



Dr. M. Russel
Managing Director
Sobhan Oncology
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Basel, December 02, 2008

PT GMP Audit at Sobhan Oncology, Rasht, Iran, November 25-26, 2008

Dear Dr. Russel,

For your attention, please find enclosed our PT audit report established by Mr. Cláudio Cappai Corrêa on the occasion of a corporate GMP compliance audit performed at your site from November 25 to 26, 2008. The main results were presented to your staff during the final wrap-up meeting. The auditors again wish to express their gratitude to all involved participants for their contributions during the audit and for the candid and constructive discussions.

The auditors' general impression of your plant in Rasht is satisfactory. It is evident that considerable improvement efforts have been made during the preceding period of time and that in general a high standard is being maintained. Accordingly, there were many favourable observations mentioned by the auditors during the execution of the audit.

There were also some deficiencies identified which need to be corrected, and these are documented in the attached report. There were not critical nor major deficiencies detected and the most important of the minor deficiencies described in the report include:

- *Improvement of the training system*
- *Improvement of the Job descriptions*
- *Improvement of some SOPs describing the current organization*
- *Pest control*

Local management is responsible for the implementation of appropriate corrective measures to address the audit findings. As an initial step we request that, using the table within the audit report, you respond to our observations with corrective actions, due dates and responsible persons within a period of 20 working days from receipt of this report.