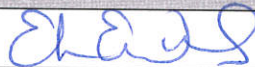


Name	Title	Date	Signature
Emma Ewins	Site Director	23mar17	
Elaine Davies	EHS Coordinator	22 mar 17	E. Davis

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## 1. Objective

This Manual defines the BTG Wales Environmental Management System (EMS) activities and contains:

- The site Environmental Policy;
- Statements of responsibility and authority;
- An overview of the company's environmental procedures and controls;
- The identification of the resources and training allocated to management, performance of work and verification activities including internal audit;
- The role of the Environmental Health and Safety Coordinator, and
- The arrangement for periodic management reviews.

The purpose of this Manual is to demonstrate that this EMS meets all ISO 14001:2004 requirements and provide guidance and direction for the implementation and operation of the EMS to all personnel including all relevant documents.

## 2. Scope

The scope of the EMS applies to the activities related to the business activities undertaken by BTG Wales and the locations and areas to be covered in the EMS.

## 3. Definitions / Abbreviations

Term/Abbreviation	Description
Auditor	Person with the competence to conduct an audit
Continual Improvement	Recurring process of enhancing the environmental management system in order to achieve improvements in overall environmental performance consistent with the organisation's environmental policy.
Corrective Action	Action to eliminate the cause of a detected nonconformity.
Document	Information and its supporting media
Environment	Surroundings in which an organisation operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.
Environmental Aspect (EA)	Elements of an organisation's activities or products or services that can interact with the environment.
Environmental Impact	Any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organisation's environmental aspects.
Environmental Management System (EMS)	Part of an organisation's management system used to develop and implement its environmental policy and manage its environmental aspects.
Environmental Objective	Overall environmental goal, consistent with the environmental policy, that an organisation sets itself to achieve.
Environmental Performance	Measurable results of an organisation's management of its environmental aspects.
Environmental Policy	Overall intentions and directions of an organisation related to its environmental performance as formally expressed by top management.



Term/Abbreviation	Description
Environmental Target	Detailed performance requirement applicable to the organisation or parts thereof, that arises from the environmental objectives and that needs to be set and met in order to achieve those objectives.
Interested Party	Person or group concerned with or affected by the environmental performance of an organisation.
Internal Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the environmental management system audit criteria set by the organization are fulfilled.
Nonconformity	Non-fulfilment of a requirement.
Organisation	BTG Wales (Protherics UK Ltd)
Preventive Action	Action to eliminate the cause of a potential nonconformity.
Prevention of Pollution	Use of processes, practices, techniques, materials, products, services or energy to avoid, reduce or control (separately or in combination) the creation, emission or discharge of any type of pollutants or waste, in order to reduce adverse environmental impacts.
Procedure	Specified way to carry out an activity or a process.
Record	Document stating results achieved or providing evidence of activities performed.

#### 4. Associated Documents

4.1 See appendix 1

#### 5. References

N/A

#### 6. Revision History

- 6.1 All reference to 'Protherics UK Ltd' replaced with 'BTG Wales'
- 6.2 Minor grammatical changes throughout the document.
- 6.3 Names replaced with specific job titles.

#### 7. Environment, Health and Safety

N/A

#### 8. Process Flow Map

8.1 Ref 10.1

## 9. Policy

### 9.1. BTG Wales– Environmental Policy

9.1.1. BTG Wales is a manufacturing site producing specialized highly purified polyclonal antibodies for acute medical emergency applications, notably CroFab™ and DigiFab™.

9.1.2. BTG Wales is a professional and environmentally conscious organization, which acknowledges the impact that our operations may potentially have on the environment. The clear objective of BTG Wales is to minimise any impact on the Environment by:

- Preventing pollution, reducing waste and ensuring, wherever practicable, that measures are implemented to protect and preserve natural habitats, flora and fauna.
- On-going continual improvement of environmental management systems and performance.
- Consider the effects that our operations may have on the local community
- Taking action to eliminate or reduce, as far as reasonably practicable, any potentially adverse environmental aspects.
- Promoting environmental awareness amongst our staff, suppliers, contractors and partners by implementation of operational procedures and the monitoring of performance against specific environmental targets.
- Promoting the increase in recycling methods, in particular, the recycling of water used as part of the manufacturing process.
- Seeking to work in partnership with the community by behaving in a considerate and socially responsible manner.
- Ensuring effective and expedient incident control, investigation and reporting.

9.1.3. Managers and supervisory staff have responsibilities for the implementation of the policy and must ensure that environmental issues are given adequate consideration in the planning and day to day supervision of all work.

9.1.4. BTG Wales will fully comply with the duties placed upon it within the requirements of legislation, whilst at all times complying with, as a matter of best practice, the requirements and duties set out within approved guidance as issued by the Natural Resources Wales (NRW) and other organisations. As part of the company's commitment to maintaining the highest levels of environmental management, it is the intention that the company will work towards the implementation and maintenance of an environmental management system compliant with ISO14001.

In recognition of the importance that BTG Wales places on Environmental matters, the company created the role of Environmental, Health and Safety coordinator whose environmental responsibilities will include:

- Implementing and maintaining the Environmental Management System;
- Keeping the Environmental Policy up to date;
- Coordinating environmental improvements;
- Monitoring environmental performance and competence;

Owner(s): Trystan Johns



- Communicating on all environmental issues, both internal and external;
- Keeping staff aware of environmental responsibilities, commitments, roles, authorities and environmental performance;
- Reporting to senior management on the organisation's environmental performance and the effectiveness of its Environmental Management System.

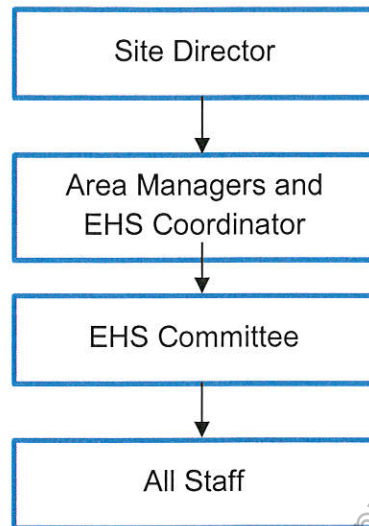
9.1.5. All employees and sub-contractors are expected to co-operate and assist in the implementation of this policy, whilst ensuring that their own works, so far as reasonably practicable, are carried out without risk to themselves, others or the environment. This includes co-operating with management on any environment related matter.

9.1.6. BTG Wales will take all practical steps to ensure that potential hazards and risks to the environment are identified and that suitable and effective preventative and corrective control measures are implemented. All employees will be provided with the necessary resources, equipment, information, instruction and training to fulfil the requirements of this policy.

9.1.7. The Site Director has overall responsibility for all environmental matters on the Wales site. The operation of this policy and the associated procedures will be monitored and reviewed on a regular basis to ensure they remain current and applicable to the company's activities, both locally and globally. This policy has been endorsed by the Site Director and the local management team which gives its full support to its implementation.

## 10. Organisation

### 10.1. EMS Organisation Chart



### 10.2. Responsibility

#### 10.2.1. Site Director

The Site Director is responsible for:

- Endorsing the Environmental Policy;
- Ensuring appropriate resource allocation to enable the effective operation and continual improvement of the EMS.

#### 10.2.2. Environmental, Health and Safety Coordinator (EHSC)

The EHSC has the responsibility and authority for:

- Ensuring that EMS requirements are established, implemented and maintained in accordance with the ISO 14001 standard;
- Ensuring that sufficient resources are allocated for the proper implementation of the environmental policy and the EMS;
- Regularly reviewing the policy and the effectiveness of the EMS, and ensuring that the necessary changes are made.
- The EHSC is also the Chairperson of the EHS Committee and has the responsibility and authority for:
  - leading the EHS Committee to establish and implement the EMS according to ISO 14001 standard, and monitoring the performance of the EMS;
  - coordinating internal EMS audits to ensure the EMS has been properly implemented and maintained;
  - handling and investigating nonconformity and ensuring corrective and preventive action has been taken to mitigate any impacts caused;



- Reporting on the performance of the EMS to the Site Director for review and as a basis for improvement of the EMS.

The EHSC, the EHS Committee and Site Director shall undertake the EMS management review annually to ensure management commitment and integration of the EMS with business strategies for its implementation and continual improvement.

#### 10.2.3. Environmental, Health and Safety Committee (EHS Committee)

The Committee is responsible for:

- The establishment and implementation of the EMS;
- The establishment and review of objectives, targets, and programmes;
- Ensuring the effective implementation of environmentally-related operational controls and programmes;
- The internal communication of environmental matters between management and employees; and promoting environmental awareness among company staff;
- The review of complaint records, nonconformity, corrective action and preventive action reports and the adoption of preventive actions as necessary;
- Providing leadership in the pursuit of environmental issues;
- Any other EMS activities that are assigned by the EMR;
- Holding regular meetings.

#### 10.2.4. Management EHS Operations Review Committee

The Committee systematically examines the EMS to ensure the suitability, adequacy and effectiveness of the EMS. The Committee comprises of the Site Director, EHSC, and designated area Managers. This committee will meet on a monthly basis and minutes are recorded. A more detailed annual review will take place in January of every year.

#### 10.2.5. Area Manager

The Area Managers are responsible for:

- Establishing controls for the identified significant environmental aspects for his/her function department according to procedures and instructions;
- Ensuring that the EMS is properly implemented and that environmental matters are properly handled at all stages.

#### 10.2.6. All Employees

All employees are responsible for:

- Working in accordance with the documented environmental procedures and instructions, specific responsibilities defined in individual procedures and instructions; and
- Reporting problems or deviations associated with environmental issues and the EMS to the EHS Committee via the established EHS reporting system.

## 11. Environmental Management System Requirements

The EMS of BTG Wales is developed to manage significant environmental aspects so as to limit their impacts on the environment. The EMS is established in accordance with ISO 14001, and is described in this section. Procedures for each component are given in the relevant Environmental Health and Safety Procedures (EHSPs) listed in Appendix A.

### 11.1. Environmental Management System Documents

11.1.1. The purposes of these EMS documents are as follows:

<b>Environmental Policy</b>	Describes the intention and principles to be adopted in relation to environmental performance, including but not limited to legal compliance, continual improvements and pollution prevention for the Wales site.
<b>Environmental Management System Manual (EMS Manual)</b>	Describes the environmental management system and outlines how the requirements of the International Standard (ISO 14001) are achieved. A cross-reference of the ISO 14001 clauses to the sections of this Manual is listed in Appendix A.
<b>Objective(s)*</b>	The overall environmental goals that BTG Wales set to achieve.
<b>Target(s)*</b>	The set of measurable performance requirements that BTG Wales establishes to achieve the objectives.
<b>Programme(s)*</b>	The programme and schedule which BTG Wales implements to achieve the objectives and targets.
<b>Environmental Health and Safety Policies (EHSPS)</b>	Define the roles, responsibilities, and actions to be taken to ensure that activities are performed and the EMS implemented in accordance with the environmental policy and the requirements of ISO 14001. A cross-reference of the ISO 14001 clauses to the EHSPs is listed in Appendix A
<b>Register of Environmental Aspects</b>	Compiles the environmental aspects that are derived from the activities and services of BTG Wales. The register also denotes the significance of the environmental aspects and the respective operational controls for significant environmental aspects.
<b>Register of Legal and Other Requirements</b>	Compiles the legal and other requirements, which include legislation, codes of practice, regulatory and non-regulatory guidelines that are applicable to BTG Wales.
<b>Environmental Health and Safety Procedures Instructions (EHSP)</b>	Describe which and how activities should be performed to manage significant environmental aspects and to achieve the EMS ISO 14001 requirements.
<b>Environmental Health and Safety Records (EHSR)</b>	Record information for the audit trail and the assessment of environmental conditions and performance.

\* Objectives and Targets, and associated Programmes are provided as a single document.



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## 11.2. Environmental Policy

(ISO 14001 Standard Clause 4.2)

- 11.2.1. The environmental policy of BTG Wales is included in Section 2 of this document. It outlines the environmental commitments of BTG Wales with respect to its operations, activities, and overall environmental performance. During the development of this policy, the appropriateness to the nature, scale and environmental impacts of BTG Wales activities, products and services has been considered. The policy is endorsed by the Site Director and the policy shall be reviewed during the management review meeting.
- 11.2.2. The policy shall stipulate the commitments of BTG Wales to continually improve its environmental management and prevention of pollution. BTG Wales is also committed to comply with applicable legal requirements and other requirements to which BTG Wales subscribes which relate to its environmental aspects. The environmental policy shall provide a framework for setting and reviewing objectives and targets, and must be maintained, implemented and communicated to all employees of BTG Wales and its contractors.

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## 11.3. Planning

- 11.3.1. BTG Wales shall follow a “plan-do-check-act” process to facilitate continual environmental performance improvements. The planning process includes the identification and updating of BTG Wales Register of Environmental Aspects, and the Register of Legal and Other Requirements. Together with BTG Wales environmental policy, BTG Wales objectives and targets are established, and appropriate programmes are formulated to achieve the objectives and targets.

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## 11.4. Environmental Aspects

(ISO 14001 Standard Clause 4.3.1)

- 11.4.1. The planning process commences with the identification and updating of environmental aspects. In order to evaluate the impacts of its activities to the environment, BTG Wales shall establish, implement and maintain a procedure to identify the environmental aspects of its activities, products or services that it can control and those that it can influence taking into account planned or new developments, or new or modified activities, products and services. These aspects, inclusive of those arising from works carried out by contractors, are registered in the "Register of Environmental Aspects – Legal Compliance Manager Database".
- 11.4.2. BTG Wales shall ensure that all environmental aspects that may pose significant impacts to the environment are under control and prioritised for improvements.
- 11.4.3. BTG Wales shall keep this information up-to-date.
- 11.4.4. Relevant procedure: EHSP 8.035 Environmental Aspects (Legal Compliance Manager)

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### 11.5. Legal and Other Requirements

(ISO 14001 Standard Clause 4.3.2)

- 11.5.1. BTG Wales shall establish, implement and maintain a procedure to identify and maintain access to legal requirements that are relevant to the company, as well as other requirements that the company subscribes to which relates to the company's environmental aspects
- 11.5.2. BTG Wales shall identify all relevant regulations, codes of practice and guidelines that are applicable to the environmental aspects of its activities, products and services, and record this information in the online Legal Compliance Manager database.
- 11.5.3. BTG Wales shall keep this information up-to-date.
- 11.5.4. Relevant procedure : EHSP 8.035 – Environmental Aspects (Legal Compliance Manager)

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### 11.6. Objectives, Targets and Programme(s)

(ISO 14001 Standard Clause 4.3.3)

- 11.6.1. Based on the environmental policy and significant environmental aspects, environmental objectives and targets shall be established, implemented and maintained at each function and level within BTG Wales. Programmes are established, implemented and maintained for achieving its objectives and targets.
- 11.6.2. When establishing and reviewing its objectives, BTG Wales shall take into consideration the legal and other requirements, significant environmental aspects, technological options, financial/operational/business requirements, and the views of interested parties, and ensure that the objectives and targets are consistent with the environmental policy, including commitment to pollution prevention, to compliance with applicable legal requirements and other requirements, and to continual improvement.
- 11.6.3. The programmes designate the responsibility for achieving objectives and targets at each function and level of the company, together with the means and time frame by which they are to be achieved.
- 11.6.4. The Site Director shall approve the objectives, targets and programmes proposed by the EHS Committee before implementation. The EHSC shall ensure that the objectives and targets are measurable where possible, and that the progress towards achieving the objectives and targets is continually monitored and reviewed.
- 11.6.5. The achievement of objectives, targets and programmes shall be reviewed by the EHS Committee every month. The EHSC shall lead the EHS Committee in revising the objectives, targets and programmes as necessary.
- 11.6.6. BTG Wales shall ensure that the programmes are amended as appropriate for new projects and new or modified activities, products or services in order to ensure that environmental management applies to such projects and activities.



11.6.7. In the event that objectives and targets in the programmes are not met, the EHSC shall revise the programme as necessary and maintain documented evidence/records for the actions taken to mitigate the problems.

11.6.8. The EHSC shall also maintain obsolete objectives, targets and programmes as an EMS record for three years.

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## 11.7. Implementation and Operation

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11.7.1. The implementation of the EMS requires BTG Wales to clearly define roles, responsibilities and authorities of key personnel, commit to staff training, maintain effective communication channels, adopt effective document and operational controls, and maintain sufficient awareness on emergency preparedness among the staff.

### 11.7.2. Resources, Roles, Responsibility and Authority

(ISO 14001 Standard Clause 4.4.1)

Senior management of BTG Wales shall commit to provide resources (including human resources and specialized skills, organisational infrastructure, technological and financial resources) essential to the implementation and control of the EMS. The roles, responsibilities and authorities of key personnel shall be defined, documented, and communicated in order to facilitate effective environmental management.

BTG Wales has appointed an Environmental Health and Safety Coordinator (EHSC) for the implementation and maintenance of the EMS. Other employees within the Site Services Department have specific environmental responsibilities.

### 11.7.3. Communication

(ISO 14001 Standard Clause 4.4.3)

For internal communication, the EHSC shall ensure information regarding the EMS (such as the policy, objectives, targets and programmes) and environmental performance is readily available to employees on notice board, or is published on the intranet or newsletters.

Employees with enquiries/complaints regarding to the EMS and/or environmental issues of BTG Wales shall inform their area Manager. The designated member of EHS Committee representing each area shall maintain a log for the relevant enquiries/complaints. Depending on the nature and scope of the enquiry/complaint, the EHSC shall determine the corresponding action and maintain relevant records to demonstrate the response/corrective actions taken.

It is the decision of the company not to communicate externally about its significant Environmental Aspects, unless required to do so by legislative act

Relevant procedure: EHSP 8.016 – Off-Site Environmental Complaints

#### 11.7.4. Documentation

(ISO 14001 Standard Clause 4.4.4)

The Environmental Management System documentation encompasses four levels as described below:

The first level is the Environmental Management System Manual (this document) which includes environmental policy (specifying the principal objectives and environmental commitments of BTG Wales, and a broad description of how BTG Wales addresses the ISO 14001 requirements. The EMS Manual serves as an interface to interpret the relationship between BTG Wales's EMS and the ISO 14001 Standard. Objectives, Targets and Programmes are developed based on the company's environmental policy. It demonstrates the company's environmental commitment on continual improvement in environmental performance.

The second level is the Environmental Health and Safety Policies (EHSPs), which include all procedures that BTG Wales shall follow as specified in the ISO 14001 Standard. These procedures provide a detailed description of the EMS elements and define who should do what, how and when. Appendix A shows the relationship between various environmental procedures and the ISO 14001 Standard clauses. Register of Environmental Aspects, and Register of Legal and Other Requirements are derived from the procedures and act as the foundation of the EMS which the company has subscribed too.

The third level is the Environmental Health and Safety Procedures (EHSP's), which are operational control procedures or instructions, with defined responsibilities, to control the identified significant environmental aspects associated with BTG Wales's operations and activities.

The fourth level is Environmental Health and Safety Records, (EHSR's) which arise from the implementation of the Environmental Management System Manual, Environmental Procedures and Environmental Instructions. Environmental Records include various checklists, reports and meeting records, etc., as defined in each Environmental Procedure and Environmental Instruction.

#### 11.7.5. Control of Documents

(ISO 14001 Standard Clause 4.4.5)

The essences of EMS documentation controls are:

- they shall be reviewed, revised as necessary and approved for adequacy by authorised personnel;
- that current version of relevant documents shall be available at all locations where operations essential to the effective functioning of the environmental management system are performed;
- that documents of external origin determined by the organization to be necessary for the planning and operation of the EMS are identified and their distribution controlled;
- obsolete documents shall be promptly removed from all points of issue and use, or are otherwise assured against unintended use; and
- any obsolete documents retained for legal and/or knowledge preservation purposes shall be suitably identified.

BTG Wales shall ensure that documentation is legible, dated (with dates of revision) and readily identifiable, maintained in an orderly manner, and retained for a specified period. BTG Wales shall establish, implement and maintain a procedure for the creation and modification of the various types of documents and the respective responsibilities for such creation and modifications.

Owner(s): Trystan Johns



#### 11.7.6. Operational Control

(ISO 14001 Standard Clause 4.4.6)

BTG Wales shall establish, implement and maintain operation control procedures to manage its significant environmental aspects.

BTG Wales shall ensure that all operations and activities, carried out by BTG Wales employees or contractors that are associated with the significant aspects are properly controlled, and that appropriate operational control procedures, in terms of Environmental Health and Safety Procedures (EHSP) and Environmental Health and Safety Records (EHSR), are communicated to personnel whose tasks may result in significant environmental aspects. BTG Wales shall influence its staff and contractors by communicating its environmental policy and other relevant EHSP and/or EHSR to them.

#### 11.7.7. Emergency Preparedness and Response

(ISO 14001 Standard Clause 4.4.7)

BTG Wales shall establish, implement and maintain a procedure to identify potential emergency situations and responses to such situations in order to prevent and/or mitigate environmental impacts that may associate with them.

BTG Wales shall review and revise its emergency preparedness and response procedures, in particular after the occurrence of accidents or emergency situations.

BTG Wales shall also periodically test the procedure and the preparedness where practicable.

Relevant procedure: EHSP 8.005 - Emergency Preparedness and Response

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### 11.8. Checking

11.8.1. While implementing the EMS, BTG Wales shall monitor and measure the key characteristics of its operations and activities on a regular basis. These results shall be recorded together with nonconformity and the corrective action and preventive action. As part of the checking process, a periodic audit on the EMS shall provide a basis for management review.

11.8.2. Carbon monitoring will take the raw data from energy usage, transport and fuel costs which will be entered in Carbon footprint Ltd self-assessment webpage and calculated accordingly. This carbon footprint result will be monitored annually and objectives to reduce and offset decided upon at the annual review meeting

#### 11.8.3. Monitoring and Measurement

(ISO 14001 Standard Clause 4.5.1)

BTG Wales shall establish, implement and maintain procedures to monitor and measure, on a regular basis, the key characteristics of its operations and activities that have significant impacts on the environment. This shall include procedures for tracking of performance, applicable operational controls and conformity with the company's objectives and targets, as well as the calibration and maintenance of monitoring equipment. The information of environmental monitoring shall be documenting.

Owner(s): Trystan Johns

Relevant procedure: EHSP 8.043 - Environmental Monitoring and Evaluation of Compliance.

#### 11.8.4. Evaluation of Compliance

(ISO 14001 Standard Clause 4.5.2)

To meet the company's commitment to compliance, BTG Wales shall regularly monitor and evaluate the compliance status of the applicable environmental legal requirements (section 4.5.2.1) and other requirements (section 4.5.2.2) that the company subscribes to. The records of the results of the periodic evaluations shall be retained.

#### 11.8.5. Nonconformity, Corrective Action and Preventive Action

(ISO 14001 Standard Clause 4.5.3)

Continual improvement of the EMS can be achieved by identifying nonconformity, correcting nonconformity, and preventing nonconformity from occurring again. Regarding nonconformity and its subsequent corrective / preventive action, BTG Wales shall establish, implement and maintain a procedure which defines the responsibilities and authorities to:

- handle and investigate nonconformity;
- take action to mitigate the impacts caused;
- initiate and complete corrective and preventive actions;
- ensure that the corrective or preventive actions taken to eliminate the causes of actual and potential nonconformity are appropriate to the magnitude of problems and commensurate with the environmental impacts encountered;
- record the results of corrective and prevention actions taken;
- review the effectiveness of corrective action and preventive action taken;
- Implement and record any changes in the documented procedures resulting from corrective and preventive action.

BTG Wales shall also ensure that any necessary changes are made to environmental management documentation.

Relevant procedure: EHSP 8.026 - Accident and Incident Reporting Process

#### 11.8.6. Control of Records

(ISO 14001 Standard Clause 4.5.4)

Records shall be maintained to keep track of BTG Wales's environmental performance, to demonstrate conformity to the requirements of the EMS, legal compliance, and to maintain audit trails in accordance with the requirements of ISO 14001 Standard, and the results achieved.

BTG Wales shall establish, implement and maintain a procedure to denote the identification, storage, protection, retrieval, retention and disposition of environmental records, to ensure that such records



are legible, identifiable, and traceable to the activity, product or service involved, and that they are stored and maintained in such a way that they are readily retrievable and protected against damage, deterioration or loss. The retention period of each type of environmental records shall be specified.

#### 11.8.7. Internal Audit

(ISO 14001 Standard Clause 4.5.5)

BTG Wales shall plan, establish, implement and maintain a programme and procedures to carry out periodic environmental management system audits to:

- Determine whether or not the environmental management system:
  - conforms to planned arrangements for environmental management including the requirements of ISO 14001; and
  - has been properly implemented and maintained;
- Provide audit results and information for management review for environmental improvement.

The audit programme, including the schedule, shall be based on the environmental importance of the activities concerned and results from previous audits. The audit procedures cover the audit criteria, scope, frequency and methods, as well as responsibilities and requirements for conducting audits and reporting results and retaining associated records.

BTG Wales shall conduct EMS audits on a regular basis. Timely site environmental audits are required to ensure appropriate preventive actions being taken as planned, and corrective actions being carried out on a timely basis.

Relevant procedure: EHSP 8.032 - Internal Audit

#### 11.8.8. Management Review

(ISO 14001 Standard Clause 4.6)

The “plan-do-check-act” cycle shall require the top management of BTG Wales to act and review the environmental management system periodically to ensure its suitability, adequacy and effectiveness.

Before the review, the EHSC shall schedule for the management review and inform all the participants, and gather all relevant records/requirements (such as change in legal requirements) and prepare a summary report (if necessary) for discussion.

The Site Director, EHSC and area Managers shall take part in the annual management review. They shall assess the work done in the past year in environmental management and evaluate the existing EMS with respect to changes in legislation, concerns of interested parties, current and planned business activities, technology and product requirements, and lessons gained from previous experience, etc.

Topics to be discussed in the management review shall include but not be limited to:

- review of the environmental policy, objectives, targets, and programmes;
- review of legal compliance and compliance with other requirements (including contractor compliance on BTG Wales’s activities);
- environmental aspects of activities and their disclosure to public;
- findings of the internal audits;

- review of nonconformities and the status of corrective/preventive actions;
- communications from external interested parties, including complaints;
- areas for improvement with respect to environmental performance;
- adequacy of emergency preparedness and response;
- changing circumstances, including developments in legal and other requirements related to its environmental aspects,
- identify the need for modification of the existing EMS in light of the above items.
- Follow-up action from previous management reviews.

The review shall initiate a new “plan-do-check-act” cycle with improvements in BTG Wales’s environmental performance and further enhancement of the EMS.

Findings from the management review shall be recorded in the meeting minutes and the EHSC shall retain it as an EMS record. Maintenance of the records shall be in accordance with.



## 12. Appendix 1 - Cross Reference of ISO 14001 Requirements\* and Sections in the EMS Manual and Environmental Procedures

ISO Clause		EMS Manual Section	EHSP Ref. No.
4.1	General Requirements	4.1	EHSPS 015
4.2	Environmental Policy	4.2.	POL-EHS-007
4.3	Planning	4.3	EHSPS 015, EHSP 8.035,
4.3.1	Environmental Aspects	4.3.1	EHSP 8.035
4.3.2	Legal and Other Requirements	4.3.2	EHSP 8.035
4.3.3	Objectives, Targets and Programme(s)	4.3.3	POL-EHS-007 EHSP 8.035
4.4	Implementation and Operation	4.4	EHSPS 015
4.4.1	Resources, Roles, Responsibility and Authority	4.4.1	EHSPS 015
4.4.2	Competence, Training, and Awareness	4.4.2	Appraisal system
4.4.3	Communication	4.4.3	EHSPS 015, EHSP 8.016
4.4.4	Documentation	4.4.4	EHSP 8.040
4.4.5	Control of Documents	4.4.5	EHSP 8.040
4.4.6	Operational Control	4.4.6	All SOP, Risk Assessments
4.4.7	Emergency Preparedness and Response	4.4.7	EHSP 8.034
4.5	Checking	4.5	EHSPS 015
4.5.1	Monitoring and Measurement	4.5.1	EHSPS 015
4.5.2	Evaluation of Compliance	4.5.2	EHSP 8.043
4.5.3	Nonconformity, Corrective Action and Preventive Action	4.5.3	EHSP 8.026
4.5.4	Control of Records	4.5.4	EHSP 8.040
4.5.5	Internal Audit	4.5.5	EHSP 8.032
4.6	Management Review	4.6	EHSPS 015

\* ISO 14001:2004 is referred.

## 13. Appendix 2: Water Discharge Consent

PROTHERICS UK LTD (BTG Wales)  
BLAENWAUN  
FFOSTRASOL  
LLANDYSUL  
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### 13.1. Introduction – Waste Water

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- 13.1.1. There is discharge consent for waste water [Consent No: BPO281501/Schedule No: BPO281501/01].
- 13.1.2. The discharge consent has not been used extensively since it was issued. It is now proposed to direct waste-water to the stream, as per the Consent.
- 13.1.3. The stream is identified as Afon Cwerchyr, and the discharge point is noted as SN 3670 4637.
- 13.1.4. The discharge will be limited to 50 m3 per day, and the rate of flow will not exceed 0.6 litres per second.
- 13.1.5. Analysis has shown that the waste-water has a COD of 14 mg/l, and contains <0.1 mg/l of Ammoniacal Nitrogen and <10 mg/l of suspended solids. pH is analysed at 6.6. All other elements are at very low levels.
- 13.1.6. Analyses will be undertaken annually, unless there is a material change to the qualities and characteristics of the waste-water.
- 13.1.7. The flow of waste-water will be monitored and recorded by the sites' environmental services personnel. To assist this monitoring and recording, a flow meter will be installed to MCERTS standards.

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### 13.2. Water Volumes

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- 13.2.1. The volume of discharge will normally be approximately 21 M3 per day, but may occasionally rise to 50 M3 per day. The processes by which the water originates are continuous; therefore the flow at maximum would amount to less than 0.6 litres per second.
- 13.2.2. The water derives from a non-contact aspect of production [it does not come into contact with the pharmaceutical products]. It is currently incorporated into the effluent system, but this is seen as inefficient as it increases the volumes of effluent to be disposed of.
- 13.2.3. When the discharge consent is issued, the water will be diverted away from the effluent stream and directed to the discharge point indicated on the accompanying plans.
- 13.2.4. An MCERTS qualified contractor has been engaged to inspect, install and maintain the flow meter.



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### 13.3. Water Quality

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- 13.3.1. The analytical report includes 2 samples, labelled Sample 1 [Sample Number 79193] and Sample 2 [Sample Number 79194]. The samples were taken several hours apart, but describe consistent characteristics.
- 13.3.2. Generally, the critical elements are of a low order, and as such are unlikely to cause any significant impact on the stream to which they are directed.
- 13.3.3. Because of the very low occurrence of deleterious elements, there is unlikely to be any adverse effects on the flora and fauna associated with Afon Cwerchyr
- 13.3.4. Samples will be taken at regular intervals [not greater than 12 months] to ensure that the water quality remains within any limits defined by Natural Resources Wales.
- 13.3.5. Records of flow and water quality monitoring will be kept on-site and available for inspection.

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### 13.4. Access to the Discharge Point

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- 13.4.1. Access to the discharge point is via a gated path, with firm standing.
- 13.4.2. The path should be kept clear of debris, and maintained in a safe condition for pedestrian access.