Milieu & ISO Policy parts from: Business Manual Bilthoven Biologicals

1 Scope and objective

This Business Manual describes the business processes in use by Bilthoven Biologicals B.V.
The Business Manual together with the Site Master File serves as a guide to get acquainted with Bilthoven Biologicals B.V. main principles and core business regarding processes and quality.
Bilthoven Biologicals B.V. is ISO 9001, 14001 and GMP certified and in implementation phase for PEF (Poliovirus-essential facility) certification, with an integrated quality management system that is based on EU guidelines, WHO and ISO standards.
Activities with impact on the environments is allowed under conditions of an area-wide environmental permit. One of the conditions is to maintain a environmental management system following ISO_14001 standards. At the Poonawalla science park, this is given substance by the mandatory follow-up of the area specific KAM-rule.

2.3 Vision

We operate safely in a high quality production facility to reliably meet the global demand. We are the European Hub and knowledge center within the Poonawalla Group. We take responsibility for the community and the environment.

To deliver our high quality products and services, we need to comply to the most up-to-date law and regulation. We adopted policies and guidelines to guarantee the safety, quality and integrity of our products, processes and employees. To achieve this, we believe in our BBio Values: Ownership, Deliver, Collaborate, Positivity and Agility. Our Code of Conduct describes how both our employees and our customers and suppliers collaborate together in an ethical and responsible manner.

We deliver on our promise of providing vaccines for a better world.

2.4 Quality Statement

As part of the Cyrus Poonawalla Group, BBio embraces the quality statement of the parent company Serum Institute India:

We, at Serum Institute Of India Private Ltd., the largest manufacturer of immunobiologicals and Anticancer products in India, believe that consistent Quality products of International Standards are produced by Quality people through latest technology, process automation, cGMP, regulatory requirements and training.
We are always working collectively to produce, distribute and make available immunobiologicals, which are safe, potent and efficacious, for our customers, especially children of the world.

2.5 Bio Risk Management Statement

This statement is based upon the Bio Risk Statement of Cyrus Poonawalla Group with adjustment to fit BBio.

BBio will collectively:

- Set overall bio-risk management objectives to develop procedures, implement and maintain management standards and systems, in order to meet regulatory and industry standards and ensure continuous improvement of our EHS performance.
- Operate our business in an environmentally and socially responsible manner, enabling us to identify, monitor, assess and manage environmental, health and (bio)safety/security (EHS) hazards and associated risks.
- Ensure that Environment Health and (bio)Safety/Security is an integral part of our decision-making process associated with plants, equipment, machines and materials as well as selection and placement of personnel.
- Provide adequate training and instruction for employees / contractors / partners and suppliers to ensure we live up to our commitment, responsibility and accountability to the environment and to ensure the health and safety of those involved

- Adopt suitable techniques and methods to assess our EHS performance followed by implementing remedial measures.
- Operate, maintain and upgrade all our environment protection and waste management systems to meet the environmental requirements and reducing the risk of the accidental release.
- Promote EHS awareness among our employees and contractors through participation, regular engagement & effective communication.
- The policy is regularly monitored by senior management in order to ensure it continues to be appropriate, adequate, effective for the business.

2.6 Health and Safety Statement

BBio is committed to be a responsible employer with respect to both the physical and mental health of her employees. BBio will organize her activities in such a way that none of her employees, or contractors that perform activities for BBio on her premises, will be harmed in any way.

2.7 Environmental statement

BBio is committed to reduce her impact on the environment. Not only the impact of her own activities but also upstream with respect to the supply chain and downstream with respect to the transportation, use and disposal of her products.

In addition the ISO standard also gives substance to the durability project, which consists of solid components, such as limiting emissions, waste and decreasing the use of water, energy and raw materials. Also one-time or temporarily durability plans will be implemented when the circumstances is allowing to do so. Durability plans and measures are approved by the LT and follow a multiple year planning which is checked frequently on effectiveness. An important goal is ‘BBio strives for or works on a continuous improvement of its energy performance and the reduction of CO2 emissions' both direct as indirect emissions.

2.8 (Bio) security statement

BBio is committed to implement an effective monitoring and control mechanism related to personnel/physical and information (Bio) security. BBio ensures that (containment) facility is located on a secure site with perimeter control to prevent unauthorized access or release of information/materials.

- Physical safeguards of potential hazardous and infectious materials like poliovirus materials, including cultures, specimens, samples and potentially contaminated materials, are implemented to minimize the potential for release or removal from the facility due to a breach in security.
- Personnel security is in place to ensure the controlled access of staff to facilities or work.
- Information security policy is in place which ensures secure storage of all sensitive written documents, records and data. Strict procedures are in place regarding accessing/sharing of confidential documents/data with other parties (i.e.Visitors/contractors, Competent authority inspections) which is in compliance with local and national laws.
- A bio - risk management committee is constituted to ensure that issues addressed are formally recorded and actions are effectively assigned, tracked and closed out.

4 Legislation

Based on the products BBio produces and the generic legislation in The Netherlands, the legal landscape BBio has to comply with has a few major parts:

- ARBO: Control of employee risks (“Arbeidsomstandighedenwet”)
- WHO GAP: Control of Polio Virus Containment and biosafety (in process for PEF certification)
- ISO 14001: Control of Environmental risks
- GMP/GxP: Patient safety, product quality, Data integrity
  Control of Product Contamination

4.3 ISO

NEN-EN-ISO 9001, October 2015. Quality management systems – Requirements (ISO 9001:2015)

NEN-EN-ISO 14001, October 2015. Environment management systems – Requirements and guidelines for usage (ISO 14001:2015) .

6 Management – Control

6.1 Management mechanism

BBio uses the PDCA cycle to manage initiation and realization of the strategies and objectives.
PDCA = Plan, Do, Check, Act.
This can be defined as:

PLAN	Set goals and objectives that are needed to implement the strategies as defined by the company	See 6.2 and 6.3
DO	Implement the goals and objectives and the relevant actions	
CHECK	Monitor, measure and report processes and products with regard to the policies, objectives and requirements of the product.	See 6.4
ACT	define actions to improve proces performance (on a continuous basis)	Back to 6.2