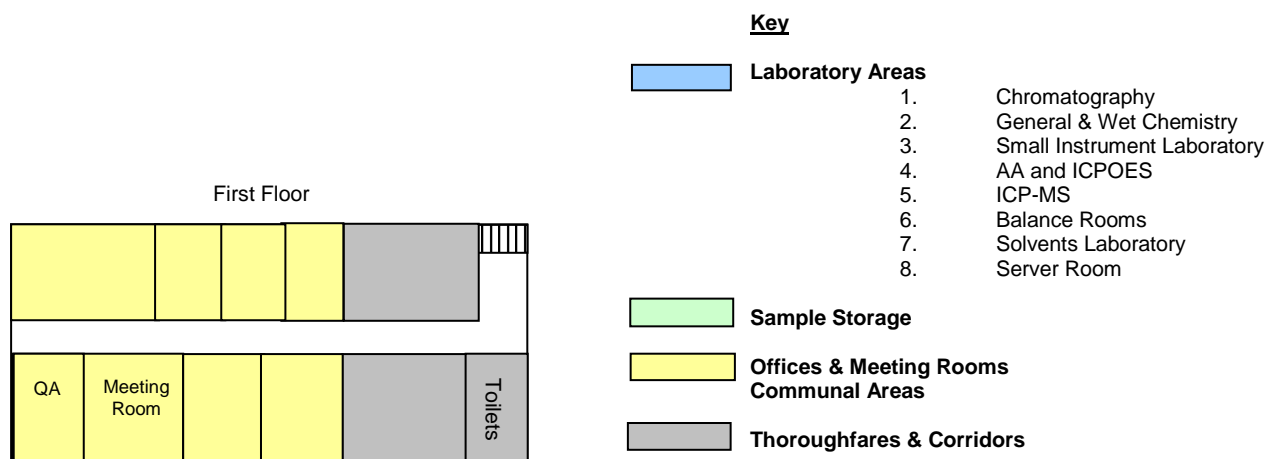
*It is the duty of **all** employees to conform to health and safety policy and safe working practices.*

The Directors of Butterworth Laboratories Ltd give their full support to the implementation of these principles.

Current List of Instrumentation

Gas Chromatograph MS-MS (electron and chemical ionisation)
Gas Chromatographs (with gas sampling valves)
Gas Chromatograph + Headspace Sampler (x6) (FID, TCD and ECD detectors)
HPLC Systems (x5) (various detectors; ultraviolet, refractive Index, fluorescence & diode array)
LC-MS (Liquid Chromatography– Mass Spectrometry)
Ion Chromatograph (x4) (various detectors; conductivity, ultraviolet and pulsed amperometric)
Inductively Coupled Plasma Optical Emission Spectrometer (ICP-OES)
Inductively Coupled Plasma Mass Spectrometer (ICP-MS)
Inductively Coupled Plasma Mass Spectrometer (ICP-MS/MS)
Atomic Absorption Spectrophotometer + Graphite Furnace
UV/Visible Spectrophotometer with reflectance sphere
Fourier Transform Infrared Spectrophotometer (MIR optical Bench)
Carbon Hydrogen Nitrogen (CHN) Elemental Analyser
Autotitrator (x2) (inc Karl-Fischer)
Coulometric Karl Fischer Titrator
Brookfield RVDV-II+ and LVDV-II+ Viscometers
Dissolution Testing Station
Polarimeter
Refractometer
Osmometer
Melting Point Apparatus (Automated)
Bomb Calorimeter
pH/Ion Meter
Hand held pH Meter
Conductivity Meter
Six Figure Balance
Five Figure Analytical Balance (x4)
Top Pan Balance (x3)
Differential Scanning Calorimeter
Moisture Balance
Density Meter
Liquid Counting System (APSS 2000)
Microwave Digester System (x2)
Centrifuge
Multiexact Oxygen Analyser
TOC Analyser

Floor Plan of Laboratories & Offices



Scale: 1:1000

Total Area: Approx. 10,000 sq. ft

Insurance Declaration

Butterworth Laboratories Limited can confirm that it holds Insurance Policies, covering all aspects of services provided by the company.

To confirm that the level of the sums insured for each of the Individual Insurance Policies meet specific Company Requirements, customers should contact John M Gearey, Finance Director and Company Secretary (see Company and Management Details, page 2).