

Press release

Mijdrecht, March 14th 2014.

bioTRADING Benelux B.V. is proud to announce that its QC laboratory, performing the quality control of their Ready Prepared Culture media, is accredited by the Dutch Council of Accreditation (reg.nr. L588) in accordance with the recognised International Standard **ISO/IEC 17025:2005** 'General Requirements for the competence of testing and calibration laboratories'.



The accredited methodology conforms to ISO/TS 11133-2:2003 + Amd. 1:2011.

It is the policy of bioTRADING to achieve the highest degree of product quality, ensuring that processes and services are continuously improved and are also in line with international standards, FDA/cGMP/GLP-guidelines and customer requirements.

The ultra-modern production facility in Mijdrecht, The Netherlands, that opened in 2009 is designed and equipped to meet pharmaceutical regulations. Some of the most advanced equipment available is used for the production of Ready Prepared Culture media, including specially designed media preparation vessels and autoclaves, an ultrapure water system, multi-lane petri dish filling machines and touchscreen PC's with 2D-datamatrix scanners to name a few.

The facility and environmental monitoring systems (including microbiological and particle measurement) are 'FDA 21 CFR part 11 compliant' and manufacturing takes place in cleanrooms class 5 to 8 (conform ISO15644-1).

Today, bioTRADING offers more than 1.200 different Ready Prepared Culture media recipes.

Custom specialised media can be manufactured to order in both small or large batch volumes, to a preferred recipe, bottle or tube size, or volume. Current batches range in size from small quantities of 10 petri dishes, up to batch sizes of 25.000 units.

The company's total commitment to quality and performance was reflected in 1994, when bioTRADING successfully achieved ISO 9001 accreditation. Furthermore, partly due to many external audits being regularly undertaken at the manufacturing facility, the quality management system is adapted to FDA/cGMP/GLP; this is confirmed by any of the numerous audits carried out each year.

Some of the quotes, reported by external auditors, are:

"The quality documentation system of bioTRADING is meeting the current ISO and cGMP standards."

"A strongly developed computerised system controls orders, the process, delivery to customers as well as quality and traceability of microbiological media."

"All critical process steps are automatically monitored and controlled. Equipment is validated and maintained on a regular basis and records are kept."

"Hygiene, housekeeping, storage space and routing were seen as very impressive."

bioTRADING also takes Corporate Social Responsibility (ISO 26000) seriously and for example only uses green electricity and green gas.

bioTRADING also supplies a wide range of diagnostic test kits, antisera, biological indicators, dehydrated culture media & supplements, ATCC[®]-reference strains, animal blood products and proficiency testing programs for microbiology and chemistry (food, dairy and water samples).

The ISO/IEC 17025:2005 accreditation is another milestone in the 35 year history of bioTRADING.

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