Confidential

15th January 2018

Compliance Follow up Report

Part 1: The Company

Name of manufacturer	Bharat Serums and Vaccines Limited
Physical address site	Plot No. K-27, Anand Nagar, additional MIDC., Ambernath (East), Thane – 421 501, Maharashtra, India
Postal address - HO	Hoechst House, 17th Floor, Nariman Point, Mumbai – 400 021, Maharashtra, India
Summary of activities of manufacturer	Manufacturer of sterile injectable in general category, Human Biological and Equine Biological products
Contact person(s):	Mr. Parag Shah (DGM Regulatory Affairs)
e-mail	parag.shah@bharatserums.com

Part 2: Audit Trail

Date audit	7th & 8th November 2017
Date audit report and conclusion audit	6th December 2017
Date compliance report I (action report)	10th January 2018
Date of compliance follow up:	15th January 2018

Part 3: Evaluation of the Compliance report.

We like to thank you for the compliance report we received on 10th January 2018.

Reviewing the different observations and the answers provided, with the appropriate supportive data, and the implementation dates of the different corrective actions you committed, we consider the audit observations from 7th & 8th November 2017 as closed.

We thus consider your facility as GMP approved for supply of sterile injectable in general category (Ampoule and Vial line) to IDA. IDA needs to be informed on major and critical changes in facility or manufacturing procedure.

As per IDA quality policy we have the intention to come for a routine follow up audit within a three years time frame.

Yours Sincerely,

Michiel de Goeje
Director Quality Affairs
IDA Foundation
mdgoeje@idafoundation.org

Annexe : N/A
c.c: IDA Procurement