TGA THERAPEUTIC GOODS ADMINISTRATION

Manufacturer Assessment Section
Office of Devices, Blood and Tissues

(19)

Commonwealth Department of Health and Ageing

Conformity Assessment Audit Deficiency Report

COMPANY NAME: **Poly Implants Protheses**	
ADDRESS: **337 Avenue de Bruxelles, 83507 La Seyne sur Mer, France**	
FILE REF. NUMBER: **Submission No. 2003/098**	TYPE OF AUDIT: **Full Conformity Assessment**
DATE OF AUDIT: **17-19/11/2003**	PREVIOUS AUDIT: **Not Applicable**
MANUFACTURING STANDARD: **ISO 13485:1996**	
COMMERCIAL – IN – CONFIDENCE	

The undersigned officers would like to thank Mr J Mas and the staff of Poly Implants Protheses for the courtesy and cooperation extended when they visited the company on 17-19 November 2003. The purpose of the visit was to assess the company's compliance with the manufacturing requirements for conformity assessment of medical devices under the Therapeutic Goods Act (1989).

Specific nonconformities observed during the audit are recorded hereunder for the company's information and attention. It is important that these be considered as symptomatic of items requiring attention as it is not possible in an audit of limited time frame to identify every area requiring attention. Other matters requiring attention may have been identified during a longer audit.

Clause references below are to the ISO 13485:1996 Standard.

A response to this audit report including objective evidence of completion of corrective action (which could be in the form of copies of documents or photographs) of the major nonconformities should be received by the Chief GMP Auditor within four weeks of the receipt of the audit report. Where corrective action cannot be completed within this time a plan for completion within an agreed time frame, including dates for progress reports to be submitted, should be provided. Objective evidence for the corrective action for the minor nonconformities is not required but these matters will be reviewed at the next audit.

A final compliance rating will not be determined until the response has been reviewed and all nonconformities corrected to the satisfaction of the auditors. A recommendation on acceptance of the manufacturer cannot be made until the compliance rating is determined.

The auditors would be pleased to answer any further questions relating to this report.

Major Nonconformities:

1. A number of problems relating to the construction and maintenance of the cleanroom were noted. These were considered to pose a risk of harbouring micro-organisms and to be a potential source of particulate contamination. (Clause 4.9)

   1.1. There were gaps in the vinyl flooring in the silicone preparation area.

   1.2. There were unsealed penetrations in the wall of the envelope filling room.

   1.3. Benches and storage cabinets in most of the clean rooms were constructed of laminated particle board. There were various examples of unsealed edges and/or unsealed holes in cupboards and under benches.

2. The external door and inner door to the raw materials receiving area were left open simultaneously. Consequently dust, dirt, birds and insect pests could enter the storage area. (Clause 4.9, 4.15.1)

3. The use of Plate Count Agar (PCA) incubated at 30°C for 5 days had not been validated for the recovery of low numbers of bacteria and fungi. Additionally the validation of the microbiological monitoring programme for work surfaces and equipment in manufacturing areas was not complete.

Minor Nonconformities:

4. The traceability of some individual raw materials was not adequate. Materials used in production were identified using the manufacturer's lot number. Subsequent deliveries of a raw material were identified using the same manufacturer's lot number as the original delivery. (Clause 4.8 b)

5. Incorrect Quarantine labels had been applied to some drums of MED6 6400 in the quarantine store. Additionally, there was inconsistency in the manner of sign-off of "Accepte" labels on other materials in the store. (Clause 4.12)

6. The following matters relating to control of documents and records were noted. (Clause 4.5, 4.16)

   6.1. Some uncontrolled photocopies of SOPs were observed in the intermediary packaging room. The copying of documents was prohibited by SQ1/05 PCD 001 (F)

6.2. The period of time for retention of obsolete documents was defined in SQ1/05 PCD 001 (F). The period for retention of level 3, 4 & 5 documents was stated as 15 years only. This time period was considered insufficient as it was stated that the lifetime of the implants may exceed 15 years.

[redacted]

Lead Auditor
Manufacturer Assessment Section
TGA

20 November 2003

[redacted]

Audit Technical Specialist
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TGA Laboratories

20 November 2003

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