

blue inspection body GmbH confirms the following:

The company:

Infraserv Höchst Gruppe
Infraserv GmbH & Co. Höchst KG
Industriepark Höchst
65926 Frankfurt am Main

Subsidiaries

Infraserv Logistics GmbH
Provadis - Partner für Bildung und Beratung GmbH
Infrasite Monheim GmbH

has been audited in accordance with EU GMP part II (ICH Q7) requirements on the following dates:

- October 6th, 2015 (Frankfurt site)
- November 9th and 10th, 2015 (Frankfurt site)
- November 16th, 2015 (Monheim site)

Audited areas:

- General GMP System (Computerized System for Water generation and E-Learning)
- Technical Gases (Oxygen as Active Substance, Nitrogen, Compressed Air, Hydrogen as Excipient)
- Facility Management (buildings H769 / H500)
- Ammonia (liquid) as raw material
- Purified Water (generation / testing) as Excipient
- Infraserv Logistics (Storage) GMP / GDP
- Creative Campus Monheim (Facility Management)
- Provadis (E-Learning)

The results of the audit are laid down in the inspection reports:

- BLUE-IRN-2015-11-09-01-INFRA SERV (14.12.2015)
- BLUE-IRN-2015-10-06-01-INFRA SERV (09.12.2015)

From the knowledge gained during this audit, it is considered that the company complies with applicable Good Manufacturing Practice *1.

This certificate reflects the status of the site at the time of the audit noted above and should not be relied upon to reflect the compliance status if more than 3 years have elapsed since the date of that audit. The authenticity of this certificate may be confirmed by blue inspection body GmbH upon consultation.


Inspection Review Board **blue**
inspection body
Münster, 02.02.2016

blue inspection body GmbH, Hafenweg 18-20, 48155 Münster, Germany

This certificate is valid until: 2018-10

*1 The accreditation according to DIN EN ISO/IEC 17020 of blue inspection body is limited to the scope "Inspection of excipient and active pharmaceutical ingredient manufacturers and determination of conformance with international GMP rules"

CERTIFICATE