

Hebei Bimeda Factory Introduction



Global Excellence in Animal Health

 **Bimeda**

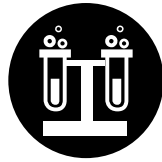


Bimeda Group

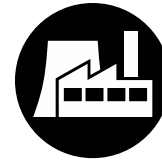
Bimeda in Numbers



OPERATES
IN OVER
75
countries



6 R&D and
7 REGULATORY
LABS



9 MANUFACTURING
facilities in
7 COUNTRIES



800+
EMPLOYEES



150 in
SALES AND
MARKETING



60 YEARS
SINCE FOUNDED
IN IRELAND
in 1960



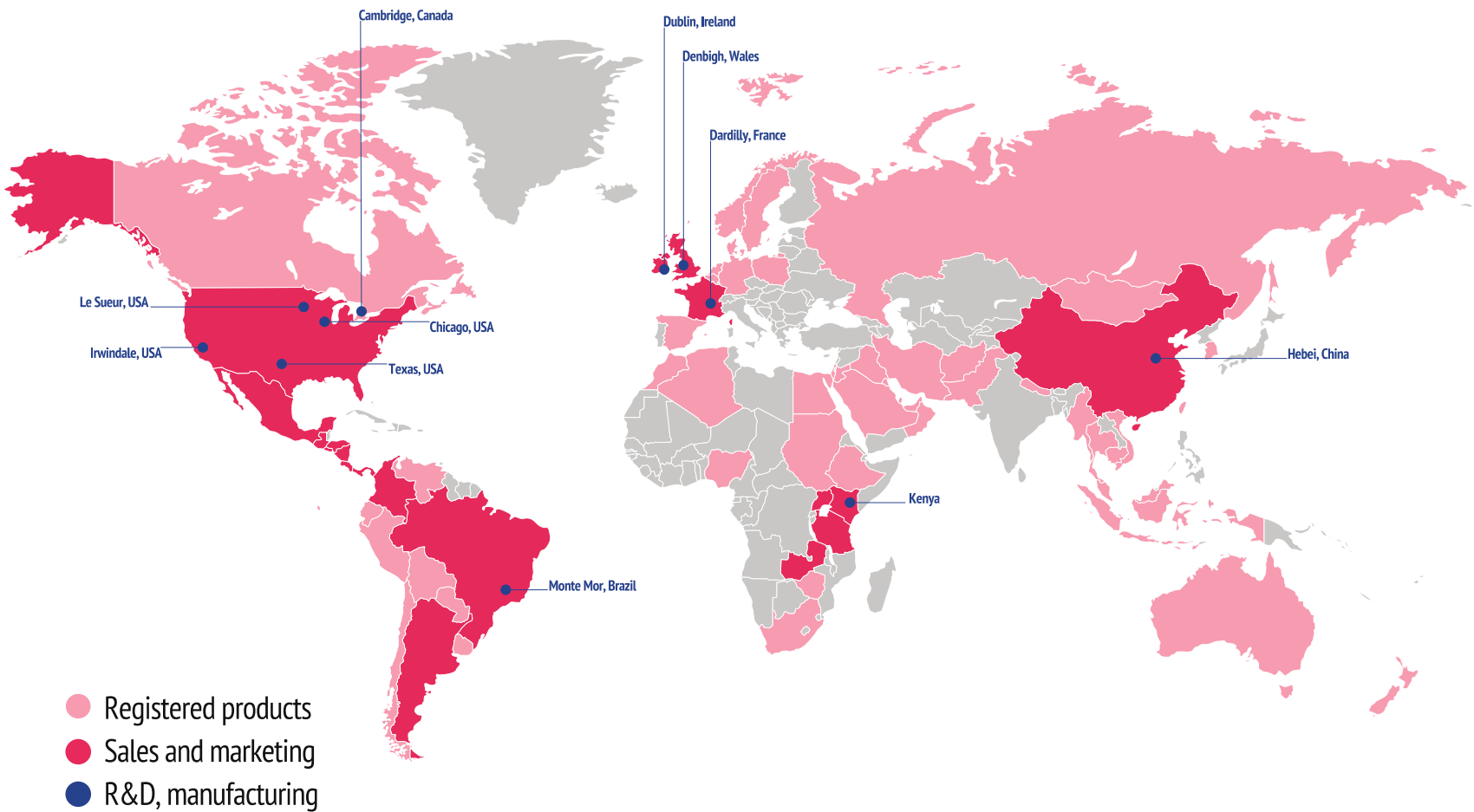
#17 IN THE WORLD
by sales*



+\$200m
revenue

*Source: Citibank report

Bimeda's Global Presence



Bimeda Brands



Bimoxyl LA

Bimectin[®]
(ivermectin)

Ectofly

1.25% w/v Pour On Solution for Sheep

Bimectin[®]
Horse Oral Paste 18.7 mg/g

Dermodoo[®]
Skin healing foam

Endospec 10% SC



**Cronyxin
Injection**

COSECURE[™]



CyperGuard
CONCENTRATE - FOR DIP EMULSION
NON
OP **Sheep Dip**

Bimeda

OUR VISION



To be the partner of choice for optimizing the wellbeing of the world's animals

OUR MISSION



As a family-owned company with over half a century's experience in improving global animal health, we are passionate about providing our customers with efficient science-driven solutions to continuously optimize the wellbeing of animals

OUR VALUES



Collaboration



Accountability



Learning



Customer Focus



Innovation



Hebei Bimeda Factory

Bimeda in China



| Office | Number of staff |
|--------------|-----------------|
| Shanghai | 4 |
| Beijing | 3 |
| Shijiazhuang | 56 |
| Hong Kong | 4 |

Factory Overview

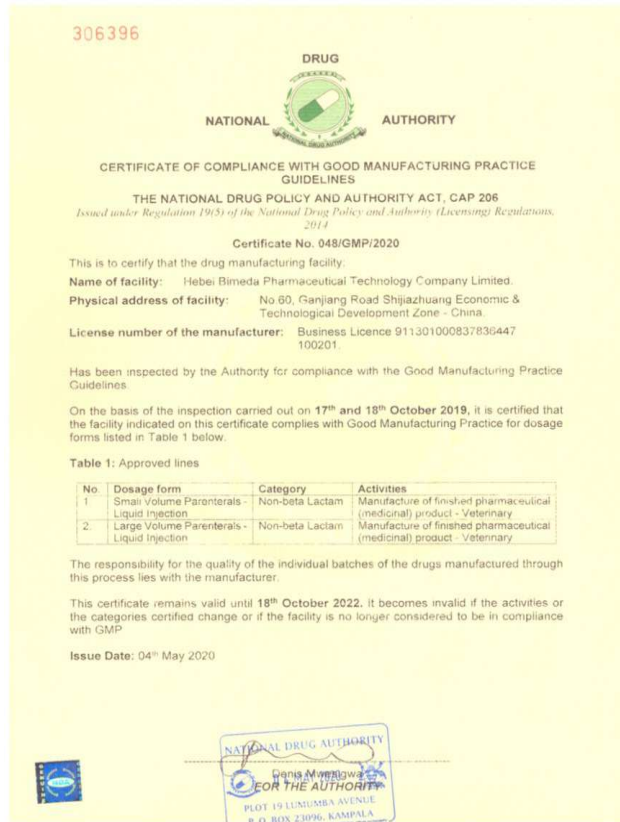
Key Specifications

- Initial site surface 22,520m²
- Sterile injectable filling in a grade B+A environment
- Automatic filling line
- Non-penicillin and non-hormone
- 1st Line, 10ml – 100ml, aseptic sterilisation
- 2nd Line to be installed, 250ml to 500ml aseptic sterilisation
- Currently approved for China, East Africa, Australia & New Zealand



Current Audit History

AFRICA GMP



Date Achieved: SEPT. 2019

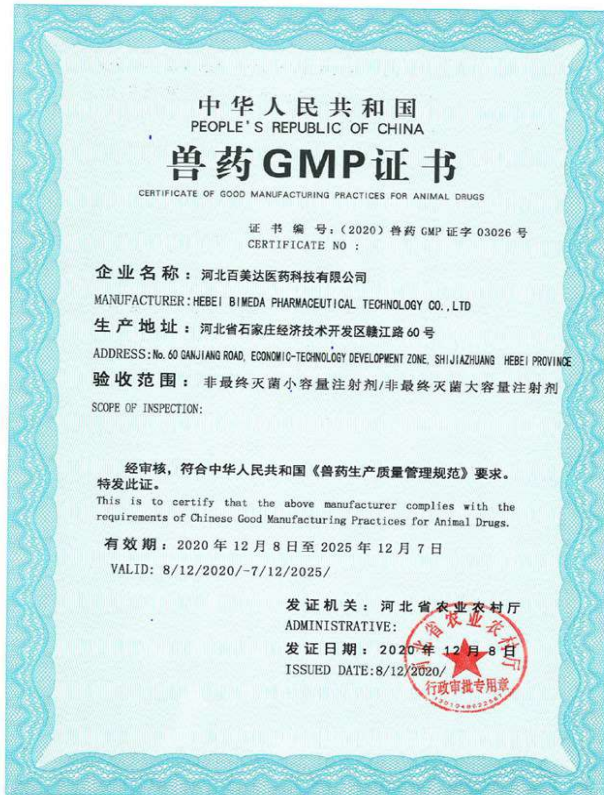
ISO 9001:2015



Date Achieved: JUNE 2020

Current Audit History

2020 CHINESE GMP



Date Achieved: DEC 2020

AUSTRALIA GMP

OFFICIAL: Sensitive



Australian Government
Australian Pesticides and
Veterinary Medicines Authority

Ref: M-7964

30 June 2021

Mr Jeremy Li
Plant Manager

Hebei Bimeda Pharmaceutical Technology Co., Ltd
No. 60 Ganjiang Road, Economic – Technology Development Zone
Shijiazhuang, Hebei Province, CHINA

Dear Mr Li,

CONFIRMATION: OVERSEAS SITE GMP COMPLIANCE

The APVMA is satisfied that this manufacturer meets the requirements for the manufacture of the products nominated in your most recent Pre-Audit Notification form (FM_MQL45) dated 16 March 2021.

The following site was last remotely inspected for GMP compliance by an APVMA-authorized auditor on 12-19 April 2021. Provided no further contrary evidence is received, the APVMA will recognise the GMP compliance of this site, for the steps and/or products specified, for a period of 30 months from the date of the last inspection.

Therefore, provided no further contrary evidence is received, the following site will be recognised until **12 October 2023** for the following steps and product types:

Manufacturing site name:

Hebei Bimeda Pharmaceutical Technology Co., Ltd

Manufacturing site address:

No. 60 Ganjiang Road, Economic – Technology Development Zone
Shijiazhuang, Hebei Province, CHINA

Date Achieved: APRIL 2021

Why Hebei Bimeda?

Key Specifications

- State of the art sterile injectable facility
- Built to the exceptionally high standards of Bimeda's worldwide facilities
- Full control over testing/analysis through to production and labelling/release
- Competitive pricing
- Access to Rainbow Labs, our raw materials testing and innovation centre approved by the FDA
- Shijiazhuang is a major industrial city and the economic centre of Hebei Province.
- Nicknamed the "medicine hub of China", Shijiazhuang is home to major Chinese pharmaceutical companies and factories
- The city is well connected with transport links to the Beijing–Guangzhou Railway and the new Beijing–Guangzhou–Shenzhen–Hong Kong High-Speed Railway

Appendix

Equipment Overview



Batching Tanks

The volume is 500, 1000 and 2500 cubic meters



Vial Washing Machine and Tunnel Oven

Equipment Overview



Filling Machine



Capping Machine

Equipment Overview



Purified Water System

The purified water is prepared by multi-medium filter, activated charcoal filter, softener, two-stage RO, EDI and distributed to storage tank and distribution system.



Water for Injection System

Purified water is the raw water for WFI system, goes through multi-efficiency distiller water machine into WFI storage tank.

Purified water and WFI circulates all the time.

Equipment Overview



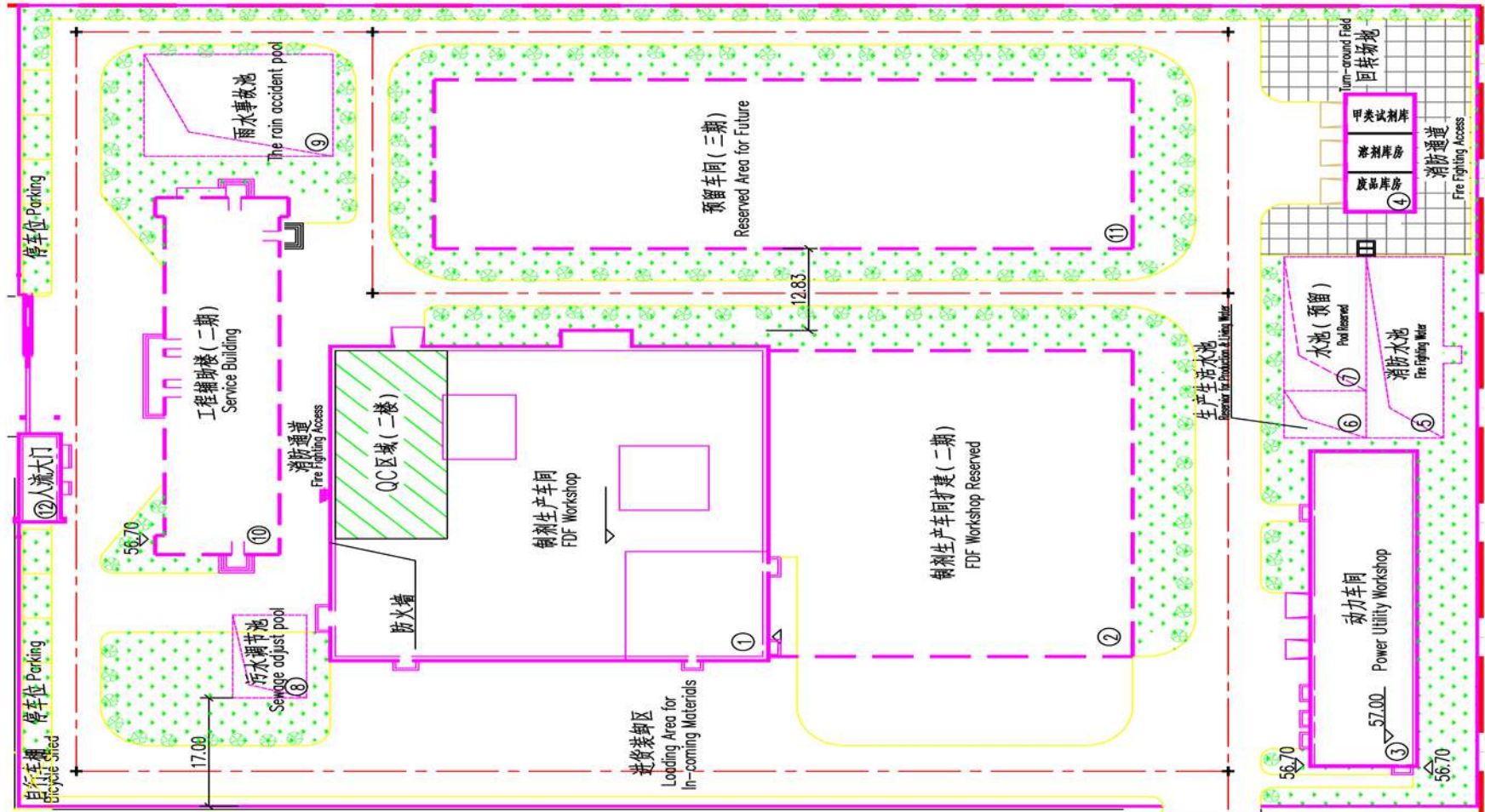
HVAC System

There are 13 HVAC systems in total.

9 for cleaning areas.

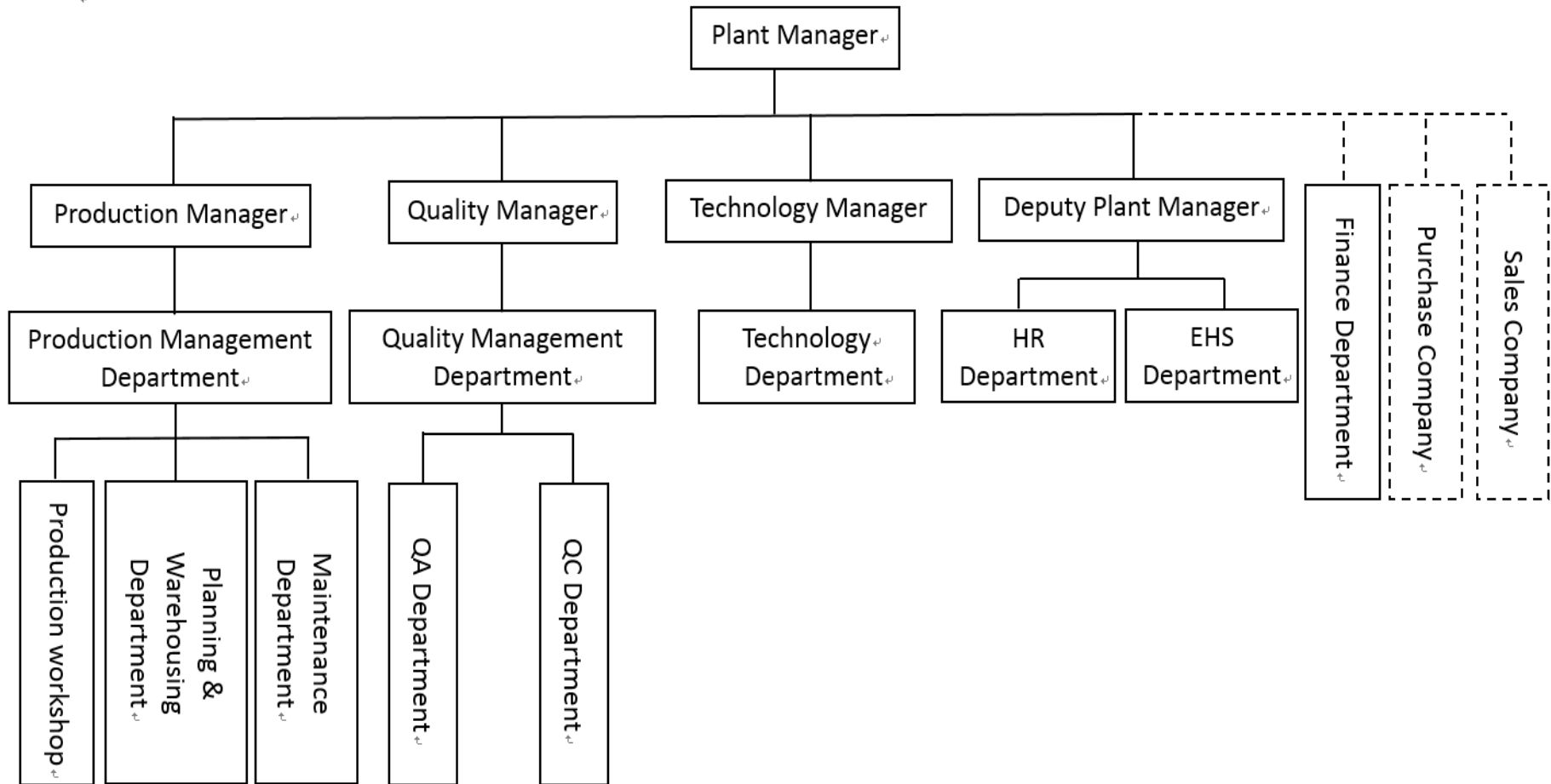
4 for unclassified areas.

Site Layout



- Site area: 22,520 m²
- Construction area: 5,594.91 m²
- Filing Line configuration: 10ml/20ml/30ml/50ml/100ml vial

Organisational Structure



Quality Management Systems



HPLC mainly used for assay and related substances testing.



Polarimeter and UV tester



IR spectrophotometer



GC mainly used for residual solvent testing

Quality Management Systems



Isolator used for sterility testing



Incubators

Rainbow Labs Overview

- Rainbow Labs JV created in 2011
- Raw materials testing and innovation centre
- Approved by European authorities
- Approved by FDA authorities
- Provides auditing services throughout China





**WE LOOK
FORWARD TO
WORKING
WITH YOU!**