LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Drug Inspectorate
Lars Hackzell

24:2010/511972, EMEA/H/C/1249

# GMP INSPECTION REPORT – Final report

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| **Report Reference no.** | 24:2010/511972 |
| **Inspected site** | Eminent Services Corporation<br>Frederick, MD 21703-9401<br>USA |
| **Activities Carried out** | Storage and Distribution |
| **Inspection dates** | June 18, 2010 |
| **Inspectors** | Lars Hackzell, Medical Products Agency (MPA), Sweden<br>John Boutelje, Pharmaceutical Inspector, MPA, Sweden |
| **References** | EMA reference number: EMEA/H/C/1249 (contract #24515). |
| **Introduction** | Eminent Services Corporation provides contract services to the pharmaceutical and biotechnology industry in the fields of regulatory affairs, product development, clinical trials, compliance and material management.<br>For [redacted] the company provides storage and distribution services. |

## Brief report of the inspection activities undertaken

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| **Scope of Inspection** | The inspection was carried out following a request by the Committee for Medicinal Products for Human Use, CMPH, for the on-site assessment of the compliance with the Community GMP in connection with a new marketing application for [redacted]<br>The inspection was a general GMP inspection with focus on the storage and distribution of [redacted] |

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66

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| **Inspected areas** | Inspection was carried out of the following plant facilities and areas:<br>• Products receiving, storage and shipping areas.<br>• Quality documentation |
| **Activities not inspected** | The inspection focused on areas used for storage and distribution of [redacted] |
| **Personnel met during the inspection** | K. Paul Thadikonda, PhD, President and CEO<br>H Sanagapati, QA/QC Manager<br>A Kantareddy, Vice President<br>[redacted] |

## Inspectors findings and observations relevant to the inspection; and deficiencies

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| **Inspection findings from last inspection and corrective action taken** | The previous inspection by MPA October 6, 2005 was a re-inspection to confirm GMP compliance and requirements of the Marketing Authorization. The implementation of the corrective actions from that inspection was reviewed during the present tour of the facilities and as part of the document review and was found to be acceptable |
| **Quality Management** | A quality system according to what is described in the SMF was in place.<br>QA has general responsibility for issuance and distribution of documents.<br>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.<br>QA meetings are held every 3 months where quality issues such as deviations are reviewed. Deviations are reported to the contract giver. The total number of deviations was 37 so far this year. |
| **Personnel** | Training for employees is given through in-house and external training programs. Yearly GMP-training is provided. Reading of SOPs is documented by use of electronic signatures. |
| **Premises and Equipment** | The facility operates from 8 am to 5 pm. Among changes that had taken place since the previous inspection can be mentioned the validation of a custom developed Investigational Drug Management System (IDMS) in 2006. The system is used to track inventory management and production control. |

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, refrigerators and freezers are maintained under preventive maintenance plans scheduled in IDMS. Requalification is performed every 3 years and maintenance twice a year. Temperature and relative humidity is monitored continuously. Monitoring devices are calibrated.

The facility has not been exposed to any acts of housebreaking or sabotage. The facility is fitted with motion detectors on the inside and outside of the building.

Power-backup for storage areas is secured with diesel-generators.

Premises are sprayed with pesticides as part of the pest control program.

**Documentation**

The following are examples of documentation (systems) that were reviewed during the inspection:

- Deviation/ Incident Report Processing, SOP 2012.06
- Corrective and Preventive Action, SOP 2013.02
- Calibration and Maintenance Procedure, SOP 2014.06
- Internal Audits, SOP 2015.06
- Change Control Procedures, SOP 2029.03
- General Maintenance, SOP 4005.07
- Qualification summary report for Harford Duracool Walk-In Refrigerator, May 4, 2010
- Refrigerator and Freezer Maintenance and Operation, SOP 4006.07
- Temperature and Relative Humidity Monitoring, SOP 4014.05
- Employee training, SOP 5050.05
- Drug Product Receiving and Inspection Procedure, SOP 2008.04
- Deviation handling was reviewed for 4 randomly selected deviations
- Qualification protocol for refrigerator EE-0386

Documentation is archived for at least 5 years according to SOP on archiving but in reality indefinitely. Electronic data is also backed up off-site.

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| **Production** | All receiving/shipping operations are fully traceable. A notification is received by e-mail from [redacted] upon delivery from [redacted] Upon receiving packages are given a receiving # in IDMS. Products received from [redacted] are kept in quarantine until a release certificate has been received. Each shipment and lot gets a unique IDMS #, product and shipper labels are copied and the product is then stored at allocated location.<br>In a similar way as for other [redacted] products shipping to [redacted] is carried out in a validated system.<br>Packaging diagrams visualize the different configurations to be used for different products and destinations.<br>Upon shipping packaging slips are printed based on data from IDMS and the product pulled from the appropriate location. The receiving site sends a receipt upon arrival of the package.<br>An instruction for shipping during systems failure, SOP 6003.0, details procedures for handling of receiving and distribution during automatic systems failure. |
| **Quality Control** | Received materials are checked for condition, labelling and against the packing list according to the SOP6001.05; Incoming Shipment Receipt Procedure. A receiving inspection report is filled out. |
| **Complaints and Product Recall** | The Complaints SOP 2011.05 described that customers have to be informed about complaints received. |
| **Self Inspection** | Internal audits are to be performed at least annually according to the SOP. They can be performed by the Vice president, QA personnel or a Manager from the different departments. A schedule for planned self inspection for 2010 was seen. |
| **Other specific issues identified** | None |
| **Site Master File** | A Site Master File effective January 12, 2010 was provided to the inspectors in advance of the inspection. |

## List of Deficiencies

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| **Critical deficiencies:** | *No critical deficiencies were noted.* |
| **Major deficiencies:** | *No major deficiencies were noted* |

**Other deficiencies (D):**

**1 QUALITY MANAGEMENT**

*No deficiencies were noted.*

**2 PERSONNEL**

D2.1 No documented training in basic theory and practice of GMP was given to an employee until after more than 4 months of recruitment (EU-GMP 2.9).

**3 PREMISES AND EQUIPMENT**

D3.1 Sliding doors in the receiving dock did not seal completely against the floor (EU-GMP 3.4).

D3.2 The SOP describing pest control did not state to what extent the use of pesticide spray was restricted and whether precautionary measures not to contaminate goods were present e.g. in the receiving area (EU-GMP 3.1).

**4 DOCUMENTATION**

D4.1 The SOP on Employee Training did not clearly identify the need for introductory training. Furthermore, the SOP contained a reference to a check list for new employees. The check list was not a controlled document (EU-GMP 4.5, 4.3)

**5 PRODUCTION**

*No deficiencies were noted.*

**6 QUALITY CONTROL**

*No deficiencies were noted.*

**7 CONTRACT MANUFACTURING AND ANALYSIS**

*No deficiencies were noted.*

**8 COMPLAINTS AND PRODUCT RECALL**

*No deficiencies were noted.*

**9 SELF INSPECTION**

*No deficiencies were noted.*

## Summary and conclusions

During the inspection the inspection team noted **4 deficiencies** according to current EU-GMP. None of the deficiencies was critical or major.

The response from the company, dated August 13 2010, has been evaluated.

The inspectors have accepted the plan for corrective actions.

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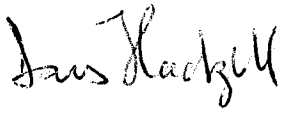
| | Eminent is in compliance with EU-GMP with regard to storage and distribution of drug products. |
| **Names** | Lars Hackzell<br>Pharmaceutical Inspector |
| **Signatures** |  |
| **Organisation** | Medical Products Agency (MPA), Sweden |
| **Date** | November 9, 2010 |
| **Distribution of Report** | Eminent Services Corporation, Att: K. Paul Thadikonda, Frederick, MD 21703-9401, USA.<br>Copy; EMA |