

**POLICY****SIMBEC-ORION**

Occupational Health and Safety Policy Introduction

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# Occupational Health and Safety Policy Introduction

Facilities

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## 1 POLICY MANUAL INTRODUCTION

Simbec-Orion Group Limited including its UK affiliates recognise that it has a responsibility as an employer to ensure the “Health, Safety and Welfare” of all employees whilst at work, (herein called "Simbec Orion Group Ltd") to ensure this policy extends to all other persons not adversely affected by our current work activities. In this way, each and every individual employed by Simbec Orion Group Ltd has a vital and specific role in maintaining our health and safety standard.

Simbec Orion Group Ltd is a clinical research organisation that incorporates Simbec Research Ltd providing clinical research services to both the European and International pharmaceutical industry with its primary medical and laboratory procedures and testing carried out at the Merthyr Tydfil “Simbec House” site located on the Merthyr Tydfil Industrial Park, Merthyr Rd, Pentrebach, Merthyr Tydfil CF48 4DR.

**UK affiliates:** - Orion LR Limited, Simbec Research Limited, Orion Clinical Services Limited, Seirian Laboratories Limited (Dormant), Orion Clinical Services (Australia) Pty Limited (dual-registered)

The scope of this policy lays out the Occupational Health and Safety Management System adopted by Simbec Orion Group Ltd to manage the company’s non-medical areas and staff.

All medical, clinical, laboratory and other technical areas also ensuring patient/volunteers care is professionally managed by Simbec Orion Group Ltd suitably qualified medical managers in compliance with all current clinical medical research legislation at Merthyr Tydfil

This specification provides the overview of the management systems relevant to Simbec Orion Group Ltd along with the responsibilities placed upon members of staff for ensuring continuing Occupational Health and Safety compliance

## 2 HEALTH AND SAFETY POLICY STATEMENT

Simbec Orion Group Ltd recognises that it has a commitment to provide safe and healthy working conditions for the prevention of work-related injury and ill health. The commitment will include eliminating hazards and reducing health and safety risks and to the consultation and participation of workers and workers representatives.

Responsibility for the overall implementation, maintenance and development of our safety management system, however, rests with the senior management of this Simbec Orion Group Ltd, including the regular setting and reviewing of objectives, and the provision of adequate resources to allow those objectives to be achieved.

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It is also the responsibility of senior management within Simbec Orion Group Ltd to ensure that our health and safety policy conforms to all applicable legislation.

Management recognises the importance of its staff and encourages the reporting of any hazard or risk that may adversely affect our health and safety standard. We also recognise the importance of ensuring that staff are adequately trained, informed and supervised to fulfil their activities in a safe manner.

Simbec Orion Group Ltd is committed to a management system that demonstrates a pro-active approach through the continual improvement of our health and safety performance. This is further achieved by the regular setting and reviewing of objectives to achieve compliance to current safety legislation applicable to Simbec Orion Group Ltd, and through matching our industry's best practices.

Simbec Orion Group Ltd also recognises the need for the identification of hazards and the recording and reviewing of risk assessments.

The effectiveness of our health and safety policy and its implementation are subject to regular management reviews and all related processes and procedures are subject to an on-going audit schedule.

### 3 PLANNING

#### 3.1 PLANNING FOR HAZARD IDENTIFICATION, RISK ASSESSMENT AND RISK CONTROL

Ensuring that sufficient resources are made available for the safety system to be fully affective. It is the aim of Simbec Orion Group Ltd to first identify the extent of the risks that are posed by routine and non-routine activities undertaken as part of our own work processes.

The basis for identifying these risks within Simbec Orion Group Ltd is the process of hazard identification, risk assessment and risk control.

Reviews of the risk assessment /safe operating procedures will be completed on an annual basis unless there is a change in the activities, equipment or fabric of the building, which demand that an amendment or new assessment is to be completed.

The results of all risk assessments will be entered on the relevant risk assessment forms and any remedial actions if cannot implemented within a short time highlighted as part of the assessment may be entered onto an action plan; this plan then forms part of Simbec Orion Group Ltd's on-going commitment to the setting and reviewing of occupational health and safety objectives.

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All Action Plans identify the task to be completed, the person responsible for ensuring the task is completed and a deadline date for its completion

### 3.2 LEGAL AND OTHER REQUIREMENTS

Many of the procedures and operations used within Simbec Orion Group Ltd that are included in our risk assessment process have relevant guidance published by external agencies (Health and Safety Executive etc) that will assist Simbec Orion Group Ltd in complying with health and safety legislation

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### 3.3 OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT PROGRAMME

To ensure that nominated tasks are completed against designated target dates it is the responsibility of the designated appointed persons to carry out a review of the actions plans on a regular basis. More frequent reviews (if required) may be delegated to Simbec Orion Group Ltd's health and safety consultant.

Where tasks have been identified as behind the designated time scales, a joint decision between the senior management and its health and safety risk assessor will be made concerning the best corrective action to be taken.

### 3.4 IMPLEMENTATION AND OPERATION

All employees and management members within Simbec Orion Group Ltd have a responsibility for their own safety and the safety of others, specific responsibilities have been assigned to designated personnel within Simbec Orion Group Ltd. This allows us to ensure that the health and safety management system operates in an effective manner.

A communication chart is provided within this policy which outlines the structure within Simbec Orion Group Ltd for the maintenance and development of its safety management system. Although specific responsibilities and authorities may be contained within various procedures in our health and safety manual, the main system responsibilities have been assigned as follows: -

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Has overall responsibility for ensuring that the Health and Safety Management System is formulated, reviewed annually, and provided with sufficient resources in terms of financial, human, time and materials to ensure that it can succeed. GCEO also approves Simbec Orion Group Ltd's Health and Safety Policy and appoints a Management Representative or Designated Appointed Person to implement the management system in line with the Policy. These tasks may be supported by Managing Director – Clinical Pharmacology.

**3.4.1.2 FACILITIES MANAGER (DESIGNATED APPOINTED PERSON)**

Has the overall responsibility for ensuring the success of the Health and Safety Management System through regular review of risk assessment, safe systems and any action plan activities and reporting to the Group Chief Executive Officer and Managing Director – Clinical Pharmacology any variations from the original target dates that may have been set

Takes overall responsibility for ensuring that any health and safety issues or Re-active Objectives are identified, documented and monitored.

Ensures that statutory, mandatory and other health and safety related training is identified, organised and delivered in a timely manner so as to ensure the maintenance of any necessary licensing / certification of individuals.

Ensures that the risk assessment process is completed on an annual basis, or more frequently where changes in the normal activities occur.

Ensures that any non-routine work is effectively controlled through the inspection of method statements and risk assessments, where appropriate, or by other measures that are from time to time implemented.

Ensures correct supervision and control of contractors carrying out work onsite, ensuring they are working safely with the correct safe systems of work in place, if required they may consult the external health and safety advisor with any issues they may have

**3.4.1.3 HEAD OF DEPARTMENT RESPONSIBILITIES (WHEREVER LOCATED)**

Ensure that they meet their welfare and health and safety responsibilities toward employees under their control as far as reasonably practicable

Support the Designated Person by fulfilling their responsibility toward health and safety

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during their employees' daily tasks

Ensure that employees receive all the information and access to health and safety documentation they require to ensure they are carrying out their daily tasks in a safe manner as far as reasonably practicable

#### 3.4.1.4 EMPLOYEE RESPONSIBILITIES (ALL LOCATIONS)

In accordance with Simbec Orion Group Ltd's Health and Safety Policy, all employees have an individual responsibility and duty for:

Making themselves familiar with, and conforming with, Simbec Orion Group Ltd's Health and Safety Policy at all times.

Conforming to the Safety Rules and Safe Systems of Work Procedures at all times, including risk assessments, permit to work systems, inspection and testing etc.

Wearing appropriate safety or protective equipment, personal footwear or clothing and using appropriate safety devices, as specified, at all times.

Making suggestions to improve health and safety in the company if they notice an issue by informing their Departmental Manager or the designated persons.

Reporting without delay all risks or hazards, including defects to machinery, unsafe practices, and "near miss" situations directly to their Departmental Manager.

Reporting without delay any injury suffered as the result of any accident during the course of their work to their immediate supervisor or First Aider as appropriate.

Ensuring that good housekeeping is maintained at all times at their workstation and surrounding area

Taking reasonable care of themselves and other persons who may be affected by their actions whilst at work.

#### 3.4.1.5 HEALTH AND SAFETY CONSULTANT

Has responsibility for advising the designated persons on the health and safety management system giving advice and support ensuring the system is regularly monitored, also advising on any problematic issues/accidents/incidents that are investigated by the designated persons and correct remedial actions

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Ensures that the annual risk assessment process is completed in a timely fashion and any issues arising are entered onto the Remedial Action Plan if required.

Develops and Maintains the Legal Register and advises the Management on any changes that affect the information contained therein.

Advises on all other ongoing relevant aspects of health and safety highlighted by the designated persons

## 4 TRAINING, AWARENESS AND COMPETENCE

Simbec Orion Group Ltd recognises training as a key feature in its on-going program to ensure an effective health and safety management system.

Training provisions within the Simbec Orion Group Ltd are divided into three main areas: -

### Induction Training

This is an internal program covering the general health and safety issues and activities of specific importance to employees which have been recruited / employed within Simbec Orion Group Ltd.

Job / Task Specific - This is an internal or external program where specialist skills or knowledge is required to conduct a specific task or activity.

Refresher - This is an internal or external program where additional training will be provided at specified intervals for updating personnel trained in specific tasks.

As a means of ensuring training needs are identified and that relevant training is sourced either internally or externally, it is the responsibility of the designated appointed person to ensure the ongoing training needs of Simbec Orion Group Ltd are completed in a timely manner

## 5 CONSULTATION AND COMMUNICATION

Due to the overall size of Simbec Orion Group Ltd, consultation and communication of health and safety issues is generally undertaken on an informal basis between the management and the staff. The management recognises the importance of its staff in ensuring that we maintain an adequate safety management system.

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The setting / reviewing of safety objectives is publicised to all members of staff to make sure that all employees within Simbec Orion Group Ltd are involved in the development of the safety management system.

However, where more formal means of communication are required (e.g. accident / incident reports, buildings maintenance etc.), formal reporting procedures exist, and employees are encouraged to report any item they feel may present a potential hazard.

Simbec Orion Group Ltd holds health and safety meetings at periodic intervals to ensure the health and safety system is operating effectively. This meeting provides Simbec Orion Group Limited with a forum to communicate health and safety related topics to all attendees. It also provides a forum for any employees to contribute to the development of Simbec Orion Group Ltd's health and safety system by the publication of minutes which are also on display in the reception area. All personnel within Simbec Orion Group Ltd have a responsibility to ensure they read the minutes and communicate any issues to senior management.

Signs and notices are displayed throughout the main site to provide additional safety related information to all personnel

The GCEO health and safety meeting is held annually between Group Chief Executive Officer, Managing Director of Clinical Pharmacology and Facilities Manager.

## 6 DOCUMENTATION AND DATA CONTROL AND RECORD MANAGEMENT

All documentation held within Simbec Orion Group Ltd's health and safety management system is the responsibility of the designated appointed person. That person is responsible for retaining the "MASTER COPY" of the document and for ensuring that necessary copies are issued to employees or any other interested parties.

Additional reviews of these documents along with any other related guidance / legislation / standards may also be delegated to Simbec Orion Group Ltd's health and safety consultant

Procedures exist within the health and safety manual for the issue, review and revision of all documents and forms relevant to the health and safety management system. Procedures also exist for controlling documents used within Simbec Orion Group Ltd including the retention period and location of documentation

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## 7 OPERATIONAL CONTROL

Procedures and safety working practices are retained in the health and safety manual have been produced to outline the operational and management controls of relevant activities within Simbec Orion Group Ltd, these may include:

- Routine and Non – Routine activities or operations, that may carry a significant risk.
- Activities / Operations that may require the assistance of external agencies (e.g. contractors).
- Building monitoring and maintenance.
- Equipment monitoring and maintenance.

In the majority of instances, the production of any procedures or safe working practice will normally follow the completion of a suitable and sufficient risk assessment.

On occasions, it may be necessary to acquire risk assessments and method statements from a third party. This documentation will be reviewed by Simbec Orion Group Ltd's health and safety consultants.

### 7.1 EMERGENCY PREPAREDNESS AND RESPONSE

The nature of the work activities undertaken within Simbec Orion Group Ltd are such that protracted emergency plans are not necessary and the provisions of C.O.M.A.H. (Control of Major Accident Hazard regulations) do not apply. However, where appropriate, procedures and safe working practices have been developed to address the potential emergency situations that could arise within the Simbec Orion Group Ltd.

## 8 CHECKING AND CORRECTIVE ACTION

### 8.1 PERFORMANCE MANAGEMENT AND MONITORING

The health and safety management system within Simbec Orion Group Ltd allows for both pro-active and re-active monitoring.

Pro-active monitoring within Simbec Orion Group Ltd can be achieved by any of the following means:

- Occupational health and safety risk assessments
- Fire risk assessment – carried out by a competent contracted person
- Monthly Workplace Inspections (if required)
- Periodical Fire Protection Media Inspections – As per company fire logbook

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- Periodic Statutory Inspections (i.e. Portable Appliance Testing, Fixed Electrical Testing, Gas Appliances, etc.).
- Compliance with the various Action Plans (if required)

Re-active monitoring is undertaken following serious accidents or incidents, reports of ill-health or property damage.

It is the responsibility of the designated appointed person to review both aspects of monitoring on a periodical basis as reasonably practicable. This may also be achieved through the assistance of the Simbec Orion Group Ltd's health and safety consultant.

There is no measurement equipment used within Simbec Orion Group Ltd that affects the performance of the health and safety management system.

Measurement of performance therefore focuses on an on-going evaluation of achieving the safety objectives within the timescales agreed and from review of the relevant inspection documentation.

## 8.2 ACCIDENTS, INCIDENTS, NON-CONFORMANCES, CORRECTIVE AND PREVENTIVE ACTION

Procedures exist within Simbec Orion Group Ltd's health and safety policy to ensure that any variations from its policies and any uncontrolled activities are investigated and where appropriate remedial actions are planned and implemented

- Major Accidents / Incidents (These are always investigated and where appropriate reported to the enforcing Authorities – RIDDOR, support from the Health and Safety Advisor may be required)
- Minor Accidents / Incidents (These are only investigated when sufficiently serious to warrant investigation)
- Substantial variations to working practices resulting in dangerous occurrences arising (These are always investigated)

All investigations will be conducted by the designated appointed person with any further assistance provided by Simbec Orion Group Ltd's health and safety consultant

Any remedial actions resulting from the investigation will be recorded on an objective plan form for implementation by the designated appointed person.

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### 8.2.1 CORRECTIVE AND PREVENTITIVE ACTION

The need for corrective action is identified from the Inspection Documentation, Accident / Incident Reports or internal system audits. Where remedial action is required, this action is divided into specific measurable tasks and entered onto the objective plan form. Any corrective actions resulting from management review will be entered onto the management action plan.

The need for preventative action is normally identified through the Risk Assessment Process; it may also be determined via the Remedial Action Plan process.

In both instances, on-going monitoring within Simbec Orion Group Ltd assesses the suitability of the remedial actions taken and the successful implementation of these actions. In both instances the activities are reviewed at management review on an annual basis

It is the responsibility of Simbec Orion Group Ltd's designated persons for maintaining an on-going audit schedule of all aspects of this health and safety policy and ensuring that it is applied across Simbec Orion Group Ltd.

It is the responsibility of the designated appointed person to ensure that audits cover every aspect of the policy at least once per year unless otherwise stated within the policy manual or objectives plan.

The results of all safety audits are reviewed at management review on at least an annual basis

## 8.3 MANAGEMENT REVIEW

### 8.3.1 PURPOSE OF THE REVIEW

It is the responsibility of the designated appointed person to ensure that annual Health and Safety Review Meetings are conducted at least annually and that all key personnel attend. The persons to be present at these meetings are: -

The Chief Executive Officer (if required)

Managing Director (Clinical Pharmacology) (if required)

The Designated Appointed Person | The Relevant Departmental Heads (if required)

The Health and Safety Consultant (if required)

Any Other Person Co-opted to assist in the maintenance and development of Simbec Orion Group Ltd's health and safety management system (if required)

The review meeting determines the successful implementation of the health and safety management system and is the main forum for the discussion of any system objectives

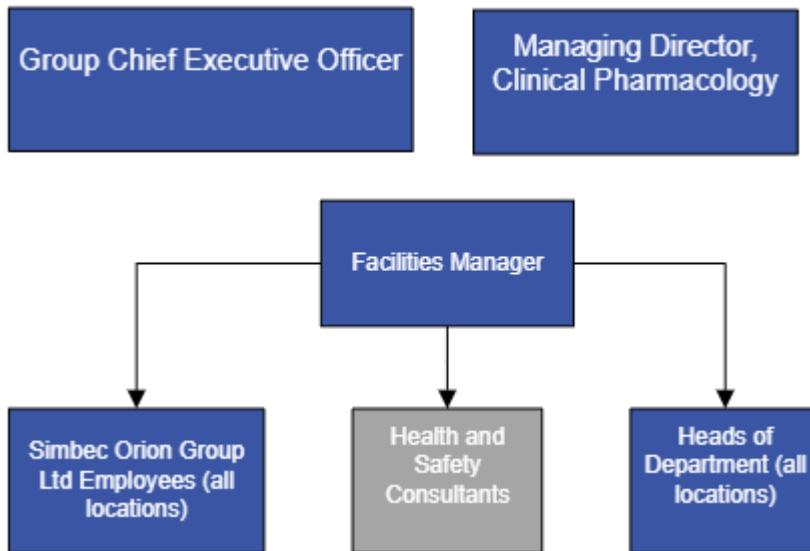
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## 9 HEALTH AND SAFETY COMMUNICATION STRUCTURE



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Document Number	Document Title
N/A	N/A

**11 PREVIOUS VERSION HISTORY**

Previous Version	Current Version	Details of change
1.0	2.0	Uploaded to new template
2.0	3.0	Classification change to draft to effective in order to trigger periodic review. Document number changed from POL-00086 to POL-00233 as a consequence. Some formatting and meta data corrections implemented
2.0	3.0	Undertake changes at the request of ISO 45001 audit

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## Document Approvals

Approved Date: 10 Dec 2025

Task: Approvers Approval Verdict: Approve changes & release Approval to be made Effective	Jonathan Womack, (Jonathan.Womack@simbecorion.com) Approver 10-Dec-2025 08:34:40 GMT+0000
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Task: QA Approval Verdict: Approve changes & release QA Approval to be made Effective	Anne Hall, (anne.hall@simbecorion.com) QA Approver 10-Dec-2025 16:18:00 GMT+0000