



Sustainability Report 2015-16 GRI G4 - In Accordance - Core

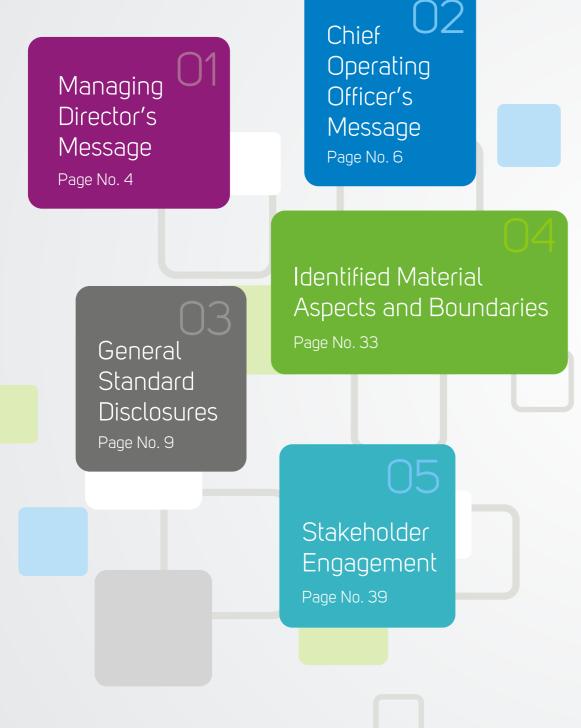






# Being The Change is our endeavour to impact sustainability

# Chief







# Managing Director's Message

Dear Colleagues,

It gives me immense pleasure to address you through our first sustainability report.

First and foremost, I congratulate the entire team involved in this initiative for their scientific approach, sense of urgency and proper execution. I am sure a lot of coordination and background work amongst various functions and teams must have happened before this report reached to its current shape and set the foundation for the beginning of a concerted system to further sustainability.

In recent times, sustainability in business operations has become a key focus area for organizations across the globe.

Environmental degradation, global warming and depletion of natural resources caused by human activities have

become major threats. While efforts have been underway on various fronts to address some of these challenges, the severity of the risks involved necessitate that we evolve as a community to set up frameworks towards conservation efforts as well as towards addressing important environmental challenges. Globally there is increasing realization, support and movement towards a culture of more sustainable business models. In the vaccines world, regulatory bodies such as WHO and others are becoming more and more cognizant and appreciative of organizations with such a bent of business philosophy.

While efforts geared towards protecting environment, conserving natural resources and contributing to society will be the central theme of our sustainability efforts, we aim to imbibe the culture of sustainability in other areas as well including – health & safety, supply chain, human capital - ultimately increasing the scope to the entire value chain of our organization. One of the milestones in this journey is to establish a sustainability practice center within the organization to consolidate all the related initiatives under one umbrella to ensure continued focus, drive and delivery. As a part of our reporting mechanism, this report will help us measure performance, track progress and help improve on key parameters for different functions. Hence, it's important that we dedicate sufficient thoughts in selecting the right parameters within a robust system. All these efforts should also help us develop more efficient and effective processes towards operational excellence in all areas of our operations.

While we acknowledge this as a beginning of a long journey, I encourage the teams involved to keep up the enthusiasm displayed so far. Over a period of time, this initiative will enable us to become more conscious of the essence of sustainability in our everyday activities and thus help us contribute in our own ways towards the betterment of our society and environment.

Best Wishe

Mahima Dalla

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Dear All

My greetings to you!

I have been looking forward to begin our sustainable reporting practice and here we are!

It is with great pleasure that I formally announce the launch of our maiden sustainability report. We have been practicing sustainable business in most of what we do, and this report aims to reinforce the same. At Biological E. Ltd, we have conscientiously made efforts within our facility to move towards a greener and a safer world. Now, we are one of the few companies in the Vaccine industry in the Country to report our responsible practices. The World Health Organisation (WHO) also has shown an inclination towards greener companies and we want to count ourselves as one amongst them.

The global Vaccines market is expected to reach USD 40.03 Bn by 2021 at at CAGR (Compound Annual Growth Rate) of 8.3% from 2016 – 2021. India's ministry of Health is expected to introduce newer vaccines to the EPI Schedule which will significantly increase the opportunity size for vaccine manufacturers in India. In the last four years, we have grown close to 90% CAGR by 2015 – 16. While maintaining our competitive stand, we at BE are also working on an interesting range of pipeline products and this is an exciting time for us to be part of the vaccine industry. We want sustainability to be weaved into our growth story and apart from providing access to good health for the world's citizens, we also strive to put our efforts towards creating a more habitable environment on earth.

With India Ranking 110 of 149 countries in the sustainable development Index, we know that we have work to do! The leaders in our Government in the state and the center have initiated progress in this direction. The Swachch Bharath (Clean India) Program and Harithaharam (Green Garland) Project are allusions to this. On those lines, at BE, we have launched Swachh BE (Clean BE) and a plantation drive (550 saplings) to contribute to a cleaner and greener environment to name a few. We also shoulder the responsibility of judicious use of water, especially because that is a primary resource for our products. The consumption of fresh water and promote 100% recycling of sewerage water. We have installed and are maintaining an RO water tank in Kolthur village to provide the residents of the village access to clean and safe drinking water.

We have embraced Safety, Health, Environment and excellence in all the operations of the company and now, we are looking at a more global perception of transforming this company towards providing sustainable solutions to the world. The company's commitment to sustainability becomes achievable only when it gets embedded in all our operations and through collaborative work. And, for a company with a focused workforce like ours, strengthening our processes to provide sustainable solutions is undoubtedly the right thing to do.

In partnership with our workforce, customers and all other stakeholders, we see BE making a significant contribution to make way for a better tomorrow. We hope sustainability will become the centerpiece of all the work that we do.

Best Regards

Lakshminarayana Neti

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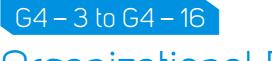




General Standard Disclosures



Sustainability Report 2015-16



# Organizational Profile

Celebration is a way through which humanity expresses its fondness for life. At Biological E. Limited, we express this fondness through our continuous efforts to make disease prevention a distinct reality. Biological E Limited was established in 1953 as the first private sector biological products company in India and the first pharmaceuticals company in South India. BE is also a pioneer in preventive medicine.

Originally incorporated as Biological Products Private Limited in 1953, and launched by Dr. D.V.K. Raju, Biological Etoday, is a leader in Vaccinology in India and a significant player in the world vaccine market.

Early on, Biological E Limited partnered with Evans Medical of UK to develop pharmaceutical formulations. Later BE teamed with Glaxo, India to focus on building the pharmaceutical business in India. We have also collaborated with Pasteur Meriux Connaught of France and Solvay & Cie of Belgium. Every tie-up we entered into has sought to strengthen and advance our overall strategy of being innovative, expanding and developing product lines and building infrastructure with an eye to the future.

Biological E Limited supplies most of the essential and lifesaving drugs to Central and State Government Hospitals, Public Sector Undertakings, the Indian Armed Forces and the domestic retail market. Our International division provides global-access to high quality innovative products and caters to the health and wellbeing of people worldwide.

Our manufacturing facility is WHO Prequalified and certified for ISO 14001: 2004 and OHSAS 18001: 2007

BE holds distinctive competitive positions in India, UNICEF/PAHO and other semi-regulated markets









#### Products of BE

#### **SAVING LIVES** AND IMPROVING HEALTH



#### Biological E's offices



From being one of the first endeavors to promoters of the indigenous pharmaceutical industry to a formidable presence in the preventive spheres of vaccines; producers of bulk drugs to cutting edge genetic and cell-based technologies to treat disease, Biological E Limited has always displayed the vigour, energy to surmount ever higher peaks and the vision to constantly expand it's horizons.

Biological E Limited has a long and richly textured history but the future promises to be even more exciting and successful.

Please note that this report only covers the vaccine business and the pharmaceutical products of the company are not included in this segment.

# G4 9 to G4 12

# Scale of the organization

Total number of employees - Vaccine



Location	Employees
JUBILEE HILLS	33
AZAMABAD	43
GAGANPAHAD	164
SHAMEERPET	892
Grand Total	1132



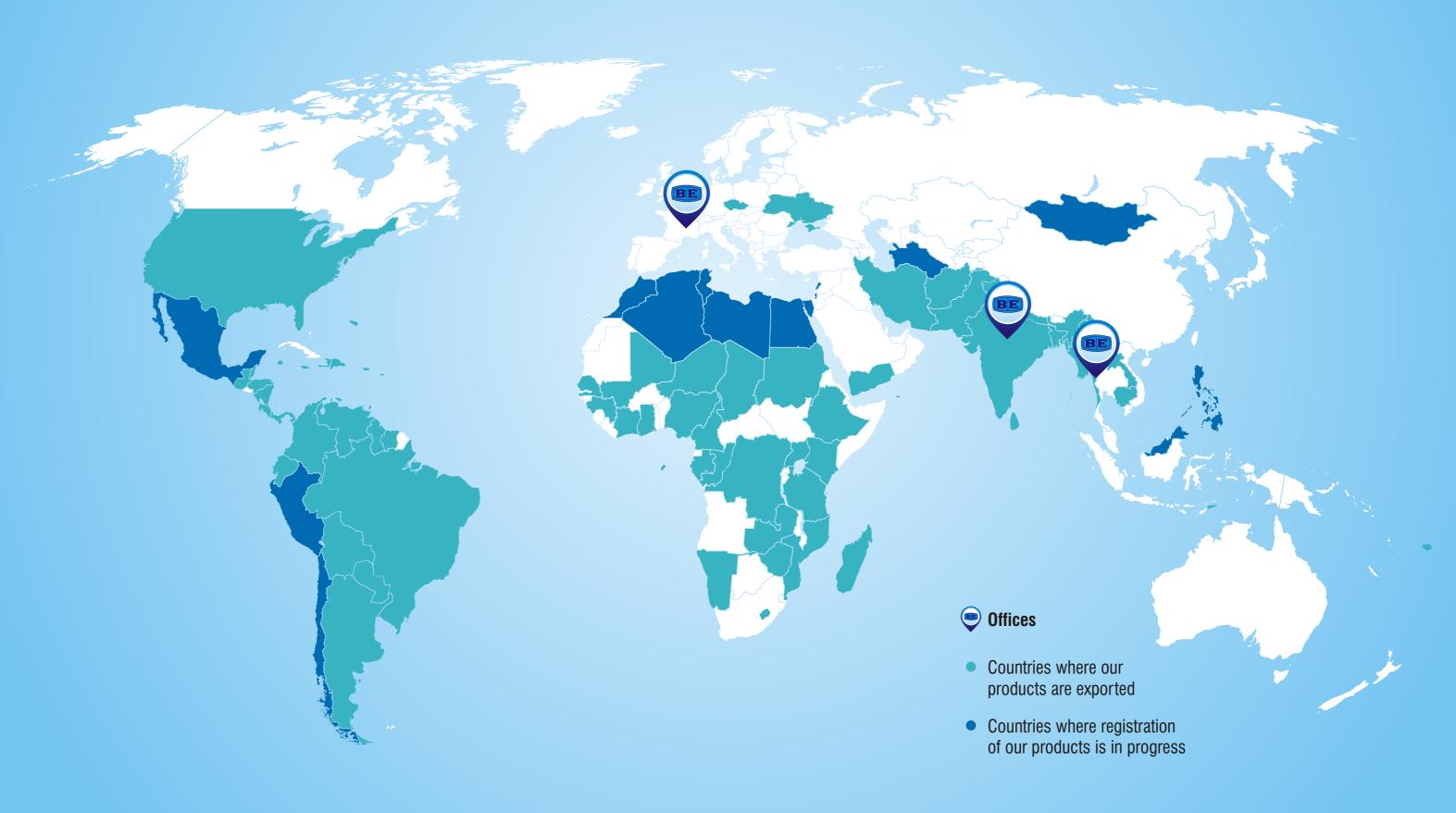
Net Sales: 380 Mds\* in 2015 -16

Total	380 Mds
Exports	200 Mds
Domestic	180 Mds

\*Million doses



# GLOBAL PRESENCE Ensures Uninterrupted Supply







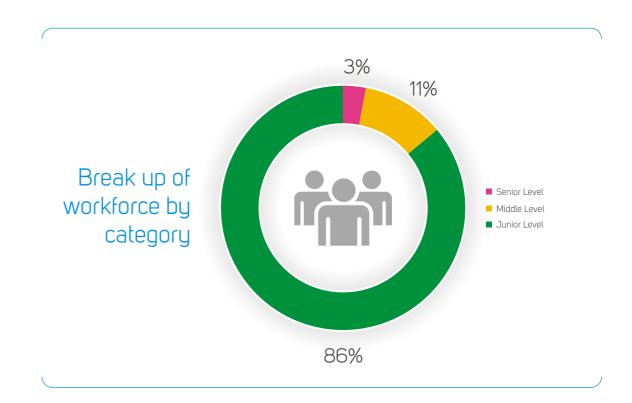
# Human capital at BE

Human capital is one of the important factor in BE's sustainability and is directly dependent on the organization's ability to attract and retain the right talent.

The total number of on roll employees at the end of FY 15-16 was

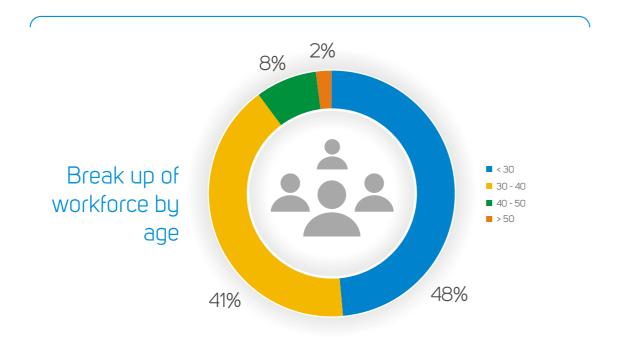
856 employees as compared to 757 employees at the end of FY 14-15. Additionally, BE workforce on temporary basis comprised of 645 individuals. 49% of our workforce constitutes of contractual labour and we have no trade unions at the Vaccine business unit.

It is predominantly a young workforce, with an average age group of 30-33 years at Shameerpet – Vaccines division.





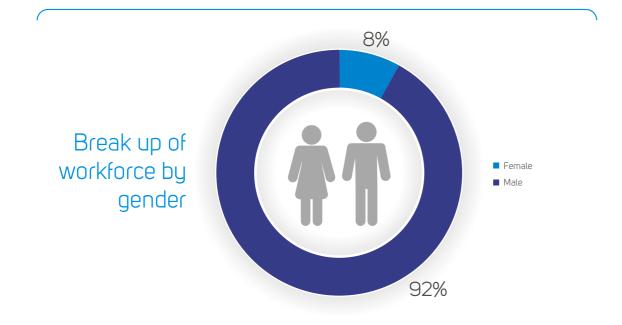




#### Talent Acquisition and Talent Retention

In FY 15, BE recruited 278 employees at the Shameerpet facility. Of this, 68 i.e., 24% of the hires were freshers.

BE views talent retention as another critical factor – as important as talent acquisition – and has invested in building employee friendly culture and developing people oriented processes towards improving it. Employee retention has been enhanced through a wide range of competency enhancement and career growth options, role mobility, challenging assignments, competitive and differential compensation, rewards, recognition and benefits.





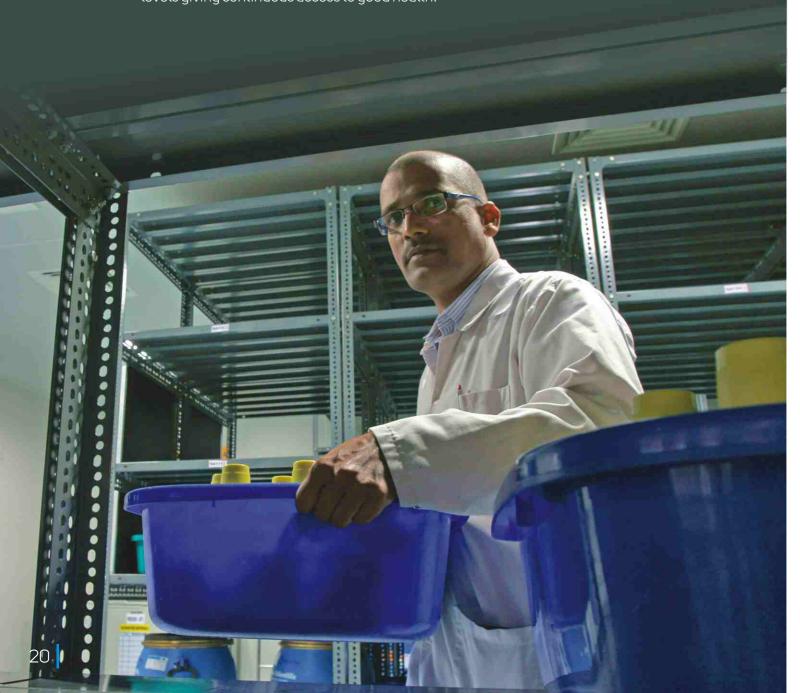


2015-16

# G4 – 12

# Supply chain:

Supply Chain sustainability is increasingly recognized as a key component of corporate responsibility. Managing the social, environmental and economic impacts of supply chains, and combating corruption, makes good business sense and is also the right thing to do. BE's supply chain is in par with international standards and firmly believes that successful immunization programmes are built on functional, end-to-end supply chain and logistics systems. The role of the supply chain is to ensure effective vaccine storage, handling, and stock management; rigorous temperature control in the cold chain; and maintenance of adequate logistics management information systems. The ultimate goal is to ensure the uninterrupted availability of quality vaccines from manufacturer to service-delivery levels giving continuous access to good health.







Right from the raw materials to the final product, the handling and storage of material is done meticulously, helping us deliver high quality products every time. The Supply Chain Management Team engages with almost 752 vendors in total.

The three principles followed at BE for successful supply chain sustainability management are – Governance, Transparency and engagement.

Governance: Determine the scope, based on business priorities and impacts.

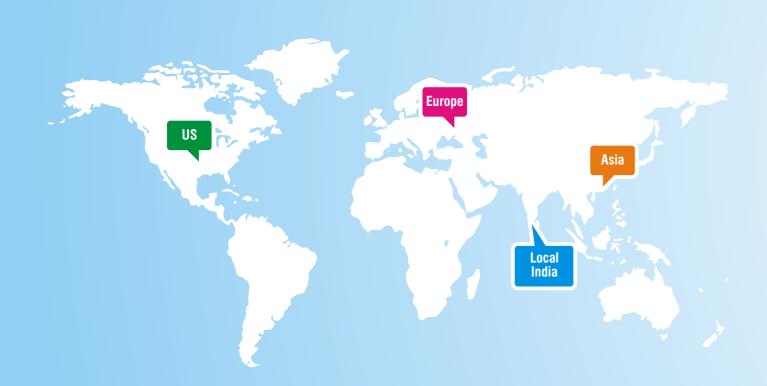
**Transparency:** Track performance against goals and be transparent and report on progress for measurement and communication.

**Engagement:** Communicate expectations and engage with suppliers to improve performance.





# The location of Suppliers by Country or Region



BE Interacts with over 752 vendors in total with a service value of Rs 3755 Million.

# Cold Chain Logistics Cold Chain Logistics Cold Chain Logistics Cold Chain Logistics Chain Receipt of Materials Supply Chain Receipt of Mat

Supply Chain Cycle

\*Vaccine Vial Monitor





# G4 – 13

Facilities openings and expansions

Measles Rubella Block,

Animal House Expansion,

Raw Material Warehouse Expansion,

Pertussis Cold Room,

Quality Control Lab 2

#### Utilities

Power supply feeder has been upgraded from 11 KV to 33 KV, 2 Tonne boiler is replaced by 4 Tonne to enhance the Boiler capacity to 8.5 tonne in total, was installed.







G4 – 14

# Applying the Precautionary approach

Biological E's manufacturing facility boasts of a sprawling green campus with a plethora of flora and fauna on the site, this innate nature of preserving the environment is also reinforced in the way we work. We have a robust system that ensures that our people and environment are kept hale and healthy.

The Aspect/Impact exercise that is done at the beginning of every year and reviewed regularly, ensures that all the potential environmental hazards are taken into account and appropriate preventive measures are followed. During the year, there have been some initiatives that have greatly contributed to the environment.

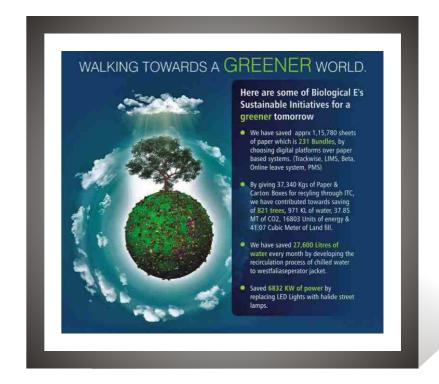
#### Paper based to online systems:

We have made a conscious progress towards digital systems from paper based work flows leading to a lot of paper, trees and capital saving during the year. Some examples are:

- Trackwise
- Leave application
- Stationery requisition
- Migration to LIMS (Laboratory Information Management System)
- Gate pass request
- Purchase requisition
- Engineering and support services requisition

We have also been appreciated by ITC for our paper saving endeavor









# Our People's Safety



SAILOR – Safety Incident Logging and Reporting System is an online tool that our employees have access to. This tool acts as a bridge between the employees and the Safety, Health and Environment (SHE Team).

#### Immediate response to medical emergency 24 x 7



# Occupational Health Centre







# G4 15 to G4 16

# List of the Memberships of the Associations National or International Advocacy Organizations

We have been associated with and certified by SGS (Société Générale de Surveillance) for ISO 14001 and OHSAS 18001 standards. We have a system called Integrated Management system which adheres to the requirements of these two standards from time to time.

#### National and International Associations



ISO - International Organization for Standardization OHSAS - Occupational Health and Safety Assessment Series





Identified Material Aspects and Boundaries





#### G4 18

#### Process for defining report content:

A lot of spade work was done before we began gathering information for the report. To start our Sustainability reporting journey, we had an external assessment of our readiness as an organization to report by BSI (British Standard Institute) and on being shown a positive go – ahead, we started by studying and understanding the GRI guidelines. The team underwent GRI training by an expert from KPMG. The training was imparted to all the cross functional leads who will play a crucial part in determining the report's content.

The core team has spent a lot of time in studying the GRI Guidelines and understanding its application in the form of a report by referring reports of like minded companies.

The material aspects were decided by calculating the importance of each aspect with a materiality score and plotting it on the matrix. This exercise was done with the relevant internal stakeholders this time, as it is our maiden report. The internal stakeholders are the management, functional heads of various department and the core sustainability working team which also happens to be cross functional. After several meetings being conducted, the material aspects for Biological E were finalized.



# G4 – 19

## The sustainability materiality matrix

#### Choosing what is material for BE

The material aspects scoring for Biological E. was done in consultation with representatives of our stakeholders.

For each aspect, a score is given against its importance to the stakeholders and its impact on BE's success. All the aspects which have an average scoring between 8 – 10 are considered material for the company and are considered.

Category	Economic		Environmental		
Aspects <sup>VII</sup> • Economic Performance • Market Presence • Indirect Economic Impact • Procurement Practices		ts	Materials     Energy     Water     Biodiversity     Emissions     Effluents and Waste     Products and Services     Compliance     Transport     Overall     Supplier Environmental A		
Category	Social				
Sub Categories	Labor Practices and Decent Work	Human Rights	Society	Product Responsibilit	
Aspects <sup>vii</sup>	Employment     Labor Management Relations     Occupational Health and Safety     Training and Education     Diversity and Equal Opportunity     Equal Remuneration for Women and Men     Supplier Assessment for Labor Practices     Labor Practices     Grievance Mechanisms	Investment Non-discrimination Freedom of Association and Collective Bargaining Child Labor Forces or Compulsory Labor Security Practices Indigenous Rights Assessment Supplier Human Rights Assessment Human Rights Grievance Mechanisms	Local Communities     Anti-corruption     Public Policy     Anti-competitive Behavior     Compliance     Supplier Assessment for Impacts on Society     Grievance Mechanisms for Impacts on Society	Customer Health and Safety Product and Service Labeling Marketing Communications Customer Privacy Compliance	





# G4 20 to G4 21

## Boundaries of each materiality aspect







Biological E. Limited

Celebrating Life Every Day







Stakeholder engagement



# G4 24 to G4 26

# Stakeholder Groups

Biological E is already interacting with a broad spectrum of stakeholders, internal and external to understand their concerns and priorities and use those inputs to guide policy formulation and decision-making. These are restricted to the more traditional stakeholders such as the employees, suppliers, business partners, investors and customers. The more non-traditional stakeholders such as the NGOs, consumer groups, special interest groups and activist groups as relevant however need focus. The interaction framework is also generally in place with interactions through website portal, employee feedback / counselling, customer satisfaction surveys, personal interaction, surveys, periodic reviews etc. being the primary mode.

This time, BE is only involving internal Stakeholders in the selection and the preparation of the Sustainability report. Our Internal Customers include employees and the contract workforce.

BE interacted with these stakeholders in regular meetings that were conducted to progress on our sustainability report. The first meeting was a brief about Sustainability and why BE has chosen to take first steps in this direction. The GRI training as conducted for all the relevant stakeholders who will contribute towards the report, the leadership team was involved. One of the major forums where the leadership meets to discuss Occupational Health, Safety, Sustainability and Environment is the Central SHE Committee that meets every quarter. The leadership is introduced and briefed about the progress in sustainability in this forum on a regular basis. Sustainability is a topic of discussion in the Leadership review meetings which happens every month.







Governance and Ethics





#### External Assurance:

We are not seeking external assurance for the first report and will be doing so from our next sustainability report. However, all the information provided in this report is validated and authorized by the respective functional heads to ensure the accuracy of the data provided.

G4 - 34

# Sustainability Governance

Biological E Limited is one of the pioneer pharmaceutical and vaccine manufacturing company in India. The company has strong ethos in the manufacturing, sales and governance standards of business for the last 65 years. The Company has been a closely held, unlisted and professionally managed since its establishment. Across various departments in the organizations, BE has academically and technically strong leaders guiding a group of bright talent in making our superior quality products and delivering it to the customers.

The company is managed by Board of Directors comprising of professionals from and within the family promoters. The Board supervises and controls the operations of Managing director and other senior management team. The senior management is given full functional freedom and autonomy to operate and they will be made accountable for their individual functional operation targets.

The leadership meet on a regular basis for discussion over the economic, environmental and social impacts on a regular basis. The Internal Board review happens once every month where the leaders of the vaccine and pharmaceutical verticals are accompanied by the marketing and the finance heads. The economic impacts are discussed in detail in this forum.

Social Impacts are discussed at a Business Unit level with representation from the heads of various departments. A fixed time slot is allotted for a discussion on sustainability as well, during which the social, environmental and economic aspects of the business are discussed.

The company is developing its own corporate social responsibility policy under which the company will provide its philanthropy's to the genuine needs and in needy areas to spend the amounts it allocates towards social responsibility. The company has its philanthropy policy for the past several years and now it's incumbent on the company to have its corporate social responsibility post company acts 2013.









#### G4-56

## Ethics and Integrity

#### Values, principles and conduct:

Biological E. has been built on a very strong foundation of values that are practiced everyday as the company functions. Quality and Safety are values that have a special emphasis in all that we do.

The company has effective internal control mechanism through which the operations are effectively conducted and performances supervised. Career progression at BE is purely on the basis of performance. The company has a wide network of 2700 employees working in various functions, at various levels to provide scientific management and sustainable growth. The leadership team is responsible for meeting the annual operational targets, in adherence to the organisation's mission and vision statements.

The company always complies and adheres strictly to various legal compliances under various applicable laws namely drugs and cosmetics acts , income tax act, central excise acts, custom acts, central sales acts, sales promotional employees acts, industrial disputes acts, payments of wages acts, factories acts, minimum wages acts, payment of bonus acts, payment of gratuity acts, employees provident act, employees state insurance acts, national and festival holidays acts, environment protection act, water act, air act, national green tribunal act etc. The professional managers who have adequate exposure and knowledge are the leading staff in making various compliances and adherences on day to dau basic.



Upon new employees joining the company, the Vision, Mission and Values of the company are introduced to them during the one week elaborate orientation session. The sign boards placed on site in both English and local Languages reinforce and remind the employees of the values of the company and its importance.





#### Economic

Specific Standard Disclosures





Sustainability Report 2015-16

# Category: Economic

The impetus for the growth of the vaccine industry in the semi-regulated markets was provided by the establishment of GAVI (Global Alliance for Vaccines and Immunization) in 2000; GAVI operates through the UNICEF Supply Division to procure vaccines from WHO pre-qualified manufacturers for distribution in low-income and semi-regulated countries. Biological E is a closely linked member of GAVI.

BE has been consistently maintaining its esteemed position over the last few years and our pipeline products make the future seem brighter. Additionally, India's ministry of health is expected to introduce newer vaccines to the EPI schedule which will significantly increase the opportunity size for vaccine manufacturers.

# BE's Strengths

- BE holds distinctive competitive positions in India, UNICEF/PAHO and other semiregulated markets
- BE ranks among the Top-5 pure play vaccine manufacturers globally, and among the Top-3 from emerging markets
- BE is actively addressing other middleincome markets through tie-ups with government agencies and distributors
- BE ranks among the 6 globally prequalified suppliers of the liquid pentavalent vaccine, and among the two globally prequalified suppliers of the Japanese Encephalitis vaccine to UNICEF
- BE has comprehensive product pipeline that plays to the strengths of the company
- BE has successfully developed and commercialized 6 vaccine products in the last decade, and has built up a robust pipeline
- BE has made significant investments in building world class delivery capabilities and culture of "Quality or nothing"





The Economic Health of BE is fiercely dependent on the quality of our products and quality is subsequently reliant on the Supply chain systems. Hence, utmost care is taken in ensuring that our Supply Chain is ethical and sustainable.

The Ten Principles of Supply Chain sustainability in Biological E. Ltd which guide us in our operations are:

#### Human Rights

Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights;

Principle 2: Ensure that they are not complicit in human rights abuses. Companies have a responsibility to respect human rights. The baseline responsibility of BE is to not infringe on the rights of others.

#### Labour

Principle 3: Uphold the freedom of association and the effective recognition of the right to collective bargaining;

Principle 4: The elimination of all forms of forced and compulsory labour;

Principle 5: The effective abolition of child labour; and

Principle 6: The elimination of discrimination in respect of employment and occupation. Labour conditions in our offices, factories and all across the distribution network are scrutinized for human rights abuses and only then approved or taken on board.

#### Environment

Principle 7: Support a precautionary approach to environmental challenges;

Principle 8: Undertake initiatives to promote greater environmental responsibility; and

Principle 9: Encourage the development and diffusion of environmentally friendly technologies.

#### Anti-Corruption

Principle 10: Should work against corruption in all its forms, including extortion and bribery.

The significant corruption risks in the supply chain include procurement fraud and suppliers who engage in corrupt practices involving governments. The direct costs of this corruption are considerable, including product quality, but are often dwarfed by indirect costs related to management time and resources spent dealing with issues such as legal liability and damage to a company's reputation.





Sustainability Report 2015-16

# G4 EC - 9

#### Procurement Practices

BE gives paramount importance to engaging with suppliers, this is to develop a shared mind set about sustainability issues, to build supplier ownership of our sustainability vision, strategy and performance and to work more closely with suppliers with shared priorities.

The Quality of BE Vaccines are superior and hence the products and services that we receive from our vendors should be the best in class. Our Vaccines are mostly administered to children and hence we want to aid them to grow into healthy individuals and global citizens without a glitch. We are committed to producing High Quality Vaccines and hence have an extensive Procurement practice in place. We have about 323 Vendors of which 10 provide Import services for our Manufacturing Facility in Shameerpet. Our Service Value stands at INR 21Cr.



Most of our Products and Services are procured from Local sources, by local we mean Indian Vendors from various states across the country. 80 – 85% of our procurement spend is on the Indian Vendors and around 18 – 20% of the budget is spent on Imported services and Products. Predominantly, most of our products are procured from within the state of Telangana and about 15% is procured from other states. Since our Vaccine Manufacturing Plant is in Shameerpet, this is the significant location of Operation.







Environmental





Biological E. is compliant to all the requisite norms and statutes for its safe and just operations with respect to the environment and we do not have any non – compliance or fines paid for our manufacturing facility.

BE is certified for ISO 14001: 2004 and has been nourishing the Environment in all its sites and specifically with regards to our Shameerpet site, 50% of the land area is a green belt. Our site is diverse not only in terms of the workforce that we have, but we also share our green space with a diverse variety of birds, butterflies, insects, numerous Trees and shrubs







We have an elaborate procedure to identify the Aspects and Impacts relating to the environment specified in our IMS Procedure. All the activities that might pollute the environment are considered, and the concerned individuals working for those teams along with our SHE\* experts determine these aspects and impacts. Some of the tests that we conduct to maintain the quality of the environment are mentioned below

#### Environmental Quality Check

S. No.	Test	Frequency	Test conducted by
1	Boiler Chimney Stack Monitoring	Monthly	External Party
2	DG Set Stack Monitoring	Monthly	External Party
3	Noise Levels Monitoring	Monthly	External Party
4	Effluent Parameters	Daily	In House

\*Safety Health and Environment



# G4 EN 8

# Aspect: Water

Water is the primary resource that we use to produce our product. If there is scarce or no water, the existence of our product is itself questionable and hence we ensure that we use this resource judiciously. As a responsible organization, we have put in efforts in our capacity to replenish the water that we use and to ensure the sustenance of the future generations.

Our site is equipped with rain water harvest systems and we are working towards expanding the number of rain water pits on site.

Some of our pipeline projects are to establish a 300 KLD of Effluent Treatment Plant and 100 KLD of Sewerage Treatment plant and the treated sewerage water will be used for gardening and in the washrooms.

#### Water Consumption by source:

Source	Unit	Consumption in 2015-16
Hyderabad Metropolitan Water Supply & Sewerage Board Supply	KL	110863
Manjera Water Supply Through Tankers from Private Lands	KL	1479
Bore well Water Supply for Process Private Lands and Borewell	KL	6084
Bore well Water Supply for Gardening from Private Lands	KL	51947

Since this is the first report, the year 2105 – 16 data will be considered as the base year and the future data will be trended against this.





#### G4 EN 15 and G4 EN 16

#### **Emission**

We have a systematic approach towards checking emissions.

Scope 1 & 2 Co2 and Greenhouse Gas Emissions			
	Co2	GHG	
Scope 1	5761	74680	
Scope 2	14146	62103	
Total 1 + 2	19907	136784	
Scope 1	Gross Direct Emissions ( Diesel & Furnace Oil Consumption in premises)		
Scope 2	Gross Indirect Emissions (Electrical Power from the Grid)		

From the next report, we will start tracking the reduction in emissions year on year. To neutralize the emissions, we have an extensive green belt that acts as a buffer for the environment. We have about 1000 trees in our Shameerpet Facility and each tree is known to neutralize 20 Kgs of emissions.

Our aim for the next year is to add 200 more trees to our facility to further neutralize the emissions.

#### G4 EN 22

#### Effluents and Waste

Effluents generated from the facility are segregated into different streams and are collected separately into the designated collection tanks. The process effluents and effluents from laboratories are collected into the kill tanks through the dedicated pipelines.

The effluents of washings from the production areas and utilities are collected separately into the common effluent collection tank through dedicated pipelines.

The domestic effluents (Sewage) are conveyed through separate pipelines and mixed in the effluent at equalization tank.

After the Primary treatment the treated effluent is sending to Common Effluent Treatment Plant of Pattancheru Enviro-Tech Limited at Pattancheru for further treatment and disposal.

In the year 2015 – 16, We generated the following quantities of waste:

Effluent	22071.7m <sup>3</sup>
Bio Medical Waste	93.249kg
Hazardous Waste	2.46kg

Our Bio-medical and Hazardous waste is handed over to the authorized vendors of the State Pollution Control Board, for disposal.

#### G4 EN 29

# Aspect: Environmental Compliance

The following are some of the compliances that we adhere to:

- 1. Consent for Establishment (CFE) for establishing the facility under Air, Water & Hazardous waste Acts
- 2. Consent for Operation (CFO) for Operating the facility under Air, Water & Hazardous waste Acts
- 3. Bio Medical Waste Authorization for Generation, collection storage & disposal to Pollution Control Board authorized vendors
- 4. Water Cess submission and due payment to Pollution Control Board.
- 5. Environmental Mentoring of Stack Emissions, Ambient Air Quality, Noise Levels & Effluent Parameters with GOI & MoEF authorized vendors.
- 6. Timely disposal of Hazardous Waste, Bio Medical Waste & other waste.

Submissions Annual Returns of Hazardous Waste disposal in Form - IV, Bio Medical Waste disposal in Form – II and Environmental Statement.







Biological E, in its logo carries a tag line that is a reflection of the way the organization looks at life and the value it associates with it. BE makes products in a way to ensure that its workforce, customers, children and all other stakeholders have celebration of life as the core of everything we do.

Celebrating work: BE goes the extra mile beyond merely adhering to all the labor laws ensuring decent workplaces and is on a constant endeavor to make work comfortable and a pleasant experience.

Celebrating Humanity: sustenance of Quality human life is the end purpose of the products that we manufacture. Owing to that, we have an added responsibility of ensuring humane practices across our product chain.

Celebrating Society: Since BE is an organization that is deeply rooted in ethics and conduct, care is taken to ensure that there is no injustice or mal practice happening anywhere across the product lifecycle and beyond.

# Category: Labour Practices and Decent Work

# BE's site is certified for OHSAS 18001:2007

Occupational Health and Safety: Safety is embedded as one of the values in BE and hence a lot of emphasis has been laid on Occupational Health and Safety as a norm over the last few years. We made significant progress in our continuous effort to improvise on the Safety systems and practices in the company.

We strive to have Zero Incidents on site and have oriented all the workforce towards that goal!

BE is a staunch protector of employee's right and ensures that the workforce work only in a comfortable and Safe environment. The support from the higher management towards this is immense. The SHE Policy, which is driven and signed by the managing Director is up for display across the site and all operations have to ensure SHE (Safety, Health and Environment) as the priority in everything we do. A wide array of IMS\* Policies guide the workforce on the Safe Handling and operations of various activities.

\*Integrated Management System







During the reporting year, we made important progress in our continuous effort to improve the safety of our operations. These Included:

- Updating the SHE Management System Standard and streamlining all the policies under its umbrella and signed by the senior management.
- All the policies under the SHE standard are easily accessible for employees on the Intranet.
- Successfully faced the surveillance audit and enhanced SHE systems to raise the bar.
- Continued to release regular communication through outreach activities like mailers and newsletters with updated SHE information, news, events, trainings and updates.
- Improving our year over year performance for employee engagement with over 300% increase in participation.



# SHE POLICY

#### BE is committed to:

- Prevention of Environmental Impacts, Hazards and Risks while
   Developing, Manufacturing, Storing, Handling and Distributing their
   Vaccines.
- Providing training and disseminate information to all employees to take individual responsibility for SHE and to create a culture of continual improvement.
- Instilling a sense of duty in every employee towards personal safety and safety of others who may be affected due to operations
- Ensuring safe handling, storage, usage and disposal of substances and materials that are hazardous to health and environment.

It is BE's endeavour to institute and implement periodical reviews of SHE objectives and targets to ensure compliance with laid down policies, procedures, applicable legal and other requirements.



Ms. Mahima Datla Managing Director





# G4 – LA 5

Percentage of total Workforce represented in formal Joint Management Worker health and Safety Committees that help monitor and advise on Occupational Health and Safety Programs.

As one of our core values, Safety and Health is integral to how we operate as a company. Biological E. believes that all injuries, occupational illnesses and safety and environmental incidents are preventable. The company's goal is zero for these incidents.

BE is a staunch protector of employee's right and ensures that the workforce work only in a comfortable and Safe environment. The support from the higher management towards this is immense. The SHE Policy, which is driven and signed by the managing Director is up for display across the site and all operations have to ensure SHE (Safety, Health and Environment) as the priority in everything we do.

A wide array of Integrated Management System (IMS) Policies guide the workforce on the Safe Handling and operations of various activities.

All the workforce at BE including the contract workmen are covered under Occupational Health and Safety Programs. Safety is an important value studded in the company's ethics. All the people entering the premises of BE will receive a Welcome card which enlists the various Safety Rules that they will have to follow in the premises of BE. Compliance to BE's Safety rules is a mandate for all the employees joining the company and also others who enter the site. On joining, all employees are given an exclusive SHE orientation before they join their teams to start their job. The team has developed a SHE Induction kit for employees as well as casual laborers and contractors.



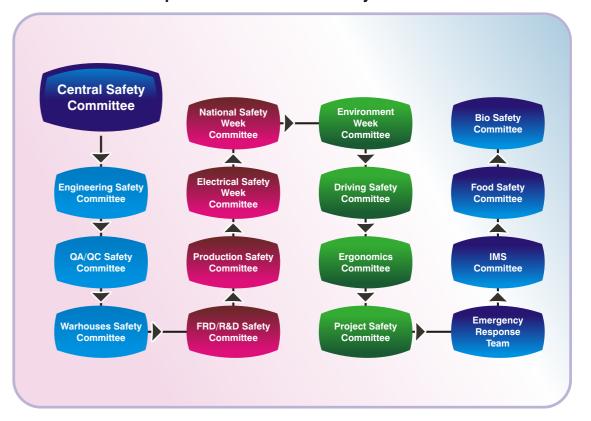
BE Sports Carnival - Encouraging good health amongst employees

Each and every employee on site is responsible for his safety on site and the management is responsible in training them and creating awareness.

However, we must mention of the various forums that we have to report and discuss Safety, Health and Environment topics exclusively called the Central SHE and Sustainability committee and the Sub SHE & Sustainability committee. The Central SHE committee is an apex decision making body that consist of the SHE Team along with Cross Functional Representation of Leaders. A sub division of this committee is the Sub SHE Committees of various functions which meet and discuss SHE Topics every quarter. Unresolved issues from this committee is escalated to the Central SHE Committee.

To maintain adherence to the ISO and OHSAS standards, a cross functional IMS Team consisting of members from various functions is constituted. This team ensure the upkeep of all the IMS documents and conformity to those norms all through the year in their departments.

#### **Occupational Health and Safety Committee**







# G4 – LA 9

#### Training and Education

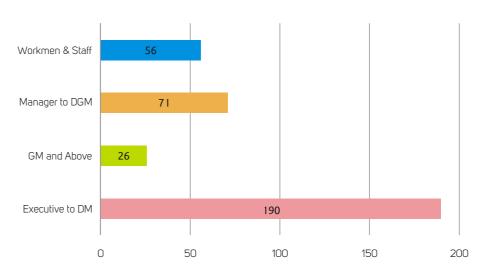
At the start of the year, every employee in consultation with her/his supervisor, works out a learning and development plan for the year, based on their interests and aspirations as well as the needs of the specific project / Business Unit. Thereafter, the employee goes through various training sessions and workshops as outlined in the plan. These could be through external certifications and classroom sessions.

The Training Man-days for Shameerpet – Vaccines during FY 15 was 343 days.

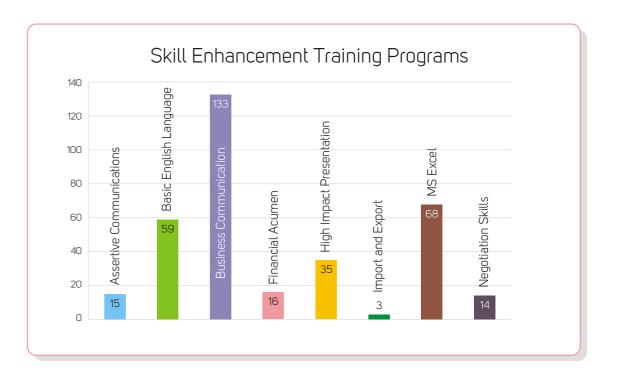
S. No.	Training Details	Shameerpet
1	No. of Internal GMP Training Sessions*	32
2	No. of External Trainings	10
3	Total Man Hours Spent on GMP Trainings (Hrs.)	2233
4	No. of New Joinees (employee)	257

The Safety, Health, Environment and sustainability trainings had 1111 participants

#### Training Man days by Category



Apart from these training sessions, the employees have to go through cGMP and SHE training at the time of joining and subsequent refresher training sessions. The number of Training Man-days spent for the cGMP training for FY 15 was 2233.







Sustainability Report 2015-16















#### Sub Category: Human Rights

BE's Vaccines are administered in the early few days, months and years in life and this enables them to contribute to the world as healthy citizens. To make the world a happier place, we need healthy citizens and our products strive to meet that end. As manufacturers of products that are predominantly administered to children, we have an added responsibility of ensuring that Child labour is not encouraged at any stage of the Supply Chain.

# G4 HR 5

#### Aspect: Child Labour

All our Supply chain agreements with the vendors both domestic and international vendors is to ensure that we have no child labour practices across the suppliers.



There is a stringent system ensuring that there is no child labour within the premises of BE. To ensure that the materials we receive from external vendors are not indulging in this evil, Vendor audits are conducted in which Anti - Child Labour is a significant factor to approve the inclusion of the vendor in the system. The vendor will be interviewed and our Vendor audit team will visit the workshop to take a view of the working system before approving the vendor.

#### Sub Category: Society

Biological E has never compromised on its unshaken pillar of ethics over the decades of operations and this perhaps has helped us develop a robust reputation globally. We strongly believe that the quality of our products is so profound because of the dedicated workforce that put all their efforts in making it. Our Products are a reflection of the values instilled in our workforce and the ethics that the organization practices.

It is not only the employees and other workforce but the Board and the top management are also subject to practicing the business in an ethical manner with no room for deviation from the same.

We have various committees that deal with issues on these lines with cross functional representation and one such committee is the POSH Committee (Prevention of Sexual Harassment). Regular trainings on topics pertaining to ethics and Integrity are organized by the Human Resources Team on a regular basis.

# G4 – SO 4

# Communication and Training on Anti-Corruption Policies and Procedures.

The code of conduct/ Ethics that the organization has created is the foundation upon which the company has been built. All the new employees joining the company are given a clear understanding of this aspect as the base upon which all the other work is built on. The Mission, Vision and the values of the company are percolated all the way down even in the Goal setting exercise.

During the reporting period, the Vision, Mission and the Values of the company were explicitly explained company wide and the goals that are set are built around that. During this period, there is an extensive training on the values of the company and a major indicator that determines the performance grading of the individual is his adherence to the Values and Ethics of the company. Hence the values of the company are internalized by all employees as it directly impacts the performance.

The various modes through which the code of Conduct and Ethics is communicated to the workforce is:

- Employees receive frequent training and Mailers and other communication from the top management that repeatedly remind them about their values and responsible working.
- Not only the employees but the visitors, vendors and other dignitaries who visit our facility are also provided with a Welcome Kit which also elucidates the values of the company.
- All the employees on joining the company are inducted with an introduction to the values and the ethics of the company. Only after receiving an authorization from the trainer, the person is admitted to join the team.

If a member of the workforce is found to be involved in corrupt practices which is validated with evidence, appropriate Remediation measures will be taken.





# Sub Category: Product Responsibility

Biological E has been producing products which are majorly administered to children and hence the Safety of the product is of prime importance.

The company has been lauded for its stringent Quality system many a times.

While ensuring that the product is safe for use, care is taken to ensure that we are conscious about the environment and the society as well. The table below is a summary of how we ensure sustainable production across the product life cycle.

S. No.	Issue	Approach
R&D a	nd Design	
1	Bio Safety	Bio Safety Policy> Bio Safety Committee
2	Animal Welfare	CPCSEA (Committee for the Purpose of Control And Supervision of Experiments on Animals) Member > External Regulation And control> 3R Replace, reduce and refine the use of Animal testing
3	Clinical Trials	Clinical Trials Policy > External standards > Independent Ethics Committee/Institutional Review Board
Materi	als Use	
4	Materials/Selection/Reduction and Innovation	Product Sustainability Review > Supplier screening > Evaluation of chemicals of concern> alignment with regulatory requirement > Conflict materials dealt with
Manuf	acturing	
5	Resource Efficiency, Environmental Impacts, Employee Health and Safety	SHE Program and Goals> ISO 14001 & OHSAS 18001 management Systems and Standards Audits > Rigorous compliance > Proactive reduction of natural resource use > Hazard identification and risk assessment
Produc	ct Transport	
6	Environmental Impacts of transport	Distribution Network optimization> Choosing Environmentally sensitive transport systems > Employee transport network buses
Packa	ing .	
7	Minimising packaging material selection	Materials reduction > Material substitution > Innovative Design
Produc	ct use	
8	Promotion and Marketing	Compliance with promotional regulations worldwide > International policies for interactions with healthcare practitioners, medical institutions and patient organizations
9	Safe Handling and use	Safety Data Sheets > Clinical Education
10	Access to health care	Affordable healthcare access in Low and Middle income countries> Business Model innovation>
Produc	ct End of Life	
11	Minimisation of Customer Waste	Pre filled syringes> Industry Collaborations

# G4PR1

# Customer Health and Safety

All of our Products are assessed for its Health and Safety Impacts all through the lifecycle of the Production and administration of the Product.

#### Quality and Safety

Quality and Safety are values that are at the core of everything we do at Biological E. Ltd. Some of our products are WHO Pre qualified and follow stringent quality systems. Robust CGMP (Current Good Manufacturing Practice) and the Integrated Management system (IMS) guide all the work that we do. Each batch goes through a series of tests and checks before it reaches the customer for safe administration.









Maintaining a secure Supply chain is crucial to ensure the safety of the product right from the arrival of the raw material to its conversion into a finished product. Regular Vendor Audits and quality checks ensure that we maintain the integrity of our finished product. Right from the finalization of a vendor to the use of raw materials, the Safety and Quality Teams are closely involved in the sampling, testing and assurance of its safe use for Production.



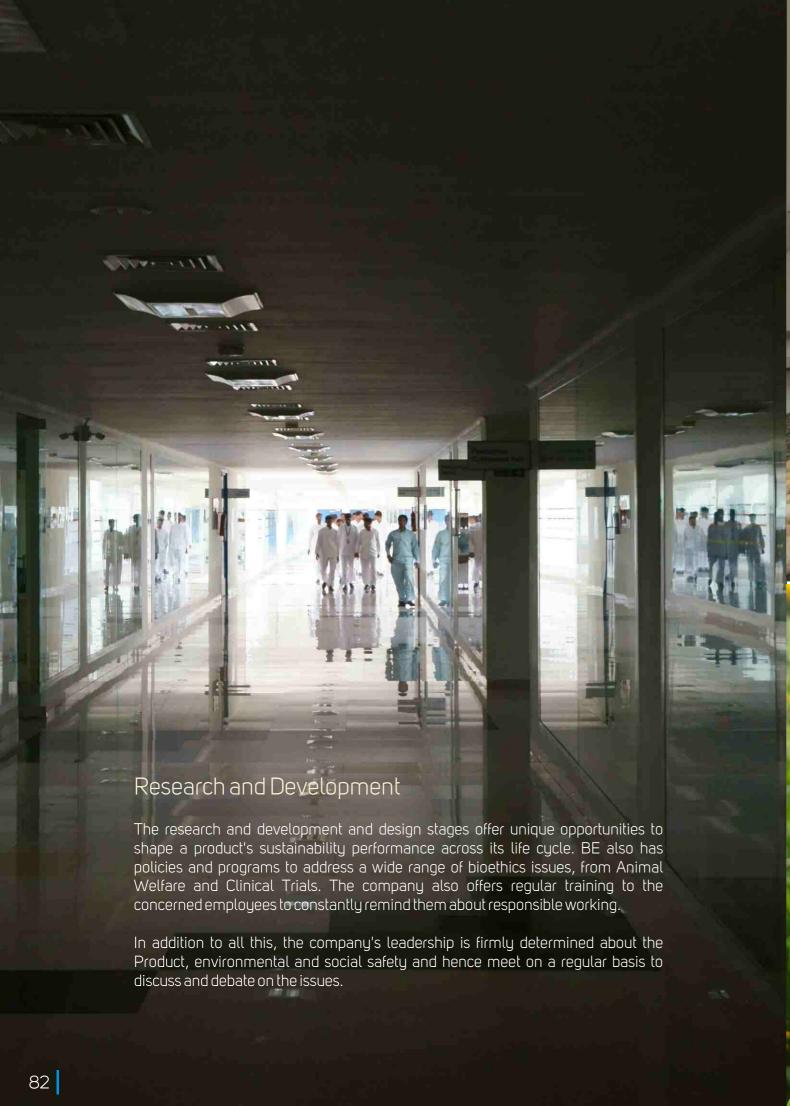
#### Collaboration with Officials and Industry Partners

BE is fortunate to enjoy the good will of many international esteemed organization because we have been consistent in producing high quality products. The company regularly collaborates with regulatory and public health officials and industry experts to share intelligence, insights and experience regarding product integrity. Some collaborations that are worth mentioning are GAVI - The Global Alliance for Vaccines and Immunizations, (Developing Countries Vaccine Manufacturers Network (DCVMN), CII (Confederation of Indian Industries).

#### Product Integrity

Counterfeit and/or adulterated medical products pose risks to patient's safety worldwide. Maintaining product integrity is a complex and multifaceted challenge, encompassing an array of risk management, supply chain, product design and packaging strategies. BE's product integrity program takes into account the differing levels of complexity and risk associated with individual products and markets. The company has conducted a series of risk assessments, examining economic incentives, supply chain and product complexity, and other factors that may contribute to this issue. Based on that analysis, BE had prioritized certain product lines and geographies for piloting and implementing various product authentication and security measures.













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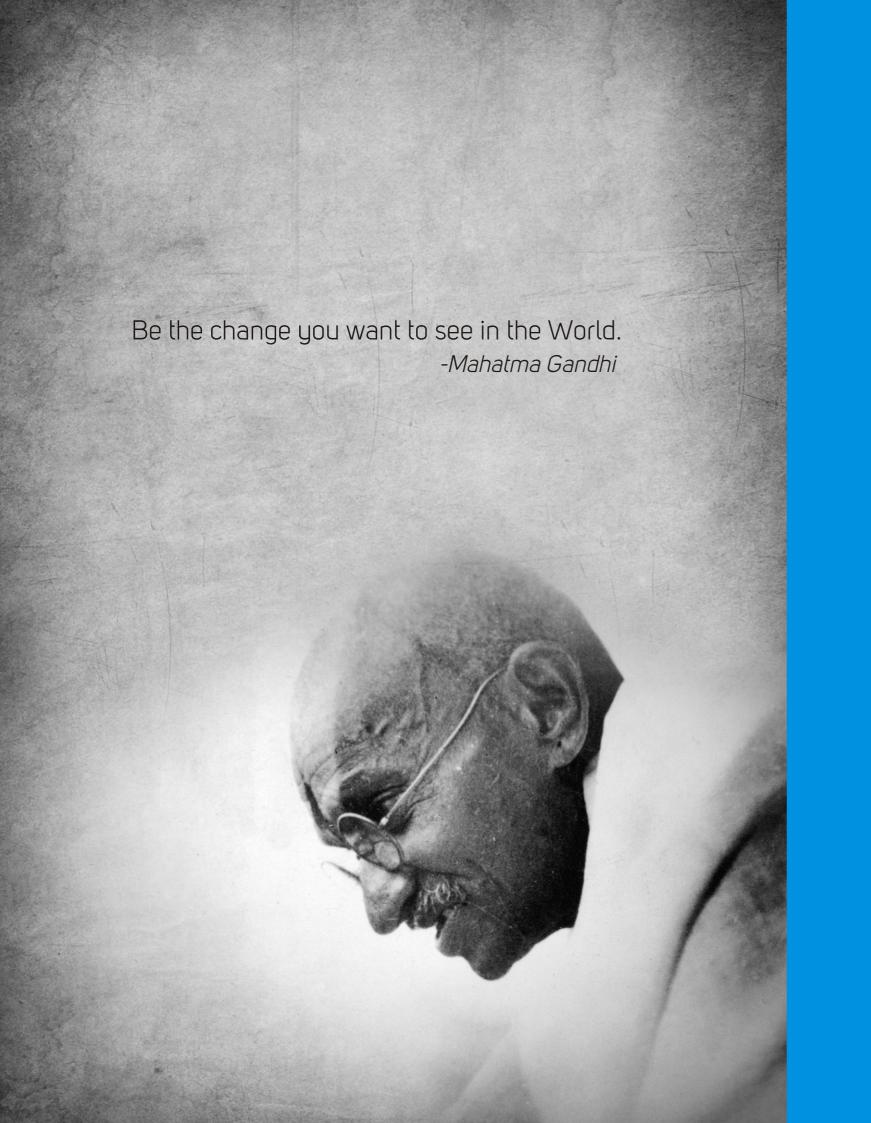


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#### Abbrevations:

- 1. UNICEF: United Nations International Children's Emergency Fund
- 2. PAHO: Pan American Health Organization
- 3. OHSAS: Occupational Health and Safety Assesment Series
- 4. ISO: International Organization for Standardization
- 5. CGMP: Current Good Manufacturing Practices
- 6. SHE: Safety, Health and Environment





For any queries related to this sustainability report, write to us at sustainability@biologicale.co.in

