EHS Management System in Ranbaxy Laboratories Limited

An Overview

National Seminar on Hazard Management in Pharmaceuticals Industry
(The Environmental Cell, Department of Pharmaceuticals)

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- Ranbaxy Laboratories Limited – An Overview
- EHS Management System
Our Mission, Vision and Aspirations

Mission
To become a research based international pharmaceutical company.

Vision - 2012

Aspirations - 2012
- Aspire to be a $5 Billion Company.
- Become a Top 5 Global Generics Player.
- Significant Contribution from Proprietary Prescription Products.
Ranbaxy Overview

- Manufactures and Markets
  - Generics
  - Proprietary Brands

- Financials
  - Sales ~ USD 1607 Mn (2007)
  - International Revenues ~ 79%

- Global Presence
  - Amongst Top 10 global generic companies
  - Ground presence in 49 countries
  - Presence in Top 5 pharma markets
  - Products sold in over 125 countries

- Resources
  - > 11000 employees worldwide
  - > 1000 R&D personnel
  - 20 Manufacturing locations conforming to cGMP standards in 11 countries
Our International Presence

Ground Operations in 49 Countries
Products Available in over 125 Countries

**North America**
Canada
U.S.A

**USA**

**Europe, CIS and Africa**
UK, Germany, France, Ireland, Poland, Romania, Spain, Portugal, Sweden, Austria, Belarus, Lithuania, Russia, Kazakhstan, Ukraine, Cameroon, Egypt, Ivory Coast, Kenya, Nigeria, South Africa, Zimbabwe, Mauritius, Senegal, Morocco

**Europe, CIS and Africa**

**Asia Pacific**
China, Malaysia, Myanmar
Singapore, Thailand, Vietnam
Australia, Japan, Cambodia

**Latin America**
Brazil, Guatemala
Mexico, Peru

**Middle East**
UAE
Sri Lanka

**RANBAXY**

*BRIC - Brazil, Russia (incl. Ukraine Belt), India, China. Europe-incl. W&C Europe*
Our Global Manufacturing Presence

USA

India

South Africa

Ireland

China

Nigeria

Malaysia

Romania

Vietnam
Corporate Office & R & D Centres

Corporate Office, Gurgaon, India

R & D Centre, Gurgaon, India

R & D Centres, Gurgaon, India
Place of EHS in Business

Need to satisfy four major elements to sustain business continuity

- QUALITY
- COST
- BUSINESS CONTINUITY
- EHS
- SERVICES
EHS Role in Corporate Citizenship

- No harm to our Employees.
- Care for the Community.
- Reduce Environmental Footprints.

Compliance to EHS aspects is at the Ground Level.
Basic Virtuous Circle of Ranbaxy EHSMS

The Continual Improvement Cycle

Annual Report

Audit

Performance Reports

Review

EHS Policy

Corporate Standards

Corporate Guidelines

Measure

Training & Implementation

Local Procedures

Local / Legislation & Divisional Requirements

RANBAXY
EHS Management System

Is achieved through...
- Leadership by Management
- Active Participation of all employees
- Use of Appropriate Technologies

Using the right...
- Equipment
- Systems and Procedures
- People
EHSMS – Salient Features

EHS Policy: Statement of Intent

EHS Standards: Shall be Done (Mandatory)

EHS Guidelines: Should be Done

Local EHS Procedures: How it is to be Done (Location specific, Mandatory)

Resource Documents: Best Practices
Corporate EHS Standards – List

1.0 Management of EHS Improvement
   1.1 EHS Management and Resources
   1.2 Continuous Improvement
   1.3 EHS Reporting
   1.4 Training and Employee Involvement
   1.5 Auditing / Conformance
   1.6 Acquisitions and Divestments

2.0 Process and Equipment EHS
   2.1 Plant Design and Hazard Studies
   2.2 Plant / Equipment Operation and Maintenance
   2.3 Contract Manufacturing

3.0 Employee / Contractor Occupational Health and Safety
   3.1 Employee Occupational Health and Safety
   3.2 Contractor Occupational Health and Safety
Corporate EHS Standards – List

4.0 Pollution Prevention
4.1 Environmental Impact Assessment (EIA)
4.2 Air, Soil and Groundwater Protection
4.3 Resource Conservation

5.0 Community Awareness and Emergency Response (CAER)
5.1 Community Outreach
5.2 Emergency Plans

6.0 Product Stewardship
6.1 Product Research and Development
6.2 Product Management
1.0 Management of EHS Improvements

EHS Standard No. 1.1 : EHS Management and Resources

CEG 1.1.1 Implementation of EHS Policies
CEG 1.1.2 EHS Management - Location
CEG 1.1.3 EHS Management - Division
CEG 1.1.4 EHS Documentation and Records
CEG 1.1.5 EHS Risk Assessment

Corporate Standard No. 1.2 : Continuous Improvement

CEG 1.2.1 EHS Improvement Plans and Reviews
1.0 Management of EHS Improvements

Corporate Standard No. 1.3 : EHS Reporting

CEG 1.3.1 Reporting EHS Performance

Corporate Standard No. 1.4 : Training and Employee Involvement

CEG 1.4.1 Training – Employees and Contractors
CEG 1.4.2 Employee Communication
CEG 1.4.3 Employee Involvement
1.0 Management of EHS Improvements

Corporate Standard No. 1.5 : Auditing and Conformance
CEG 1.5.1 Auditing against EHS Standards
CEG 1.5.2 Compliance Reporting

Corporate Standard No. 1.6 : Acquisitions and Divestments
CEG 1.6.1 Acquisitions
CEG 1.6.2 Divestments
CEG 1.6.3 Greenfield Site selection
CEG 1.6.4 Selecting A Due Diligence Consultant
2.0 Process and Equipment EHS

Corporate Standard No. 2.1: Plant Design and Hazard Studies

CEG 2.1.1 Capital Projects
CEG 2.1.2 Hazard Studies
CEG 2.1.3 Chemical Hazard Assessment

Corporate Standard No. 2.2: Plant / Equipment Operation and Maintenance

CEG 2.2.1 EHS Dossier and Documentation
CEG 2.2.2 SOPs for Plant and Equipment
CEG 2.2.3 Permit to Work System
CEG 2.2.4 Fire Safety Management
CEG 2.2.5 Electrical Safety Management
2.0 Process and Equipment EHS

Corporate Standard No. 2.2 : Plant / Equipment Operation and Maintenance (Cont…)

CEG 2.2.6 Management of Change
CEG 2.2.7 Controlled / Critical Equipment
CEG 2.2.8 Housekeeping
CEG 2.2.9 Laboratory EHS Management
CEG 2.2.10 Vehicular Safety at Site
CEG 2.2.11 Loading / Unloading of Material
CEG 2.2.12 Warehouse Safety

Corporate Standard No. 2.3 : Contract Manufacturing

CEG 2.3.1 Contract Manufacturing
3.0 Employee / Contractor Occupational Health and Safety

Corporate Standard No. 3.1: Employee Occupational Health and Safety

CEG 3.1.1 Assessment and Control of Chemical Exposures
CEG 3.1.2 Personal Protective Equipment
CEG 3.1.3 Health Assessment Programme
CEG 3.1.4 Ergonomics
CEG 3.1.5 Biological Hazards
CEG 3.1.6 Asbestos Control
CEG 3.1.7 Hearing Conservation
3.0 Employee / Contractor Occupational Health and Safety

Corporate Standard No. 3.1 : Employee Occupational Health and Safety (Cont....)

CEG 3.1.8    Traveling on Company Business
CEG 3.1.9    Working at Non-Ranbaxy Locations
CEG 3.1.10  Control of Visitors

Corporate Standard No. 3.2 : Contractor Occupational Health and Safety

CEG 3.2.1  Contractor Occupational Health and Safety
4.0 Pollution Prevention

Corporate Standard No. 4.1: Environmental Impact Assessment
- CEG 4.1.1 Environmental Impact Assessment
- CEG 4.1.2 Management of Wastes

Corporate Standard No. 4.2: Air, Soil and Groundwater Protection
- CEG 4.2.1 Land and Groundwater Protection
- CEG 4.2.2 Ambient Air Protection

Corporate Standard No. 4.3: Resource Conservation
- CEG 4.3.1 Resource Conservation
5.0 Community Awareness and Emergency Response (CAER)

Corporate Standard No. 5.1 : Community Outreach

CEG 5.1.1 Community Relations Programme

Corporate Standard No. 5.2 : Emergency Plan

CEG 5.2.1 On-site Emergency Plans
CEG 5.2.2 Emergency Response to off-site incidents
6.0 Product Stewardship

Corporate Standard No. 6.1 : Product Research and Development

CEG 6.1.1 Product Research and Development
CEG 6.1.2 Transfer of Technology

Corporate Standard No. 6.2 : Product Management

CEG 6.2.1 Transportation – Risk Management and Documentation
Need to manage the 90%

Resource Depletion and Waste
Approximately 10% of What Goes ‘in the Pipe’ Comes Out as Goods and Services, the Rest Is Waste

~10%  ~90%
Environmental Management System

ISO14001 compliant

State of the art Waste Management System employing

- Membrane technology,
- Multi Effect thermal Evaporator (MEE),
- Spray Dryer, and
- Advanced Solid, Liquid & Aqueous Waste Incinerator.
World Class Effluent Management System
(ZERO Discharge)

- **High TDS / Non bio-degradable streams**
  - MEE
    - Spray Dryer
      - Solids
      - To Solid Waste Disposal
    - Concentrate
    - Condensate

- **Bio-degradable streams**
  - ETP
    - U/F, N/F & R.O
      - Permeate
    - High TDS RO
      - Permeate
      - MEE
        - Condensate

- **Mother liquor/Bottom cut (Organic)**
  - Incinerator
    - Ash
    - Spray Dryer
    - Scrubber
    - Cooling Tower
    - To Solid Waste Disposal

Effluents:
- **Soluble streams**
- **Mother liquor/Bottom cut (Organic)**
Environmental Management System

Ultra Filtration Plant
Environmental Management System

Nano Filtration & RO
Environmental Management System

Multi Effect thermal Evaporators & Spray Drier
Environmental Management System

Incinerator
Safety at workplace is broadly achieved through:

- Hazard studies & Risk Assessment
- Permit To Work System
- Fire Safety Management System
- Electrical Safety Management System (begins with Area classification, static controls etc.)
- LEVs
- Provision of adequate PPE
- Nitrogen Blanketing in tanks & process eqpt.
- Comprehensive safety training of employees.
- Good Housekeeping & organized way of working
Safety Management

Permit To Work System

- Master permit
- Hot Work
- Confined space entry
- Excavations/ Break-In
- Working at height
- Temporary electrical connections.
- Work involving High Tension (HT) equipment.
- Cleaning of process equipment prior to repair or disposal
Safety Management

Process Safety

- Vapour/gas detectors on all dedicated recovery systems
- Process Hazard Analysis (PHA)
- Hazard & Operability Studies (HAZOP)
- Nitrogen blanketing
- Utility flow failure alarm and trip systems
- Operating procedures
Safety Management

Storage and Handling of Chemicals

- Identification & MSDS
- Spill control kits, PPE
- Safety showers, Bund walls
- Hi level / low level alarms on storage tanks
- Where practicable, manual handling of chemicals avoided.
- Pumps/ barrel pumps/closed charging.
- Bottom flap type funnels for charging
- Auto pump-trip in case of dry running
Fire Safety Management System (FSMS) includes:

- Fire Prevention
- Fire Detection
- Fire Protection (fixed systems) and Fire Fighting Facilities
- Emergency Response
- Training
- Monitoring
Safety Management

Fire Prevention

- Engineering & Administrative controls over ignition sources
  - Area classification
  - Control on static – antistatic polybags for intermediates, antistatic footwear, gloves etc., Earth-Rite system,
  - Intertization of storage tanks & equipment with Nitrogen
  - Safe use of powered tools etc.

- Storage arrangements & preventing LOC.
- Formal Permit To Work System
- Chemical Age-related fire hazards – Specify & monitor age limits for degrading chemicals.
Safety Management

Fire Detection

- Well-designed fire detection and alarm system to identify fire site
- Auto (smoke/heat detectors) & manual call points
- Fire alarm & local sounders
- Digital display of fire zone – at strategic places
- Public address system to direct the personnel
- 24x365 manning by Safety Surveillance Officers
- Night beat patrol by security
Safety Management

Fire Protection/ Fighting and Emergency Response

- Passive Fire Protection – Siting Layout at design stage
- Active Fire Protection – Fire Extinguishers, Water sprinklers
- Fire Hydrant system for 3-hour application
- Fire Tender at site
- On-site Emergency Plan – drills
- Trained Core Group.
General Safety Systems

- Safety Committees
- 24 x 7 Safety surveillance
- Machine guarding
- Breathing air network, air-line respirators
- Colour coding of pipelines, labeling
- Pressure vessels testing, Lifting tackles, hoists, safety valves
- Public address /Zone indication system
- On-site Emergency Plan - On line
- Regular training
Occupational Health Management is achieved through

Prevention

- Controlled access and movement of personnel.
- Sanitization and housekeeping.
- Regular health screening of people, food and drinking water quality.
- Advise to employees on health and personal hygiene.
- Preventive, Curative and Advisory services by in-house Occupational Health Centre (OHC).
Health Care

**Administrative Controls**
- Limited and controlled access.
- Well defined systems and SOPs.
- Bathing and washing facilities – Protection for the family.
- Training.
- Use of appropriate PPEs.

**Engineering Controls**
- Building design
- Equipment (Closed Process)
- LEV.

**Special controls for Specific Products**
- Isotretinoin
- Penicillins and Cephalosporins (separate entry/exit routes)
Occupational Health Care

Exposure Control – Full Body Air Supplied Suits
Primary purpose

- To avoid recurrence
- Eliminate disruptions

All Incidents need to be

- Properly captured
- Investigated
- Recommendations implemented
- Learning shared within the company
Incident Management

- FIR – First Information Report
- RCA – Root Cause Analysis
  - Investigation Team Nomination
  - Actual Investigation & recommendations
- CAPA – Corrective Actions Preventive Actions
  - Actions, Responsibilities & Time frame
  - Implementation
  - Closure
Last but not the least...
Audits

What we say
What we do
What we Should do
What we Actually do

Local Procedures
Operational Audit

Specialist Audit

Standards, Guidelines & Resource documents

MANAGEMENT AUDIT
Thank You