2006-04-11 24:2005/45497

Inspection Unit
Medical Products Agency
Sweden

GMP Inspection report

Inspected site:

Eminent Services Corporation
Frederick, MD 21703-9401
USA
Phone: +1 240 629 1972 Fax: +1 240 629 3298

Activities Carried out by company

Manufacture of Active Ingredient	☐
Manufacture of Finished Medicinal Product	☐
Manufacture of Intermediate or bulk	☐
Packaging	☐
Importing	☐
Laboratory Testing	☐
Batch Control and Batch Release	☐
Other: Storage and Distrubution	☒

Inspection dates: 2005-10-06

Inspector: Lars Hackzell, Pharmaceutical inspector, MPA, Sweden

References: [redacted], EMEA application number EMEA/H/C/369

Introduction: Eminent Services Corporation provide quality contract services to the pharmaceutical and biotechnology industry in fields of regulatory affairs, product development, clinical trails, compliance and material management.
For [redacted] ([redacted]), the company provide storage and distribution services.

Brief report of the inspection activities undertaken:

Scope of Inspection: Re-inspection to confirm GMP compliance and requirements of the Market Authorisation.
This was the second inspection carried out by a competent authority of EU. The previous one took place in August 2002.

Inspected areas: Products receiving, storage and shipping.
Reviewing of quality documents.

Personnel met during the inspection: K. Paul Thadikonda, PhD, President and CEO
Vijaya L. Thadikonda, MS, MPharm, Vice President
Janaki Kore, MS, Manager QA/QC

Göran Kvist, QP, TKT Europe AB

Inspectors Team's findings and observations relevant to the inspection:

Quality Management:	The Manager QA/QC reports to the President&CEO and is responsible for the quality system and for assuring the quality of manufacturing steps including storage, distribution, packaging and labelling.
Personnel:	New employees get introduction programs including orientation in cGMP. Personnel are experienced.
Premises and Equipment:	The building houses 37,000 square feet of warehouse space and 26,000 square feet of office space and is controlled by access card readers. The maintenance of the building and the pest controls are contracted out. There are 6 HVAC-units for the warehouse and one unit exclusively for the computer system room. Facility equipment like HVAC-systems, refigerators and freezers are maintained under preventive maitenance plans and monitoring device are calibrated.
Documentation:	SOPs and other reviewed documents; - Relevant SOPs on receiving and shipment - Storage handling - Maintenance on facilities and equipment - Complaint processing - Deviation report processing - Corrective and preventive actions - Internal audits - Example of job description and training records
Production:	For [redacted] ([redacted]), Eminent receive, store, ship and sometimes get returns of the product. The [redacted] product is received from CBL or Baxter packed at 2-8 °C. The product is stored in temperature monitored refrigerators. All transactions are performed using the Ivestigational Drug Management System (IDMS). The product are shipped to Inpac AB, Sweden in temperature validated boxes. For another [redacted]-product, [redacted], Eminent receive, store, label and distribute for clinical trails.
Quality Control:	The received materials are checked for condition, labeling and packing list according to the SOP; Incoming Shipment Receipt Procedure. A receiving inspection report are filled in.
Contract Manufacture and Analysis:	The last contract with [redacted] was valid from October 3, 2005. There are no subcontractors involved between the parties.
Complaints and Product Recall:	There is a Customer Complaint Processing Procedure in place. The company is not responsible for recalls of the product.

Self Inspection:	There is a SOP for internal audits in place (Doc. 2015).
Distribution and Shipment:	When shipped to Sweden, the product is packed in temperature validated boxes.
Site Master File:	A Site Master File dated August 2005 (revision 2) was sent to MPA prior to the inspection.
Samples taken:	No samples taken.
Distribution of Report:	K. Paul Thadikonda, Eminent Services Corporation

List of Deficiencies

Critical deficiencies:	No deficiency noted.
Major deficiencies:	No deficiency noted.
Deficiencies (D) and Observations (O):	
1. Quality Management:	No deficiency noted.
2. Personnel:	No deficiency noted.
3. Premises and Equipment:	O3.1 The temperature in the freezer used for transportation bricks, was not regulary checked.
4. Documentation:	No deficiency noted.
5. Production:	No deficiency noted
6. Quality Control:	No deficiency noted.
7. Contract Manufacture and Analysis:	No deficiency noted.
8. Complaints and Product Recall:	No deficiency noted.
9. Self Inspection:	D9.1 The instruction for internal audits had not been implementet. (EU-GMP 9.1)

Summary and conclusions:

During the inspection the inspector noted **one** deficiency according to current EU-GMP. The deficiency was not critical or major.

In addition the team noted one observation which are not classified as deficiency.

Eminent should submit a written plan with corrections to the Medical Products Agency.

If the corrective actions taken are acceptable Eminent will be in compliance with EU-GMP with regard to the storage and distribution of [redacted]

On behalf of

Medical Products Agency, Sweden

Uppsala, 2006-04-11

Lars Hackzell
Pharmaceutical Inspector